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Life Sciences & Pharma IP Litigation 2025

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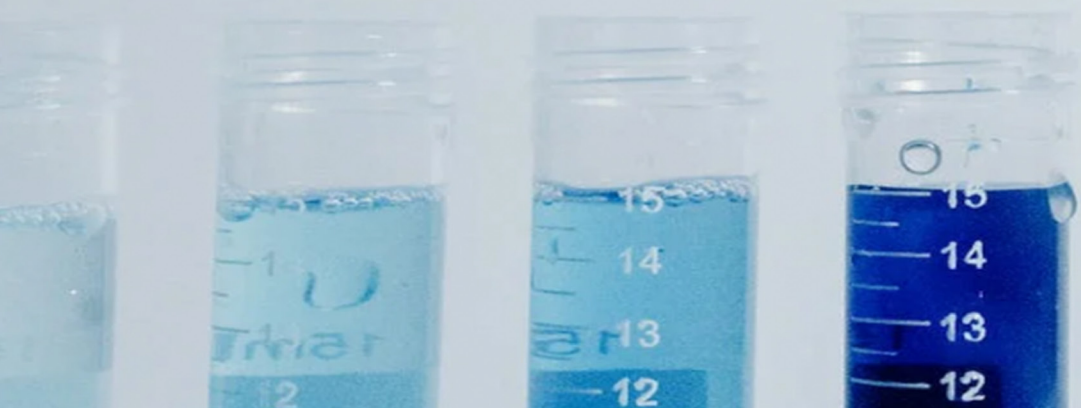
Contributing Editor
Nicola Dagg
Kirkland & Ellis LLP



Chambers

Global Practice Guides

Life Sciences & Pharma IP Litigation

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Nicola Dagg

Kirkland & Ellis International LLP

2025

Chambers Global Practice Guides

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165 Fleet Street
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INTRODUCTION

Contributed by: Nicola Dagg, Daniel Lim, Jin Ooi and Alex Magnusdottir, **Kirkland & Ellis International LLP**

Kirkland & Ellis International LLP has a patent litigation practice comprised of approximately 230 attorneys in London, Austin, Boston, Chicago, Houston, Los Angeles, New York, Palo Alto, Salt Lake City, San Francisco and Washington, DC. More than 75% of Kirkland's patent litigation attorneys are engineers and scientists, trained in a variety of technical disciplines. Kirkland's experienced IP litigation attorneys achieve extraordinary results in patent, copyright, trade mark, trade secret misappropriation and advertising matters. They represent clients across a broad range of industries, including life sciences, technology, consumer products manufacturing, financial services, automotive, and food and beverage. Other areas of practice are pharmaceutical and biologics patent litigation, co-ordinating global IP enforcement/defence cases, SEPs and FRAND disputes, post-grant proceedings before the US Patent and Trademark Office's Patent Trial and Appeal Board, and appeals of high-stakes cases in the US Court of Appeals for the Federal Circuit and the US Supreme Court, as well as the Court of Appeal of England and Wales and the UK Supreme Court.

Contributing Editor

Nicola Dagg is a partner and leader of Kirkland's IP litigation practice in London. She draws upon experience of more than 25 years at the forefront of IP litigation, particularly in relation to trade secrets and patents. Her practice includes pharmaceutical and biologics patent litigation; strategic life sciences patent and product life cycle advice; co-ordinating global IP enforcement/defence cases; hi-tech, digital and telecommunications litigation; and SEP and FRAND disputes. Nicola, who also has an MA in natural sciences, is renowned for her strategic and creative approach to solving difficult and commercially critical IP issues and regularly represents her clients in groundbreaking cases in the Court of Appeal and UK Supreme Court.

Co-Authors

Daniel Lim is a partner in Kirkland & Ellis International LLP's IP litigation practice in London, where he focuses on high-stakes life sciences patent litigation – particularly with regard to diagnostics, precision medicine, cell and gene therapy, and the pharmaceutical industry. His case experience includes oncology, molecular biology, diagnostics, antibody engineering and biostatistics, and often involves issues at the cutting edge of the law – notably in relation to second medical-use patents. He is active as a member of the International Association for the Protection of Intellectual Property (AIPPI) and the European Patent Lawyers Association (EPLAW), including as vice-chair of AIPPI's standing committee on biotechnology.

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Contributed by: Nicola Dagg, Daniel Lim, Jin Ooi and Alex Magnusdottir, **Kirkland & Ellis International LLP**

Jin Ooi is a patent litigator at Kirkland & Ellis. He has worked on matters in the pharmaceutical, chemistry, biotech and life sciences fields (second medical use, biologics/biosimilars, small molecules, DNA sequencing, vaccines, and transgenic animal platforms for antibody discovery), in the medical device space (cochlear implants, and bone cements), and in the FMCG and consumer products sector (reduced-risk products including tobacco heating products and e-cigarettes, shaving razors, dishwashing tablets, and coffee pods and capsules). Jin's cases are often multi-jurisdictional, requiring significant cross-border co-ordination across multiple forums. His dual qualifications in law and pharmacology give him a special insight into, and understanding of, his clients' legal needs and commercial and regulatory imperatives.

Alex Magnusdottir is an associate in Kirkland & Ellis International LLP's IP litigation practice in London. Alex has trial and advisory experience across the IP spectrum with a particular focus on pharmaceutical, biotechnology and medical device patents, and product life cycle advice. Her case experience includes oncology, molecular biology, antibodies, medical devices, and SPCs and medical devices. She works on high value, cross-border disputes dealing with complex technical and patent issues. Alex holds a PhD in neuroscience which gives her particular insight into the challenges facing IP clients.

Kirkland & Ellis International LLP

30 St Mary Axe
London EC3A 8AF
United Kingdom

Tel: +44 20 7469 2150
Fax: +44 20 7469 2001
Email: nicola.dagg@kirkland.com
Web: www.kirkland.com

KIRKLAND & ELLIS

INTRODUCTION

Contributed by: Nicola Dagg, Daniel Lim, Jin Ooi and Alex Magnusdottir, **Kirkland & Ellis International LLP**

A Global Overview of Life Sciences & Pharma IP Litigation

We are delighted to introduce the Life Sciences & Pharma IP Litigation 2025 edition of Chambers' Global Practice Guides, which provides an overview of litigation in the life sciences and pharmaceutical sectors in a number of countries, and an update to the trends and developments expected in the coming year by leading lawyers in each jurisdiction.

Litigation in the life sciences and pharmaceutical industries continues to be prolific across all jurisdictions. With increasing complexity of the technologies involved, innovators have ever more avenues to consider when protecting their inventions. However, the socio-political environment companies are operating in is ever more challenging – governments in key manufacturing jurisdictions, including China and India, have been taking steps to make their countries more attractive for innovators. If manufacturing countries become more patentee friendly, we could see changes in global life-cycle management and enforcement strategies and litigation dynamics in this sector, with an increased focus on enforcement against manufacturers of active pharmaceutical ingredients (API) and finished products in jurisdictions where enforcement of patent rights had previously been regarded as challenging.

Biologics (and biosimilar versions of originator biologics) are now firmly established at the forefront of pharmaceutical litigation, and comprise the vast majority of the current generation of blockbuster medicines. Whilst small molecule generic litigation continues, the rise of biologics/biosimilars has had and continues to have an impact in terms of the dynamics of, and key regular players in, large-scale pharmaceutical patent litigation. Overall, the number of patent disputes in the sector has remained steady but the disputes are increasingly complex and high-stakes and are often fought in parallel across multiple forums. Other industry trends include the continued rise in the frequency of "innovator-on-innovator" disputes. At the tail end of the year, the US Court of Appeals for the Federal Circuit released an opinion that Orange Book patents must claim at least the active ingredient of a patent. It also addressed device patents specifically, holding that patents which only claim device components do not meet the listing requirement. Parties in the pharmaceutical space will also have a particular eye out for developments in the coming year regarding implications of the European Commission's decision about the alleged misuse of divisional patents, where an innovator's conduct of filing divisional patents to extend exclusivity on the market was found to be anti-competitive. This decision could have wide-ranging implications for life-cycle management throughout Europe.

New technologies on the rise

The focus on mRNA-based vaccines and treatment continues. The litigation related to the COVID-19 vaccines persists in some jurisdictions, while the parties have settled in others. Next generation technologies such as CRISPR gene editing and base editing remain on the forefront, and approvals of new CRISPR-based therapies are bound to lead to litigation in the area, including around licensing arrangements by the many players involved with the foundational CRISPR technology. With the rapid expansion of AI-based tools and technology, there has been continued focus on AI-based inventions. The UK courts continued to grapple with AI-based technology, and the UK Supreme Court is set to hear an appeal on the patentability of AI-based inventions in the coming year. The UK Court of Appeal had previously said obiter

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that AI-based inventions were not categorically unpatentable. Similarly, the US Patent and Trademark Office issued guidance stating that while AI-based inventions are not categorically unpatentable, the inventorship analysis should focus on human contributions.

Increased sophistication of AI-systems may lead to more prevalent use in drug discovery and platform technologies, and arguments about the patentability of such inventions are bound to arise before the courts and patent offices. Given the rapid uptake of AI-based inventions in areas such as healthcare and medical devices, we expect to see litigation in this area evolve in the coming year.

Approaches to enforcement

The ability to obtain a preliminary injunction to prevent the launch of a generic or biosimilar medicine is an all-important consideration in any business/legal strategy to protect the exclusivity of an originator product. However, there has been a recent trend in traditionally more preliminary injunction-friendly jurisdictions like the UK and Australia towards fewer injunctions being granted and greater scrutiny of claimants' assertions of irreparable harm if the injunction they seek is denied. Perhaps relatedly, and with an increased awareness of the impact of public interest factors in the proportionality calculus, recently we have also seen greater forbearance on the part of claimants in seeking preliminary or final injunctive relief where critical medicines are concerned, although this continues to vary extensively from jurisdiction to jurisdiction, even across the EU where a single enforcement directive is in place. Each country guide includes an update on the steps required to obtain a preliminary injunction and the considerations for applicants.

The emergence of the Unified Patent Court (UPC) has also changed the injunction situation in Europe, with the Court granting a number of preliminary injunctions in the last year, but procedural requirements such as acceptable delay before bringing a request for an injunction have not quite crystallised between the different divisions. Given the wide-ranging scope of such injunctions, we expect to see increased interest in seeking them in parallel with other enforcement approaches.

Changing landscape in European litigation with the UPC

The UPC completed its first year of operation in June 2024, and has shaken up the patent litigation landscape in Europe, including the interplay with both national actions and the European Patent Office (EPO). As the Court matures, increasing numbers of unitary patents have been added to the register. The Court has seen a range of cases filed with it, with the number of pharmaceutical, medical devices and life sciences cases on the rise. Given the international nature of many disputes before the Court and the prevalence of UK-based firms co-ordinating the litigation, English has now become the most prevalent language in proceedings before the Court.

With the Court's many local and central divisions and their different approaches and timelines, parties have, to a certain extent, been able to forum shop to achieve desired forum and outcomes. Given the Court's infancy, many substantive and procedural issues are arising for the first time, and practitioners will eagerly await decisions from the UPC Court of Appeal regarding the proper approach to jurisdiction, bifurcated cases, and other procedural issues. These tactical opportunities also complicate considerations for both patentees and implementers, as the interplay between the UPC, the

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EPO and national rights and actions must all be taken into account in product life-cycle planning.

Litigation funding

In the medical devices, product liability and related fields, litigation funding has globally become an increasingly important factor in litigation strategies. While litigation funding has a long history in the USA, over the last year we have increasingly seen it utilised in the UK, where a proposal for reform of third-party litigation funding is expected this year. This enables parties that might historically not have been litigious, or able to undertake large scale litigation, to enter the litigation arena. While not prevalent in the medical devices or product liability space in the UK and EU as of yet, it is likely only a matter of time until the first funder-backed actions emerge.

Conclusion

Litigation in the pharmaceutical and life sciences industries is often highly complex and involves concurrent cross-border litigation in numerous jurisdictions. As the snapshot of issues provided by this brief overview illustrates, the law and practice in the area is constantly developing and continues to evolve, such that, in navigating life sciences and pharmaceutical patent disputes, it is essential to have up-to-date advice and information from experienced practitioners in the field. It is hoped that this guide is helpful to readers in providing a high-level overview of some of the essential features of life sciences and pharmaceutical IP litigation across the range of contributing jurisdictions.

AUSTRALIA

Trends and Developments

Contributed by:
Ben Miller, Stephen Rohl, Katie Pryor and Jenny Wong
Maddocks

Maddocks has extensive experience across the life sciences, pharmaceutical, biotech and digital health sectors, in both litigious and commercial matters. Maddocks' specialist teams provide strategic advice, freedom to operate advice, litigation, IP licensing and commercialisation services across the full spectrum of IP matters, in particular for patents and trade marks. The firm combines its IP expertise with market-leading healthcare and TMT practices in Australia to realise opportunities for its clients in biologics, digital health, rapid diagnostics, personalised medicine and clinical genomics. Based in offices in Sydney, Melbourne and Canberra, many of Maddocks' patent litigation team are dual qualified with degrees in a number of scientific and technical disciplines. The partners and senior lawyers have strong track records of success in some of the leading recent cases in Australia before the Federal Court and High Court of Australia, including regarding biosimilars, pharmaceuticals, chemistry, biotechnology, second medical uses and medical devices.

Authors

Ben Miller is widely recognised as one of Australia's leading patent litigators and leads Maddocks' patent litigation team. With a degree in biochemistry, he draws on over 27 years' experience leading IP disputes and transactions to develop effective litigation strategies with incisive technical and commercial focus. Ben has led clients to success in recent years in some of Australia's leading patent cases, including Novartis v Pharmacor, Mylan Health v Sun Pharma, Pfizer v Samsung Bioepis, Servier v Apotex, Lundbeck v Alphapharm, Apotex v Sanofi Aventis, Pfizer v Commissioner of Patents, and Fresenius Medical Care v Gambro.

Stephen Rohl is an IP litigation special counsel at Maddocks with more than ten years' experience in complex multi-jurisdictional patent litigation, in particular for the biotechnology and pharmaceutical, medical devices and veterinary medicines industries. Stephen specialises in life sciences patent cases before the Federal Court and High Court of Australia, as well as disputes in the Australian Patent Office, for which he draws upon his degree in applied chemistry. He also advises on IP transactions and therapeutic goods regulation.

Contributed by: Ben Miller, Stephen Rohl, Katie Pryor and Jenny Wong, **Maddocks**

Katie Pryor is a senior associate in Maddocks' IP team, with expertise in sectors including medtech, pharmaceuticals and engineering. With a degree in science (majoring in pharmacology), she has a particular focus on matters relating to highly complex technical subject matter. Katie has advised various multinational clients on IP commercialisation, transactions, enforcement and freedom to operate. She has acted in a number of global patent disputes, involving proceedings before the Federal Court of Australia, the High Court of Australia, the UK High Court and Court of Appeal, and the European Patent Office.

Jenny Wong is an IP litigation senior associate at Maddocks with experience in complex multi-jurisdictional patent disputes involving clients in the life sciences and engineering sectors. She has a PhD in biochemistry with specialist training in molecular biology. She specialises in life sciences patent cases before the Federal Court of Australia and has acted for clients in patent disputes relating to human vaccines, small molecules, biosimilar monoclonal antibodies, transgenic mice and gene editing technology. Jenny also advises clients on issues relating to freedom to operate and pricing, and reimbursement of prescription pharmaceutical products in Australia.

Maddocks

Angel Place Level 27
123 Pitt Street
Sydney
NSW 2000
Australia

Tel: +61 2 9291 6100
Email: info@maddocks.com.au
Web: www.maddocks.com.au

Maddocks

Overview

The year 2024 brought several significant intellectual property judgments in the life sciences and pharmaceuticals sector, particularly in the context of patents and consumer law. In Invisalign v SmileDirectClub, the Full Federal Court found that SmileDirectClub's comparative advertising contravened the Australian Consumer Law, emphasising the need for accuracy and fairness in health and efficacy claims in comparative advertising. The Full Federal Court also handed down a seminal judgment in Sandoz v Bayer, holding that in the context of the pharmaceutical development process, taking a drug candidate forward in a generally high-risk area is not enough to overcome an obviousness challenge. The same case also provided valuable guidance on the question of ascertainment of prior art documents under the pre-Raising the Bar Patents Act.

Meanwhile, the ToolGen v Fisher decision highlighted the scope for correcting obvious mistakes in patent claims, reinforcing that while the error and its correction must be apparent to a skilled person, the skilled person will be taken to bring all their knowledge to that question. Australia's highly contentious patent term extension regime was again tested in Novartis v Pharmacor, where the court ruled that Novartis' term extension should be removed.

The Australian Market

The life sciences sector continued to see significant growth in Australia in 2024, with close to 1,600 biotechnology and medical technology companies now operating there. This year, the federal government announced its Strategic Examination of Research and Development, the first review into R&D in nearly 20 years, aimed at growing Australia's science and innovation capabilities. The Strategic Examination coincides with an increased push by the industry for policy reforms to strengthen Australia's capacity for life sciences research, development and commercialisation, with the first National Biotech and Medtech Development and Commercialisation Summit occurring in November 2024.

The year 2024 also saw the government expand on its commitment to ensuring affordable and accessible medication. The government introduced significant new funding (AUD4.3 billion) to the Pharmaceutical Benefits Scheme (PBS), which included AUD3.4 billion allocated for new and amended listings to the PBS, and delivered a funding boost to community pharmacies of AUD3 billion per the commencement of the eighth Community Pharmacy Agreement.

Inherently risky business – the Full Court finds rivaroxaban patents obvious

The Full Federal Court has reversed a decision of Justice Rofe at first instance to invalidate Bayer's patents for a particular formulation of rivaroxaban and a once-a-day dosing regimen.

The decision held that general risks in the routine drug development process should be understood as part of the background against which the person skilled in the art operates, and are not sufficient, on their own, to defeat an obviousness challenge to formulation patents and dosage regimen patents which would have been arrived at in the course of phase I, II and III clinical trials.

Rivaroxaban is in a class of factor Xa inhibitors, and is the active ingredient in Bayer's blockbuster drug XARELTO. XARELTO is used as a treatment for deep-vein thrombosis and pulmonary embolism. XARELTO is Bayer's best-selling drug globally, earning around AUD140 million under the PBS in 2024. Internationally, Bayer

and Sandoz have been involved in a number of disputes regarding rivaroxaban, including in the UK, where the UK High Court revoked Bayer's patents.

The case concerned Australian Patent No 2004305226 (the "226 Patent") for a formulation, and Australian Patent No 2006208613 (the "613 Patent") for a once-a-day dosing regimen. At first instance, Justice Rofe rejected an obviousness challenge based on the common general knowledge (CGK) together with WO 919, the compound patent which disclosed rivaroxaban as a particularly promising candidate.

In her reasoning, Justice Rofe accepted that WO 919 would be of interest to a drug development team seeking to develop a new antithrombotic drug, and that the skilled reader would likely focus on rivaroxaban when selecting lead candidates to take into further drug development work. Justice Rofe then went on to apply the "reformulated Cripps question", finding that:

- the well-known standard series of steps of drug development were not routine steps; and
- Bayer's drug development journey was more akin to a "voyage of discovery" than "working towards the invention with an expectation of success".

On appeal, the Full Court found that Justice Rofe had placed too much emphasis on "the risk of failure to gain regulatory approval which is inherent in any drug development project", and what would have been undertaken as a matter of course following the selection of rivaroxaban as a lead candidate.

Further, the Full Court confirmed that the "relevant expectation" should be measured against the ordinary level of expectation and risk inherent in routine work in the field. It is not necessary to know a particular outcome at the outset of the hypothetical task. Rather, the Full Court stated the question as whether a person skilled in the art with the relevant CGK, would have been directly led, as a matter of course, to develop rivaroxaban in the expectation that it might produce a useful alternative (or better drug than) the existing compounds for the treatment of thromboembolic disorders.

In the absence of any evidence of any particular problem or difficulty overcome in arriving at a suitable formulation (using a standard wet granulation process) or an (obviously desirable) once-a-day dosing regimen, the Full Court found that these matters would have been arrived at in the course of conventional clinical trials.

Bayer has applied to the High Court of Australia for special leave to appeal.

Ascertaining prior art for pre-Raising the Bar patents

In the same case, the Full Court addressed the standard to be applied in determining whether the person skilled in the art could be reasonably expected to have "ascertained" a prior art document, which is a prerequisite for considering obviousness in light of the prior art.

At first instance, Justice Rofe had accepted that a person skilled in the art would have conducted searches on patent databases using search terms including factor Xa inhibitors, and that the search would have returned results that included WO 919. She accepted that Sandoz's expert, Professor Roberts, had reviewed the search of the patent database, identified WO 919 as a top priority, and had done so without the benefit of hindsight. However, Justice Rofe found that

Sandoz's evidence on ascertainment involved a "short cut" because:

- it involved a hypothetical literature search that was limited to one search term (factor Xa inhibitors) and one database; and
- Professor Roberts had been provided with a spreadsheet of search results from which he selected WO 919 as a top priority, but had not been provided with copies of the other documents.

Justice Rofe was critical of the form of this evidence, and found that Professor Roberts had not been provided with "the full suite of results from searches undertaken across all his suggested databases". Her Honour therefore held that the evidence did not establish that it would be reasonable for the person skilled in the art undertaking a search of the kind described by Professor Roberts, but not restricted to factor Xa inhibitors, to have found WO 919.

On appeal, the Full Court found that, once Justice Rofe accepted that the search results were a subset of the searches that a skilled person would have done, it was not to the point that additional searches might have been performed, or that the skilled person would have been required to review these additional documents or information. It was not, therefore, necessary for evidence to be adduced that the skilled person would select WO 919 over all other information that they would reasonably be expected to have discovered or found out.

Invisalign appeal against SmileDirectClub

In 2024, the Full Court of the Federal Court also weighed in on comparative advertising in proceedings brought by Invisalign against SmileDirectClub.

Invisalign Australia Pty Ltd ("Invisalign") and SmileDirectClub LLC (SDC) are competitors in the market of clear aligner teeth-straightening products in Australia. Invisalign alleged that SDC made false, misleading or deceptive representations in contravention of ss 18 and 29 of the Australian Consumer Law (ACL) in relation to certain material promoting its clear aligners, which are a type of orthodontic appliance that induces mechanical movement of the teeth ("SDC Aligner Treatment").

On appeal in Invisalign Australia Pty Ltd v SmileDirectClub LLC [2024] FCAFC 46, the Full Court reversed the first-instance decision of Justice Anderson, finding that SDC had engaged in conduct which contravened the ACL.

Invisalign relied on five groups of representations made by SDC, each of which was considered by the Full Court. These representations and the Full Court's holdings are summarised below:

1. The comparable treatment representations – the SDC Aligner Treatment was of comparable efficacy to, and would achieve the same or similar clinical outcomes to, traditional braces or Invisalign aligners.

The Full Court did not agree with the primary judge and held that by making the comparable treatment representations, SDC had contravened the ACL, as the dominant impression created by the promotional material was to convey to a consumer that they would end up with the same smile, irrespective of whether they chose braces or SDC Aligner Treatment; that consumers would achieve the same or a similar clinical outcome from SDC Aligner Treatment as they would achieve with Invisalign treatment; and that SDC Aligner Treatment was of comparable

efficacy to Invisalign treatment and traditional braces treatment.

2. The price comparison representations – the SDC Aligner Treatment was less expensive in all instances, or was "60% less" or "up to 60% less" expensive for equivalent treatments obtained from an orthodontist or dentist, such as braces or Invisalign.

3. The lower cost representations the SDC Aligner Treatment provided a comprehensive solution to orthodontic issues, or alternatively all non-severe orthodontic issues, at significantly less cost than that of equivalent treatments with braces or Invisalign.

Again, the Full Court did not agree with the primary judge and held that by making the price comparison representations and the lower cost representations, SDC had contravened the ACL, as the dominant message of the advertisements was that the products were interchangeable or equivalent or had an equivalent effect on consumers' teeth, but that SDC Aligner Treatment cost "60% less". This message was not qualified by reference to the severity of the problems with the consumers' teeth. Further, even though this message did not include express claims that SDC cost 60% less than Invisalign, their Honours held that the ordinary reasonable consumer interested in undertaking treatment for teeth straightening would understand that SDC could only be referring to its competitors.

4. The less than AUD4-a-day representation – the total cost associated with SDC Aligner Treatment was "less than $4 a day" for the duration of treatment.

SDC admitted that it made the representation in its advertising material but that the representation was not referring to the treatment time of an average of four-to-six months as contended by Invisalign, but rather to the 24-month period over which instalments for SDC Aligner Treatment were paid.

The primary judge held that the placement of a footnote above the full stop was sufficiently prominent to alert the ordinary and reasonable consumer to the manner in which the representation had been calculated. Their Honours considered the primary judge had made no error.

5. The total-cost representation – the total cost associated with the SDC Aligner Treatment was either AUD2,825 for upfront payment or AUD3,155 by instalments.

Invisalign alleged that the total-cost representation was misleading as it did not refer to the ongoing costs associated with purchasing retainers at six-monthly intervals after the SDC Aligner Treatment was completed, which was required to keep a consumer's teeth in their new position. The Full Court agreed with the primary judge that it was clear that the ongoing costs were outside the cost of the SDC Aligner Treatment and therefore that the total-cost representation did not contravene the ACL.

Notably, the only representations which were made by Invisalign were those concerning comparative advertising. This is an important reminder that when engaging in comparative advertising, context is key. It is always prudent to ensure that comparative advertisements have accurate comparisons that compare like products and/or services fairly.

Saved by an obvious mistake – ToolGen's patent amendments

The decision in ToolGen Incorporated v Fisher (No 3) [2024] FCA 539 serves as a useful reminder of the ability to amend patent claims to correct an "obvious mistake", even where the effect is to broaden the claims.

Justice Nicholas had previously held that each of the claims of ToolGen's patent application would, if granted, be invalid. ToolGen sought leave to amend the claims of the patent application pursuant to s 105(1A) of the Patents Act 1990 (Cth) (the "Patents Act").

ToolGen sought solace in s 102(3)(a) of the Patents Act, arguing that claims 10 and 19 when read together contain an "obvious mistake". Section 102(3)(a) provides that where an amendment is to correct a clerical error or an obvious mistake, the requirements in s 102 regarding the allowability of amendments do not apply.

The claims of a patent serve to give the public notice of the limits of the monopoly. Because amendments are retrospective, amendments which broaden the claims are not allowed – they would turn earlier non-infringing activities into acts of infringement. The narrow exceptions to this rule are amendments for the purpose of correcting a clerical error or obvious mistake. The theory is that an obvious mistake cannot have misled a person skilled in the art.

Justice Nicholas considered the principles relevant to what constitutes an obvious mistake, including:

- both the error itself and the necessary correction must be obvious to the person skilled in the art;
- "mistake" is a failure to express the real intention of the writer of the specification;
- the correction required does not cease to be "obvious" because there is more than one way of expressing it; and
- it is not an obvious mistake if extraneous evidence, beyond what is required to put the court in the position of a person skilled in the art, is needed to show the mistake.

Justice Nicholas considered that the skilled person would understand there to be a mistake in the "composite claim" (ie, claim 10 when read with claim 19) and that the relevant correction of the mistake was one which would be obvious to the person skilled in the art. His Honour considered that the skilled person would clearly understand from reading the specification that the various embodiments of the system described included embodiments in which the guide RNA was created in vitro before introduction into the cell, as well as embodiments in which nucleic acid encoding the guide RNA was introduced into the cell where the guide RNA was subsequently transcribed. His Honour further considered that the skilled person would understand that claim 10 was directed at embodiments in which the guide RNA was produced in vivo and that claim 19 was directed at embodiments in which the guide RNA was an in vitro-transcribed RNA.

The relevant correction would, therefore, involve re-writing the composite claim to eliminate the inconsistency in language between claims 10 and 19 so that, rather than referring to nucleic acid encoding a guide RNA, the composite claim instead referred to an in vitro-transcribed guide RNA. The result was that claim 10 would continue to include use of a guide RNA produced in vivo and the composite claim would include use of a guide RNA produced in vitro.

Amendments to correct obvious mistakes are an exception to the rule in s 102 of the Patents Act that amendments must not broaden the scope of the claims. Although amendments to correct mistakes can be allowed, even in a manner which broadens the claims, both the mistake and its correction must be obvious.

Term extensions remain in the firing line

As we reported in the 2024 Trends & Developments report in this guide, the patent term extension (PTE) regime continues to be a contentious battleground in Australian litigation.

A patentee may apply for a PTE if certain conditions are met, including that a "pharmaceutical substance per se" is "in substance disclosed" in the specification and "in substance fall[s] within the scope" of the claims.

In Novartis AG v Pharmacor Pty Limited (No 3) [2024] FCA 1307, Novartis sought a PTE in relation to goods containing, or consisting of, the pharmaceutical substance included in the ARTG as: "ENTRESTO sacubitril/valsartan (combined as a sodium salt hydrate complex)". Novartis obtained the PTE in relation to its patent titled "Pharmaceutical compositions comprising valsartan and NEP inhibitors", of which claim 1 is to pharmaceutical compositions comprising an NEP inhibitor, such as sacubitril, and an AT 1-antagonist, such as valsartan, and salts thereof.

Pharmacor challenged the validity of the PTE on the basis that Entresto contains "TSVH", a single crystalline complex of the anionic forms of sacubitril and valsartan. Pharmacor argued that because the claims related to two separate salts of sacubitril and valsartan, TSVH was not disclosed and claimed in the patent.

Novartis responded that the two distinct molecules had not lost their identities in forming the complex, pointing to the ARTG certificate which refers to Entresto as "sacubitril/valsartan (combined as a sodium salt hydrate complex)".

Justice Yates agreed with Pharmacor, finding that two pharmaceutical substances per se were disclosed and fell within the scope of claim 1, of which Entresto comprised neither. His Honour found that TSVH was a different compound with a unique set of physiochemical properties, and was not disclosed "or even envisaged" in the patent.

Novartis v Pharmacor is yet another decision highlighting the nuances of Australia's PTE provisions. While the Australian regime has historically been considered a relatively patentee-friendly one, more recent Federal Court judgments have tested its limits.

BRAZIL

Law and Practice

Contributed by:
Ana Paula Affonso Brito and Maria Eduarda de O Borrelli Junqueira
Montaury Pimenta, Machado & Vieira de Mello

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Montaury Pimenta, Machado & Vieira de Mello is a leading IP law firm, renowned for resolving disputes before the Brazilian IP courts. With over 150 professionals located in Rio de Janeiro and São Paulo, the firm has experienced remarkable growth and holds an important position at the forefront of the market, especially in the patents and life sciences fields. The firm's experienced patent lawyers have a successful track record in handling disputes in the areas of patent infringement, patent invalidation and pharmaceutical patents, and the team includes engineers with chemistry and biotech backgrounds, as well as leading patent and life sciences litigators who have been involved in some of the most high-profile cases in Brazil. These cases include representing clients from the pharmaceutical, healthcare, biotech and chemistry industries in high-stakes patent cases before the Brazilian courts. The firm's integrated team of legal and technical professionals is able to offer a cutting-edge blend of capabilities, and handle complex deals and cases of any size.

Authors

Ana Paula Affonso Brito has extensive expertise in IP litigation matters before the Brazilian federal and state courts, acting for both domestic and international clients of Montaury Pimenta, Machado & Vieira de Mello. She has a master's degree in IP from the Brazilian Patent and Trademark Office Academy and a post-graduate degree in IP from the Rio de Janeiro State University School of Law, where she graduated in 2000. Ana Paula's practice includes the evaluation of litigation risks, collaborating with corporate departments, and developing mitigation solutions and litigation strategies. She assists clients across different fields of activity and technologies, such as pharmaceuticals, crop science and cosmetics.

Maria Eduarda de O Borrelli Junqueira joined Montaury Pimenta, Machado & Vieira de Mello as a paralegal in 2017, became a lawyer in 2019, and a partner in 2020. She studied industrial property law at the Nova University of Lisbon in 2016 as part of a graduate exchange programme, obtained her law degree from PUC-Rio in January 2020, and a post-graduate degree in IP law at the same university. She has been working in IP litigation since 2016 and her experience includes complex cases related to patents in the pharmaceutical and life sciences fields, dealing with copyright and unfair competition issues, as well as assisting clients with judicial and extrajudicial matters in the area.

Contributed by: Ana Paula Affonso Brito and Maria Eduarda de O Borrelli Junqueira,
Montaury Pimenta, Machado & Vieira de Mello

Montaury Pimenta, Machado & Vieira de Mello

Av. Almirante Barroso, 139-7th Floor
Rio de Janeiro
ZIP 20.031-005
Brazil

Tel: +55 21 2524 0510
Email: montaury@montaury.com.br
Web: www.montaury.com.br

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

The Brazilian Code of Civil Procedure

Article 17 of the Brazilian Code of Civil Procedure (the "Brazilian Civil Code" or the "Code") provides that in order to file a lawsuit, it is necessary to demonstrate legal interest and legitimacy. Thus, an action for patent infringement must be filed by the patentee and in the case of co-ownership, the provisions of the Civil Code will apply.

Since Brazilian law does not provide further details for the co-ownership of patents, other than defining that a patent application may be filed by a group of inventors, most of the rules established between the co-owners are guided by the Brazilian Civil Code. What is not statutorily required, may be required by contract. Contractual dispositions are therefore strongly recommended in Brazil, due to the lack of detailed provisions in the Industrial Property Act.

The Brazilian Civil Code is applied subsidiarily, as the law on co-ownership of a patent is analogous to the law onco-ownership of real estate/ property, which sets forth that if two or more people own an undivided thing, each may exercise possessory acts over it, as long as they do not exclude the other co-owners.

Not all joint owners therefore have to join as plaintiffs in patent enforcement actions, and each owner has the right to enforce its property independently. Such provision may not be changed by contract, since this would be an ownership limitation rule. However, other provisions may be altered by contract.

The Brazilian Industrial Property Act

As to licensees, the Brazilian Industrial Property Act (Law #9.279/96) foresees in Articles 61 and 62 that patentees can celebrate exploitation licensing agreements with third parties, and, in this case, the licensee may be invested with all powers to act in defence of the patent. This includes the extraordinary right to figure as a plaintiff in an infringement action, even without joining the patentee as a co-plaintiff.

In the specific scenario in which the patentee does not figure as a co-plaintiff, it will not be necessary to figure as a defendant either – as this position will be solely occupied by the alleged

infringer(s). It is important to highlight, however, that the licence agreement must be recorded with the Brazilian Patent and Trademark Office (BPTO) to have an effect on third parties.

Patent nullity actions

As to patent nullity actions, Article 56 of the Brazilian Industrial Property Act foresees that these can be filed before a federal court by the BPTO or by any legitimately interested party, at any time during the patent validity term. Nullity actions are usually filed by those who have been sued in a state court for patent infringement or who have received a cease-and-desist letter from the patentee, to refrain from using the protected technology. This is because an invalidity declaration by the court will have retroactive (ex tunc) effects from the date of the patent application's filing with the BPTO – which means that should a patent be declared invalid, it will be as if it has never existed, and no infringement condemnation may be declared on a parallel ongoing infringement action.

There are also technologies where protection by patent may put a segment of society at risk, such as pharmaceutical patents, generating greater flexibility for the judge in gauging the legitimate interest of the plaintiff in the nullity action.

In a recent case (REsp No 1332417/RS decision issued on 20 June 2024), the Brazilian Superior Court of Justice (*Superior Tribunal de Justiça*, or STJ) confirmed its understanding that it is possible to argue the nullity of a patent or of a design as a defence against an infringement lawsuit before the state court in Brazil.

The issue had already been analysed by the court in 2020, when the Third Panel of the STJ decided, within the scope of lawsuit REsp No 1.843.507/SP, that although the invalidity claim of a patent has to be addressed to a federal court, the Brazilian IP Act would expressly allow the defendant the possibility to invoke nullity in an infringement action, as a matter of defence, without the need for the BPTO to participate in the lawsuit (Article 56, § 1º of the LPI).

The decision issued on 20 June 2024 standardises the case law and explicitly states that the consequence of a declaration of invalidity of an industrial design or patent as a defence strategy against an infringement lawsuit is limited to parties involved in the lawsuit.

This means that the state court's ruling is confined to the infringement case in which it arises, dealing solely with disputes between private parties without the participation of the BPTO. Thus, such decision does not constitute the formal revocation of the patent or utility model involved and will not cause general effects (erga omnes) or impact on its validity before third parties.

1.2 Defendants/Other Parties to an Action

In life science/pharma cases, the manufacturer is generally sued for infringement, as the supplier of the whole chain, although in the case of pharmaceuticals produced outside Brazil (generally generics), the importer is generally the one who will be sued. Thus, it is seen as more efficient to target the person that started the infringement or the one who has launched the product and given rise to it, as the patentee will be able to seek to cease the infringement at the "roots".

While the infringement action takes place between private parties in the state court, the nullity action may be filed by anyone with a legitimate interest against the patentee and the BPTO, in the federal courts, in accordance with

the provision of Article 57 of the Brazilian Industrial Property Act, since the BPTO is the federal agency responsible for the administrative act that granted the targeted patent.

1.3 Preliminary Injunction Proceedings

Preliminary injunctions are available in the Brazilian legal system and are regulated by Article 300 and the following articles of the Brazilian Code of Civil Procedure, as well as Article 209, § 1o of the Brazilian Industrial Property Act, which establishes that the judge may grant an injunction to cease the infringement, aiming to avoid irreparable damages.

Usually requested on an ex parte basis within the initial brief of the infringement or nullity actions, the plaintiff must attest the:

- likelihood of success on the merits; and
- risk of irreparable harm,

and if one such requirement is not fulfilled, the preliminary injunction request will not be granted by the trial court judge.

Although ex parte injunctions are allowed in Brazil for patent infringement cases, in the São Paulo State Court, judges generally allow defendants to submit a short defence within five days of the summoning, before the official deadline for a formal reply, so as to provide initial inputs to the court. In addition, in 2024 it was apparent that in patent infringement claims in the Rio de Janeiro State Court, judges were also ordering a concise unbiased expert opinion, before the issuance of the preliminary injunction, so as to clarify to the court the main aspects of the infringement.

The Usefulness and Necessity of the Claim

For both patent infringement and patent invalidity actions, the existence of a granted patent is an indispensable prerequisite of the lawsuit, as it attests the procedural interest of the plaintiff. According to a recent decision rendered by the Brazilian Superior Court of Justice on Special Appeal No 2.001.226, the procedural interest requires the confluence of two elements: the usefulness and necessity of the claim submitted to the court. While the former will be attested if the lawsuit can provide the plaintiff with the favourable result sought, the need for the state to act will be attested if it is found that the opposing party resists the claim formulated by the plaintiff.

Thus, it is inferred that the existence of a patent itself should not be used as an exclusive argument to attest to the likelihood of success on the merits, but as an argument to attest the procedural interest of the plaintiff.

Assessing the Pros and Cons

It is also the case that the sooner the patentee adopts the necessary and relevant measures to prevent the ongoing infringement practices, the better the chance that the judge will understand the real urgency of the matter, as well as the risk of irreparable harm. On the other hand, the judge must also weigh the risk of reverse damage to the counterparty, before deciding on the balance whether or not to grant the preliminary injunction.

Judges are used to rendering such decisions on an ex parte basis, but during the past few years, a specific court specialised in IP has been adopting a different practice: the São Paulo State Court – one of the major courts concentrating on IP litigation discussions in Brazil – has been summoning the defendant to present a preliminary response regarding the plaintiff's preliminary injunction request, aiming to promote the least adversarial proceeding so that the judge

can better assess the case and render a decision on whether or not to grant the preliminary injunction request.

It is important to highlight that jurisdictional remedies are not only available to the party whose right has been infringed, but also to the party whose right is about to be infringed, aiming to prevent damage from occurring. It is therefore possible for a patentee to file an inhibitory lawsuit combined with a preliminary injunction request, aiming to prevent the defendant from committing the infringement and the material damages arising therefrom. However, such lawsuits are analysed on a case-by-case basis, taking into consideration the background to the discussion, as well as the practices provided by Article 43 of the Brazilian Industrial Property Act, which are considered exemptions of infringement or threat of infringement, such as the Bolar exemption and the market authorisation application.

Should the preliminary injunction be granted on an ex parte basis, the defendant will be summoned via post or by the clerk of the court. As soon as the confirmation receipt is filed in the court's files, both the defence brief and potential interlocutory appeal deadlines will start.

1.4 Structure of Main Proceedings on Infringement/Validity

Bifurcation of Infringement and Validity Proceedings: Legal Provisions and Discussions on the Case Law

Infringement actions must be filed before a state court, while nullity actions must be filed before a federal court, since the participation of the BPTO (a federal autocracy) as a co-defendant is mandatory, as it is responsible for granting the challenged patent, in accordance with Article 57 of the Brazilian Industrial Property Act.

There is currently a discussion in the main Brazilian courts regarding the possibility of arguing the invalidity of a patent in an incidental manner, as a way of defence in an infringement action, based on the provision set forth by Article 56, § 1o of the Brazilian Industrial Property Act ("the nullity of a patent may be argued, at any time, as a matter for defence").

For some judges, it would not be possible to discuss the nullity of a patent during an infringement action, since Article 57 of the Brazilian Industrial Property Act provides that the BPTO must figure as a mandatory co-defendant (and its participation is only possible before the federal courts, due to a competence rule established by the Brazilian Federal Constitution). For this reason, Article 56, § 1o of the Industrial Property Act cannot be interpreted on its own. However, for other judges, it would indeed be possible to discuss the nullity of a patent in an incidental manner in an infringement proceeding, although the decision on the merits rendered in this respect would have inter partes effects but would not affect third parties outside the lawsuit. There is currently no uniformity in Brazilian case law with respect to this subject and each judge can adopt their own position regarding the matter.

Most recently (EREsp 1332417/RS, Motion for Reconsideration in Special Appeal – 2012/0137220-6), the STJ considered whether it is possible to claim the nullity of patents and/or industrial designs as a matter of defence. On 12 June 2024, the Second Panel of the STJ unanimously reaffirmed such understanding by authorising the claim of nullity by the defendant in an infringement lawsuit. The nullity of patents and industrial designs by the state courts is of an incidental nature, operating inter partes effects, and may serve, exclusively, as a guiding basis

for deducing the unfoundedness of requests in a related infringement lawsuit.

Staying of the Infringement Proceeding

Article 313, V(a) of the Brazilian Code of Civil Procedure establishes that the staying of a lawsuit may occur where there is a risk of conflicting decisions being rendered by different courts – that is, when the judgment of a certain lawsuit depends on the outcome of another case, or on the declaration of the existence or non-existence of a legal relationship that is the main subject of a parallel discussion.

It is then necessary to assess whether the outcome of the subordinating issue (which, in this case, is the invalidity action) will necessarily influence the decision on the subordinated issue (ie, the infringement action). In this case, the possibility of contradictory decisions being rendered by both the state and federal courts is the main legal basis for suspending the proceedings until the case understood as subordinating is decided, as it can happen that at the same time a patent is declared null by the federal court (producing ex-tunc and retroactive effects), the state court may declare the existence of a patent infringement, meaning that conflicting decisions have been generated by the two courts. However, if the decision on the patent's invalidity is upheld by the panel of judges in the second instance, the infringement lawsuit in the state court will have no purpose, as the patent will no longer exist in the legal sphere.

This is why it is not unusual for judges to stay infringement actions when there is an ongoing nullity action before another court, based upon the provision of Article 313, V(a) of the Brazilian Code of Civil Procedure. However, it must be mentioned that there are judges who prefer to stay the infringement action only when a relevant development in the nullity action occurs (for instance, a technical report concluding that the the patent is invalid, or a first instance decision on the merits of suspending the effects of the patent or declaring the patent's invalidity), aiming to prevent alleged infringers from filing an invalidity action, with no relevant arguments, simply to delay the infringement action's conclusion.

Exhaustion of the Administrative Sphere

According to Brazilian case law, it is not necessary to wait for the administrative sphere's exhaustion to file a nullity action. As long as the patent is granted by the BPTO in the first instance, an interested party can file a nullity action before a federal court, even if an administrative nullity procedure is pending analysis by the BPTO in the second instance. Should the administrative nullity procedure be granted, and the patent be declared null by the BPTO, the nullity action will lose its purpose and consequently be shelved.

1.5 Timing for Main Proceedings on Infringement/Validity

Judicial Statutory Deadlines

As to an infringement action combined with a request for material and moral damages, the plaintiff must file this within five years from the date of acknowledgement of the infringement, according to Article 225 of the Brazilian Industrial Property Act. If the infringement is continuous, the five-year term will be renewed daily.

As to an invalidity action, the plaintiff may file this at any time during the term of the patent, according to Article 56 of the Brazilian Industrial Property Act. However, if the invalidity action challenges the rejection of a patent application, the action must be filed within five years from

the date the BPTO's rejection was released in the Official Gazette.

Estimated Timeframe of Service of an Action and Lawsuit

Defendants are generally served to acknowledge the filing of a lawsuit via post or by the clerk of the court. After confirmation of the defendant's acknowledgement is submitted in the court's files, the defendant has a 15 business-day deadline to present its defence, under penalty of default. After that, the plaintiff will be summoned to submit its response to the defence within the same deadline, and the judge will establish the controversial aspects of the lawsuit to be analysed, appointing the court's expert who will be responsible for analysing the technical aspects of the lawsuit (the patent infringement or the invalidity), and preparing the technical report. Once the technical report is submitted in the court's files, the parties have a common 15 business-day deadline to present their divergent/convergent opinions and the court expert may be summoned to present potential clarifications or amendments to their report. After the conclusion of the technical evidence phase, the judge understands that the lawsuit is sufficiently developed to be judged, but there is no binding deadline for the rendering of the decision on the merits.

Based on recent case law, it is possible to affirm that once the technical evidence phase is concluded, a decision on the merits may take approximately two to six months to be rendered.

1.6 Requirements to Bring Infringement Action

According to a recent decision from the STJ, an infringement action can only be filed once the patent has been granted, since it is the registration itself that guarantees its owner the right to prevent a third party from producing, using, offering for sale or importing the patented product without consent, as set forth in Article 42 of the Brazilian Industrial Property Act. The reason for this is that, before the patent application is granted, it only exists as a mere expectation of rights, as there is no way of ensuring that the patent application will definitely be granted. Thus, although Article 44 of the Brazilian Industrial Property Act sets forth that compensation may be claimed by the patentee, including in the period between the date of publication of the application and the date the patent is granted, the procedural interest will only exist once the BPTO renders an administrative act effectively granting the patent.

1.7 Pre-Action Discovery/Disclosure

The Brazilian Code of Civil Procedure does not foresee pre-action discovery/disclosure.

However, according to Article 396 of the Code, the judge may order the parties to disclose documents and evidence. If a party refuses to comply with the exhibition order without an acceptable reason, a search and seizure order can be issued.

There is no US-style discovery in Brazil. In other words, the parties have no right to seek documents from the other side before trial. The evidentiary phase is judge-oriented, as judges have discretion to order the production of any evidence that they deem appropriate, or deny that which they consider irrelevant to the case.

1.8 Search and Seizure Orders

Search and seizure may be among the requests made by the plaintiff in an infringement action. A patentee can request such order on a preliminary injunction basis, to be corroborated on the

merits, with the aim of stopping continuation of the infringing practices by the defendant.

1.9 Declaratory Relief

Declaratory actions are available in the Brazilian legal system, according to Articles 19 and 20 of the Brazilian Code of Civil Procedure. Such proceedings are appropriate whenever the plaintiff aims to dispel doubts and solve disagreements about the existence, non-existence and way of being of a legal relationship. Thus, declarations of infringement or non-infringement may be questioned by plaintiffs and granted by the Brazilian state courts.

1.10 Doctrine of Equivalents

The doctrine of equivalents (DOE) is applicable in Brazil according to Article 186 of the Brazilian Industrial Property Act. Although the law does not set forth any statutory standards to assess DOE, discussions in lawsuits in Brazil tend to rely on the tripartite equivalence test, inspired by the international doctrine.

1.11 Clearing the Way

There is no obligation established by Brazilian regulations to "clear the way" ahead of a new product launch. However, it is strongly advisable to perform a freedom-to-operate (FTO) analysis before starting any developments on a new product. Failure to clear the way could pose a high risk to the company, since the existence of a patent covering the product intended to be launched could lead to time and financial investment loss, not to mention the potential risk of an infringement lawsuit.

1.12 Experts

According to Article 464 of the Brazilian Code of Civil Procedure, a court expert will be appointed by the judge whenever proof of the facts alleged by the plaintiff depend on special technical knowledge. Thus, given the technical complexity of patent infringement and nullity actions, the production of technical evidence by an unbiased expert appointed by the judge is mandatory, as the judge only has knowledge about legal issues. Such nomination usually happens after the plaintiff's response to the defendant's defence brief, once the judge has established the controversial points of the lawsuit that need to be analysed. The parties then appoint their own technical assistants who will be able to communicate with the court expert, and prepare queries to be answered by the expert during the technical evidence phase/final report.

It is worth mentioning that parties can challenge the nomination of the court expert if there is lack of proof that the professional is a skilled person in the patent's technology field or that the professional has industrial property knowledge. The specialisation of the court expert is therefore a relevant aspect to be double-checked by the parties, since it directly impacts the quality of the technical report that will be issued, and also impacts on the quality and fairness of the trial, as most judges tend to follow the technical report's conclusion, not having sufficient technical knowledge to assess the technology involved themselves. However, it is important to mention that judges are not bound by an expert's conclusion and can adopt a different position from the technical report, as long as such decision is well grounded.

1.13 Use of Experiments

In infringement actions, should a patent cover a method or a process, the burden of proof is on the defendant, according to the terms of Article 42, § 2o of the Brazilian Industrial Property Act. In this sense, it is the defendant (ie, the alleged infringer) who must prove that the method used by them is different from the one patented. Such

proof must first be attested in the defence brief, and can be corroborated by a technical assistant hired by the party, or by a specific employee of the defendant's company. Once the defendant provides the court with the necessary proof, the unbiased expert appointed by the court will be responsible for analysing, during the technical evidence phase, the patented method versus the method allegedly used by the defendant. Where necessary, the expert may reproduce, through an experiment in a laboratory, the alleged method used by the counterparty, in order to attest not only to the potential differences between the methods, but also, whether the defendant's method is really effective.

1.14 Discovery/Disclosure

See **1.7 Pre-Action Discovery/Disclosure**.

1.15 Defences and Exceptions to Patent Infringement

Prosecution history estoppel, references from the state of the art, and Bolar exemption, and most recently invalidity arguments (see **1.4 Structure of Main Proceedings on Infringement/Validity**) are common defence strategies used by defendants accused of equivalence infringement or literal infringement. The disclosure-dedication doctrine can also be used as defence to the doctrine of equivalents, although the Brazilian system has not adopted such designations directly in the Brazilian Industrial Property Act.

1.16 Stays and Relevance of Parallel Proceedings

See "Staying of the Infringement Proceeding" in **1.4 Structure of Main Proceedings on Infringement/Validity**.

1.17 Patent Amendment

It is possible for a patent to be declared partially invalid with respect to a specific claim, during litigation. When this happens, the trial court decision should also be considered part of the letter patent, as the BPTO will not issue a new letter patent and there are no provisions binding the BPTO to do so.

As to actions that challenge the rejection of patent applications, seeking for them to be granted in the judicial sphere, recent Brazilian case law has admitted the amendment of a set of claims as long as this is to restrict and limit it, according to Article 32 of the Brazilian Industrial Property Act.

1.18 Court Arbiter

Regarding infringement actions, the São Paulo and Rio de Janeiro state courts are the main courts when it comes to IP matters, as both have specialised judges. However, in order to file this type of action in one of them, the plaintiff must demonstrate that it has its headquarters in one of these cities, or that the infringement practice has occurred in one of these jurisdictions, since this is a prerequisite set forth by Article 53, V of the Brazilian Code of Civil Procedure. Regarding nullity actions, Article 57 of the Brazilian Industrial Property Act requires these to be filed in a federal court – and the Rio de Janeiro court is the major one with specialised judges in IP matters, since the BPTO headquarters are located in the city.

2. Generic Market Entry

2.1 Infringing Acts

The Brazilian IP Law confers the right to prevent third parties that do not have consent from

manufacturing, using, offering for sale, selling or importing for such purposes:

- a product that is the subject of a patent; and/or
- a process, or product directly obtained by a patented process.

The patentee is further guaranteed the right to prevent third parties from contributing to other parties' infringement acts.

Although marketing authorisation applications or grants are usually seen as allowed pre-launch activities, applications for reimbursement, pricing or listing, submissions or awards of tender, and offers to supply after patent term expiry, are subject to an infringement lawsuit.

Special attention is directed to marketing authorisations granted way before the patent expiry, since the regulatory framework requires the renewal of the commercialisation of the object of the authorisation within the final two thirds of the final term.

The parallel importation of a product that is covered by a patent, or that is obtained by means or processes patented in Brazil for commercial purposes, is also subject to an infringement lawsuit, if the product has not been placed on the external market directly by the owner or with the owner's consent.

As to the skinny label, the rules in Brazil changed in December 2023 when the National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, or Anvisa) issued a resolution which allows a patented indication to be carved out of a generic leaflet.

2.2 Regulatory Data and Market Exclusivity

In terms of patent protection, there is no provision for any market exclusivity extension related to orphan, paediatric, new indications, combinations, reclassifications, etc. A patent is valid for 20 years, counted from the filing date, with no possible term adjustment.

However, in view of a Supreme Court decision, which declared the ten-year validity rule of patents unconstitutional, some patentees are filing lawsuits requesting patent term adjustments based on the unjustified delay of the BPTO in the analysis of patent applications, on a case-by-case basis. Said court actions are new and, for now, it is not possible to predict how they are going to evolve and what their outcomes will be, since there is no case law available to support this new legal thesis.

2.3 Acceptable Pre-Launch Preparations

Generics are allowed to request the marketing authorisation of a product and to perform any experimental activities with the aim of having the data required for the marketing authorisation request (Bolar exemption).

The patentee has the right to prevent third parties that do not have consent from producing, using, offering for sale, selling, importing for these purposes, or contributing to such practices, a patented product, process or product obtained directly by a patented process.

However, Article 43, VII of the Brazilian Industrial Property Act expressly provides exceptions to patent protection – among them, acts carried out by unauthorised third parties, related to an invention protected by a patent, which aim to obtain a marketing registration in Brazil, or in another country, for the exploitation and mar-

keting of the product that is the subject of the patent, after the expiry of the patent term. The usefulness of the Bolar exemption is justified by the extensive and excessive bureaucracy of regulatory agencies, including the Brazilian agency Anvisa for medicines in Brazil, which can take years to authorise the marketing of new medicines.

2.4 Publicly Available Drug and Patent Information

There is no Orange Book equivalent in Brazil. Marketing authorisations (MAs) are granted by Anvisa and the grant is noted in the national Official Gazette, which should be monitored, since the holder of the MA for the reference product is not notified of any generic or bio-similar marketing authorisation applications (MAAs) or granted MAs.

On 13 August 2024, the First Panel of the STJ ruled that Anvisa does not have the legal authority to impose restrictions on drug advertising. According to the court, the regulatory agency lacks the authority to create rules that exceed the provisions of Law 9.294/1996, which regulates the advertising of pharmaceutical and related products.

The agency appealed to the STJ, arguing that its regulatory role is legitimate and essential to public health, emphasising that it is responsible for establishing regulations and for proposing, monitoring and implementing policies, guidelines and actions within its scope of competence, in addition to controlling and supervising the advertising of products under this regulatory regime.

According to the STJ decision, although the regulatory agency has general authorisation to issue regulations that ensure the fulfilment of its duties, specifically with regard to the advertising of products under sanitary control, this competence is restricted, as defined in Article 7, item XXVI of Law 9.782/1999, which stipulates that Anvisa's actions concerning medicines must comply with current legislation.

According to the judges, advertising restrictions for medicines are established by Law 9.294/1996, supplemented by Decree 2.018/1996, and have immediate application, being mandatory for all, including public administration. However, the ruling stated that RDC 96/2008 contains several provisions that exceed the limits set by Law 9.294/1996. Among them are the prohibition of indirect advertising at events and in movies; restrictions on advertisements showing people using medicines, especially if suggesting pleasant qualities such as taste; the requirement for warnings about substances that may cause sedation or drowsiness; and restriction of the use of certain expressions in the advertising of over-the-counter medicines.

Thus, it was considered that Anvisa had exceeded its regulatory authority, creating obligations for private parties, which exceeds its role of merely overseeing, monitoring and controlling advertising practices. With this understanding, the STJ suspended Anvisa's resolution on advertising and denied the special appeal.

Despite the above decision, which emphasised that Anvisa does not have the authority to create rules that exceed the provisions of Law 9.294/1996, medicines and pharmaceutical products are health-related goods, not merely consumer products. Therefore, their advertising remains subject to all other applicable regulations in Brazil.

Among these regulations is self-regulation conducted by CONAR – the National Council for Advertising Self-Regulation. Unlike Anvisa's rules and the previously mentioned laws, CONAR establishes ethical guidelines of a consultative nature and, when called upon, issues decisions that lack coercive force, but which are usually followed by advertisers. It has a significant impact on corporate behaviour and advertising regulation in Brazil, ensuring that information in advertisements is truthful and honest, and does not mislead consumers.

In Brazil, it is still Anvisa's duty, however, to ensure that medical and pharmaceutical products available on the Brazilian market comply with public health standards, are safe and effective, and contribute to the health and well-being of the population.

2.5 Reimbursement and Pricing/Linkage Markets

The Medicines Market Regulation Chamber (*Câmara de Regulação do Mercado de Medicamentos*, or CMED) acts as an inter-ministerial body overseeing the economic regulation of Brazil's pharmaceutical market, with Anvisa serving as the executive secretariat of said chamber.

CMED sets price limits for drugs, implements rules that maintain a competitive field, monitors sales, and enforces penalties for rule violations.

The primary regulatory framework governing medicine pricing is CMED Resolution No 02/2004. This resolution categorises medicines into six pricing categories, in addition to omitted cases not foreseen by the regulations, which are resolved by the CMED Executive Technical Committee (CTE).

For generic medicines, pricing adheres to the guidelines outlined in Article 3, VI, combined with Article 12 of CMED Resolution No 02/2004. These generic medicines fall under Category VI, which specifies that their price cannot exceed the maximum limit of 65% of the corresponding reference medicine's price.

3. Biosimilar Market Entry

3.1 Infringing Acts

Litigation concerning biologics or bio-similar patents remains the same as in **2.1 Infringing Acts**.

3.2 Data and Regulatory Exclusivity

For data and regulatory exclusivity concerning biologics and bio-similars, see **2.2 Regulatory Data and Market Exclusivity**.

3.3 Acceptable Pre-Launch Preparations

Litigation concerning biologics or bio-similars remains the same as in **2.3 Acceptable Pre-Launch Preparations**.

3.4 Publicly Available Drug and Patent Information

Litigation concerning biologics or bio-similars remains the same as in **2.4 Publicly Available Drug and Patent Information**.

3.5 Reimbursement and Pricing/Linkage Markets

Litigation concerning biologics or bio-similars remains the same as in **2.5 Reimbursement and Pricing/Linkage Markets**.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Initially, it is important to highlight that patent term adjustments (PTAs) or supplementary protection certificates (SPCs) are not available in Brazil, nor are they the subject of any formal legal provision.

However, in view of a Supreme Court decision issued in May 2021 (lawsuit ADI No 5529/DF), stating the unconstitutionality of the sole paragraph of Article 40 of the Industrial Property Act and abolishing the ten-year minimum validity term for patents for inventions and the seven-year minimum validity term for utility models, patentees are filing lawsuits in Brazil requesting PTAs based on the unjustified delay of the BPTO in the analysis of patent applications, on a case-by-case basis. Therefore, it is not up to the BPTO to decide a possible patent term adjustment. Rather, this discussion is being addressed in the federal courts, with the BPTO figuring as a defendant.

Such lawsuits are new and, for now, it is not possible to predict how they are going to evolve, what their outcome will be, and how long it will take to reach a final decision. It is also not possible to answer questions regarding eligibility criteria and/or provide information regarding the calculation of the duration of adjustments.

At present, there are approximately 60 lawsuits requesting a PTA before the Brasília Federal Court, and most of these have the same goal: seeking a PTA, based on an excerpt from a decision by the Honourable Judge Dias Toffoli, who quoted the PTA expression as an institute of other countries, which, in theory, allows the extension of the patent validity term.

Most of the decisions already issued are preliminary injunction decisions that do not have the purpose of effectively extending the patent term in a definitive way, but rather, that have the purpose of suspending the patent expiry date, until a decision is made on the merits of the matter (all of them still pending).

The movement to file lawsuits seeking patent validity adjustment began in the second half of 2021. All patents subject to these lawsuits refer to technologies in the pharmaceutical area. Up until April 2024, a total of 62 lawsuits had been filed seeking compensation for the term, due to unjustified delays on the part of the BPTO. These lawsuits have been filed before the federal courts, in the court of the Judicial Section of Brasília, the federal capital.

The unanimous choice of the Brasília court implies a significant impact on case law regarding PTAs, since all first-instance decisions will emanate from the Brasília court and the respective appeals will be heard by the Federal Regional Court of the First Circuit (TRF-1). By concentrating such lawsuits in a single court, the expected effect is the consolidation of the TRF-1 as a paradigmatic instance in which Brazilian precedents on the subject will be issued, at least for now.

Among the 62 actions filed, several bring claims for preliminary relief in the first instance (either with the initial brief or incidentally), that is, it is requested that the final provision (compensation for the patent term) be granted provisionally, based on Article 300, caput, of the current Code of Civil Procedure.

Among the 24 preliminary injunction claims, there are more rejections than grants of preliminary relief when analysing the decisions handed down with regard to requests for preliminary injunctions.

Regarding the merits of these lawsuits, all the judgments handed down in 2024 have dismissed requests for a patent adjustment term. The reasons behind such conclusions are similar to the arguments accepted for the denial of the preliminary injunctions. In particular, four key points have grounded the dismissal of the requests:

- the adjustment of the deadline would go against the unconstitutionality decision handed down by the STF in ADI 5529;
- the adjustment of the patent term depends on there being prior legislative activity expressly authorising this;
- by virtue of Article 44 of the LPI, companies could benefit from the lengthy patent examination; and
- social interest should guide the patent protection system and society would be harmed by the prolonged validity of pharmaceutical patents.

The only judgment that does not mention such arguments (Case No 1074941-83.2021.4.01.3400) is based exclusively on the application of the statute of limitations of the claim filed.

Therefore, it is clear that judges are hesitant to address the issue without clearer instructions from the higher courts on the admissibility of the case-by-case adjustment in view of the understanding established at the time of ADI 5529.

As a direct result of the decisions of dismissal in the first instance, appeals have been filed and it is expected that the position of the TRF-1 in the appeals stage will shape the near future of PTA actions in Brazil.

4.2 Paediatric Extensions

In Brazil, there is no division in PTA lawsuits based on a certain field of medical specialisation, nor any provision of extension based on special groups of patients or diseases.

4.3 Paediatric-Use Marketing Authorisations

See **4.2 Paediatric Extensions**.

4.4 Orphan Medicines Extensions

See **4.2 Paediatric Extensions**.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

The Brazilian legal system does not differentiate between injunctions in the area of life sciences from others aimed at other technologies, as they are treated as a whole within the industrial property law and also by the Brazilian Code of Civil Procedure. The general rules for granting injunctions in patent matters are set out in Article 209, §1 of the Industrial Property Law.

Provisional Order of Suspension

According to Article 209, Section 1o of the Brazilian Industrial Property Act, the judge may, during the course of proceedings and in order to avoid damage that is irreparable or difficult to repair, provisionally order the suspension of the violation, or of the act that gives rise to it, prior to summoning the defendant, and where necessary, order the posting of a cash bond or a bank guarantee.

In other words, the judge may request a guarantee from the patentee for granting an injunction based on the judge's sole discretion. There are many situations in which this payment is not required from the patentee, as the conditions for granting injunctions are the following: (i) likelihood of the plaintiff arguments; and (ii) risk of irreparable harm.

If the guaranteed bond is ordered by the court, however, it must remain in effect until the conclusion of the lawsuit, at least until the judgment on the merits is issued. If the plaintiff's arguments are accepted in the final decision, the security deposit can be claimed by the plaintiff.

In Brazil, there are no regulatory authorities that participate in this guarantee which, when due, will be charged solely to the patentee.

Preliminary Injunction

A preliminary injunction is enforceable from the day the defendant is informed about it by service. The parameters and enforceability terms of preliminary injunctions may vary, however, depending on the judge's decision. The timing for service will depend on the court's office backlog, as a writ of summons needs to be issued and addressed by registered mail to the defendant or handed in by the clerk of the court, which are the two possibilities of service, according to the Brazilian Code of Civil Procedure.

Preliminary injunctions remain in effect while the lawsuit is pending but may be revoked or modified at any time. Except for very specific situations, a preliminary injunction remains in effect during the period in which proceedings are stayed (Section 296 of the Brazilian Code of Civil Procedure).

The judge may order the measures deemed necessary to enforce a preliminary injunction and such parameters may vary depending on the case (Section 297 of the Brazilian Code of Civil Procedure).

If requested by the judge, the patentee may have to pay a bond before the preliminary injunction is enforceable and such amount will depend on the amount in dispute, to be set at the judge's sole discretion.

A preliminary injunction is also called a "provisional remedy" and may be based on urgency or evidence. A provisional remedy based on urgency, of a preventative nature or as a preliminary satisfaction of judgment, may be granted prior to the filing of the claim, or incidentally.

Most preliminary injunctions claimed in patent infringement cases are requested with the infringement or nullity lawsuits, and are therefore part of the claims and not part of another lawsuit.

An interlocutory appeal may be filed against the decision granting the preliminary injunction/provisional remedy within 15 days from the confirmation of the defendant's summoning. It must be addressed to the Court of Appeals.

5.2 Final Injunctive Relief

Confirmation or Revocation of Preliminary Injunction

After the issuance of a final decision on the merits, the preliminary injunction can be confirmed or revoked. Where it is confirmed, it will be transformed from a preliminary injunction to a definite injunction or relief. From the publication of the decision on the day of service, the parties can file an appeal addressed to the Court of Appeals within 15 business days. The appeal filed against the final judgment will suspend the proceedings

and the effects of the decision. However, a judgment will be enforced immediately after its publication when it confirms, grants or revokes a preliminary injunction, according to Article 1012, § 1o. V of the Brazilian Code of Civil Procedure.

There are two possibilities of enforcement: final, when the decision is no longer appealable; or definite or provisional, when the decision is being discussed on the appeal level.

Patent Infringement – Cease or Pay

Regarding patent infringement cases, there are generally two provisions in the decision to be enforced – the obligation to cease the infringement and to pay losses and damages. Regarding the cease-of-use order, the enforcement of the decision will be established by the judge, who will set the measures required for the accomplishment of the obligation, in order to fulfil the specific remedy or to obtain relief from the equivalent result. Among the measures established for enforcement, the judge may set a daily fine, search and seizure, and if necessary, request the support of police authorities. When it comes to losses and damages, these are assessed during the quantification phase and a professional accountant will be appointed to calculate the final amount due, as explained in **5.4 Damages**.

Appeal Process

A patentee does not need to pay a bond before a final injunction is enforceable, but where the plaintiff chooses to have provisional enforcement of the judgment (while it is subject to appeal), it will be the plaintiff's responsibility to compensate any losses incurred by the judgment debtor should the judgment be reversed, according to Article 510, I of the Brazilian Code of Civil Procedure.

In Brazil, all appeals will stay the final injunction, unless the preliminary injunction is confirmed in the decision by the trial court judge. In this case, the effects are immediate. However, it is possible to ask for an injunction in the appeal requesting the suspension of the final ruling, as long as the appellant proves the probability of the appeal being granted, or if there are considerable grounds to believe there is a risk of serious damage or harm that cannot be overcome. The possibilities of obtaining such stay will depend on the evidence the appellant provides in filing a precautionary measure at the Court of Appeals.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

The court has the discretion to revert any obligation into losses and damages in Brazil. For instance, if the defendant is ordered to cease an infringement under a daily penalty and does not comply with the order, the judge can increase the daily penalty or even order the pledging of an asset or of a current account. Judges can reduce the final amount due based on the reasonability and proportionality of the matter discussed.

5.4 Damages

The Lawsuit

Under Brazilian law, the injured party in a patent infringement lawsuit can request compensatory damages in addition to obtaining a court order that the infringing practice be ceased. Such damages can be divided into two main categories: (i) moral damages; and (ii) material damages, which include actual damages and the loss of profit.

For moral damages, the courts will assess the amount to be granted to the injured party on a case-by-case basis, depending on the financial situation of each party, and reasonableness and proportionality in relation to the injury.

In terms of material damages, compensation has the purpose of restoring the status of the injured party to what it was prior to the violation. Brazilian law does not provide for punitive damages.

Under Section 210 of the Brazilian Industrial Property Act, a patentee or exclusive licensee can file a civil complaint to cease the infringement and request compensation for its losses.

The damages (ie, loss of profits) will be calculated based on criteria most favourable to the injured party, considering the following:

- the benefits that would have been gained by the injured party if the violation had not occurred;
- the benefits gained by the infringer of the rights; and
- the remuneration that the infringer would have paid to the right's holder for the granting of a licence that would have legally permitted the infringer to exploit the subject's rights.

The Quantification Phase

It is important to keep in mind, however, that the quantification phase in Brazil is a separate proceeding, started only after the trial court has already rendered a merits decision on the infringement and generally, after the decision is no longer appealable. Moral damages (if applicable) will be fixed in the trial court decision.

After the quantification phase is started by the plaintiff, the judge will appoint an unbiased expert accountant with the task of examining the accounting information provided by the parties, in order to decide on the final figures of material damages. Thereafter, the parties can nominate their own accounting assistants, and each will submit queries to the expert.

The expert analysis is comprised of a report with the answers to the queries, and the final amount of damages due on the grounds of the merits decision. The parties can challenge both the report and the trial court decision confirming the expert's assessments, through an interlocutory appeal.

This means that the quantification phase can take significant time, but by having the constitutional right to challenge the arguments/evidence of all the parties involved in the dispute, the parties are guaranteed that the due process of law is being applied at all stages of the dispute.

Decisions of the São Paulo State Court

Common questions relate to how much is recoverable in damages, under which parameters, and how long it will take to receive the amount related to a damages award. Based on case law analysis, the decisions rendered by the São Paulo Court of Appeals have been setting the tone.

Infringement lawsuits need to be filed with the state courts. The São Paulo State Court receives many disputes, since most major companies are established in the State of São Paulo, which has IP-specialised judges and chambers that frequently address the applicability of Section 210 of the Brazilian Industrial Property Act.

On the grounds of the parameters established in Section 210, the expert will calculate the damages, using the criteria most favourable to the injured party. In this sense, the São Paulo Court of Appeals considers that, for the purpose of quantification, the net value of the infringing products will guide the expert in determining the damages.

Although the quantification phase can be quite lengthy, the IP holder can expect that, in Bra-

zil, material damages related to infringement of industrial property rights are due regardless of proof of actual loss, and that once the infringement is attested, damages will follow.

5.5 Legal Costs

The applicable law for legal costs recovery is the Brazilian Code of Civil Procedure.

According to Section 82 of the Code, the losing party must reimburse the legal and procedural fees which were paid in advance on the lawsuit. With the exception of free legal aid, parties are responsible for bearing the expenses of the acts they perform or request in the proceedings, paying them in advance, from the start until the final judgment or, during its enforcement, until there is full satisfaction of the right recognised in the instrument.

Section 1 – The plaintiff must advance the expenses relative to the act which the judge determines, ex officio or at the request of the public prosecutor's office, when the latter intervenes as guardian of the law.

Section 2 – The decision on the merits will require the losing party to reimburse the successful party for the expenses advanced.

The legal fees are the expenses with court fees (such as those which must be paid when the lawsuit is filed, as well as some types of appeal) and the procedural fees include the amount expended by the successful party on technical assistance, travel expenses, witness travel allowance, and court expert fees, all in accordance with Section 84 of the Code.

The losing party must pay the counterparty's (successful litigant's) attorney's fees, which may vary from 10% up to 20% of the value of the claim, as per Section 85 of the Code, which sets forth that the decision on the merits will order the losing party to pay the fees of the successful party's counsel.

However, attorney's fees set by the judge to be reimbursed are unrelated to the attorney's fees paid by the parties during the lawsuit. This amount set by the judge is based upon a percentage over the value of the claim, and goes strictly to the successful party's attorneys, as a type of "award" for the victory.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

Shame litigation can be addressed to the Brazilian Economic Defence Council (*Conselho Administrativo de Defesa Econômica*, or CADE) through a very specific proceeding, and judges can also apply bad-faith litigation fines, based on a percentage of the amount in dispute.

6. Other IP Rights

6.1 Trade Marks

Trade mark and trade dress disputes in the life sciences and pharma sector are common before the Brazilian courts, either in infringement or nullity actions. When it comes to trade marks, in the administrative sphere, Anvisa exercises an additional barrier to registration, specifically aimed at analysis of the graphic and phonetic distinctiveness regarding other pharma products, regardless of the examination process by the BPTO. The reason for this is the public agency's concern about preventing confusion among consumers between products/drugs aimed at different treatments. In this sense, Anvisa has established some resolutions, in addition to Law 6.360/76, to prevent the adoption of names, designations,

labels or packages that may cause error, confusion or undue association among consumers.

For instance, Orientation No 43/2017 of Anvisa establishes the complementary details to guide the agency when evaluating and deciding on third party's requests to register the name of a certain drug. Among other things, an analysis to decide on the approval of the name of a drug product must include research of Anvisa's and the BPTO's databases, evaluation of graphic and phonetic resemblances, assessment of potential errors, assessment of the safety of the proposed name, based on assumptions of risk of error in cases of prescriptions, dispensing and/or administration or use.

In the pharma and life sciences field, the judges tend to be extra-careful in court discussions about trade marks and trade dress which are possibly confusingly similar to a third party's prior-registered trade marks or trade dress, as the case concerns human health.

6.2 Copyright

Copyright disputes in the life sciences and pharma sector are not common in Brazil.

6.3 Trade Secrets

In Brazil, life sciences and pharma cases fall under the data package discussion on the grounds of unfair competition practices.

According to Article 195, XIV of the Brazilian Industrial Property Act, a crime of unfair competition is perpetrated by anyone who divulges, exploits or utilises, without authorisation, results of tests or other undisclosed data, the preparation of which involved considerable effort and was submitted to government agencies as a condition for obtaining approval to commercialise products.

7. Appeal

7.1 Timeframe to Appeal Decision

Regarding the Preliminary Injunction

After the trial court decision is published, the parties that do not agree with it can file a motion for clarification within five days in order to challenge omissions, contradictions, obscurities and oversights. From the motion for clarification decision, the parties will have 15 days to file an interlocutory appeal and it is possible to claim an injunction to suspend the preliminary injunction decision. The interlocutory appeal will be addressed to a rapporteur judge who will analyse the injunction claim and serve the counterparty to respond to the appeal within 15 days. Generally, it will take a couple of months to have the judgment session, which is not a hearing, but the attorneys will be able to present oral arguments before the panel as a preliminary injunction discussion allows such oral debates. It is possible to re-analyse the trial court decision and for the matter to be considered de novo. Once the panel has issued the vote, the decision will be published and the parties can file motions for clarification within five days of the publication and/or file special appeals to the Superior Court of Justice questioning the applicability of the federal law. If constitutional matters are involved, it is possible to offer an extraordinary appeal to the Supreme Court. However, this is unusual for patent matters.

First Instance Main Action Decision for Infringement and Nullity Actions

The timing to file an appeal against a first instance main action decision is 15 days from date of publication onwards. It is also possible to question the decision by filing a motion for clarification. The timing in a main action appeal judgment session will depend on the court's backlog, but it can take one to two years for a final

judgment. Once the Court of Appeals schedules the judgment session, the parties prepare summary briefs to be personally discussed with the judges designated for the judgment and to present oral arguments in the judgment session. The judgment session will be before a panel of three judges.

The decision can be unanimous, or not. In the case of 2:1 votes, an extended session will be scheduled and two other judges will join the panel, so that there is a casting vote.

Once the panel has issued the vote, the decision will be published and the parties can file a motion for clarification within five days of the publication and/or file a special appeal to the Superior Court of Justice questioning the applicability of the federal law. In the case of constitutional matters, it is possible to offer an extraordinary appeal to the Supreme Court. However, for patent matters, this would be quite unusual.

If a preliminary injunction or final injunction decision is overturned on appeal or the patent is revoked, the preliminary injunction will not automatically be lifted and the interested party must submit a brief asking for it to be lifted/revoked. An interested party might evaluate the best strategic moment to submit a brief, but this can be done at any time before the judge who first issued the injunction.

7.2 Appeal Court(s) Arbiter

Infringement matters are discussed in state courts and the final decision is appealable to the correspondent State Court of Appeals. Nullity lawsuits are discussed in federal courts and the final decision is appealable to the Federal Circuit of Appeal, which can cover more than one state. In both cases, the appeal is addressed to a panel of three judges but a rapporteur judge will be in charge of receiving the appeal, analysing a potential injunction claim and re-preparing the main vote that will be presented in the judgment session. The decision can be unanimous, or not. In the case of 2:1 votes, an extended session will be scheduled and two other judges will join the panel, so that there is a casting vote.

7.3 Special Provisions

IP lawsuits, including those for life sciences and pharma, are subject to civil and criminal proceedings that are guided by the Civil and Criminal Proceeding Codes. There are some specific rules in the Industrial Property Act, Federal Law No 9279/96, that discuss injunctions, bonds and damages criteria, but such provisions are all grounded on the general legal system applied to all types of lawsuits.

8. Other Relevant Forums/Procedures

8.1 The UPC or Other Forums

Officials using anti-counterfeiting measures at customs in ports and airports in Brazil will generally contact the patentee to take suitable legal measures when there is a notice of infringement.

9. Alternative Dispute Resolution

9.1 ADR Options

Arbitration, conciliation and mediation are all available in Brazil. However, patentees in life sciences disputes do not use these ADR options, preferring to address the discussion in a lawsuit where the ordinary provisions of injunction and damages will apply.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

Settlements are available and are used by the parties in both judicial and ADR options, especially in cases where the trial is slow and/or the costs of litigating are high.

11. Collective Redress

11.1 Group Claims

Both collective redress and group claims are available in Brazil for life sciences-related actions. They are mostly used in cases involving consumer protection, public health issues, defective medical products, or environmental harm caused by the life sciences industry. The Brazilian legal system allows for these collective legal actions to be pursued by public entities, consumer organisations and other representatives to protect the rights of affected individuals or groups.

Collective Redress in Life Sciences Legal Actions

In Brazil, public civil actions are a key tool for collective redress and can be used in life sciences cases. For example, public health-related lawsuits, such as those involving defective medical products, dangerous pharmaceuticals, or environmental harm caused by the pharmaceutical or biotechnology industries, can be pursued under this legal framework.

These actions can be initiated by public entities like the public prosecutor's office, regulatory agencies (eg, Anvisa), or accredited civil society organisations. Public civil actions aim to protect collective rights, such as consumer rights, public health, or the environment.

Examples in the life sciences sector:

- claims related to the harmful side effects of drugs or medical devices;
- actions against healthcare providers for negligence or failure to provide appropriate care; and
- cases involving misleading advertising of health products or treatments.

Group Claims in Life Sciences Legal Actions

Group claims are also possible in Brazilian life sciences legal actions, typically when a group of individuals with similar legal interests are affected by the same or related issues.

Under the Consumer Protection Code (Law No 8,078/1990), collective actions can be filed by consumer protection organisations, public entities, or other representative bodies, particularly in cases where large groups of consumers or patients are harmed by defective products or services.

In the life sciences field, group claims could involve:

- patients who are harmed by unsafe or defective drugs or medical devices;
- large groups of consumers affected by misleading health claims or illegal marketing practices in the healthcare sector; or
- actions to protect the right to access healthcare services or medications that may be limited by discriminatory practices or failures by healthcare providers.

Specific Life Sciences-Related Laws and Protections

The Consumer Protection Code (Law No 8,078/1990) plays a significant role in group claims related to life sciences, as it ensures

the protection of consumers' rights, including access to safe and effective medical products and services.

Anvisa also has a key role in regulating medical products, and regulatory failures or violations could trigger collective legal actions.

Other related legal frameworks, such as laws regarding environmental protection, data protection and public health, can also provide avenues for collective or group claims in life sciences cases.

Trends and Developments

Contributed by:
Eduardo Hallak, Juliana Neves, Isabella Bonisolo and Juliana Castelo Branco
Licks Attorneys

Licks Attorneys is one of Brazil's most respected IP law firms, offering unwavering commitment to clients worldwide. The firm focuses on complex litigation and its lawyers boast an outstanding track record in handling high-profile IP and regulatory disputes. The practice shapes the development and direction of IP, technology and regulatory law in Brazil. From offices in Rio de Janeiro, São Paulo, Brasilia, Curitiba and Tokyo, the team combines industry knowledge with legal expertise to assist a wide variety of clients – from Fortune 500 companies to hi-tech start-ups breaking into the Brazilian market. The firm's multidisciplinary attorneys have handled complex commercial and corporate claims over the past 20 years in major sectors, including technology, the internet, telecommunications, life sciences, medical devices and finance. Licks Attorneys has the most extensive patent litigation practice in Brazil and is involved in almost every high-profile case in the country concerning complex technologies.

Authors

Eduardo Hallak is a founding partner of Licks Attorneys and heads the firm's São Paulo office. For almost 20 years, he has worked as a litigator before state and federal courts in Brazil in several complex disputes and leading cases involving patent and trade mark law, competition, and regulatory compliance, most of them involving the interests of clients in the area of life sciences. Eduardo teaches IP litigation in the post-graduation course at the Pontifical Catholic University of Rio de Janeiro (PUCRJ), and also takes part in the Enforcement Committee of INTA.

Juliana Neves is a partner at Licks Attorneys, based in the São Paulo office. With over a decade of experience, Juliana is an expert in intellectual property and administrative law, dealing with highly complex IP and regulatory litigation, mostly defending the interests of clients in the life sciences area. She holds a master of laws degree (LLM) with the University of Chicago Law School and has specialised in intellectual property law at the Pontifical Catholic University of Rio de Janeiro (PUCRJ), and public bids and public agreements at Fundação Getulio Vargas (FGV-RJ).

Isabella Bonisolo is a senior associate at Licks Attorneys, based in the São Paulo office. She has over a decade of experience specialising in intellectual property protection and provides strategic counsel and enforcement in patents, trade marks, unfair competition, copyrights, and related areas. Isabella represents clients in high-profile litigation, primarily in life sciences, and since 2017, she has focused on complex lawsuits in the Brazilian courts, addressing patent validity, infringement, and regulatory aspects in the pharmaceutical and agribusiness sectors. She is completing her master's degree at the Pontifical Catholic University of Rio de Janeiro (PUCRJ), focusing on civil liability in patent infringement, and holds a postgraduate degree in intellectual property and civil procedure.

Juliana Castelo Branco joined the São Paulo office of the firm as an attorney at law in 2024. Over the years, Juliana has successfully handled prosecutions involving complex IP disputes, infringements, nullities, and domain name disputes, as well as assisted in drafting and reviewing contracts, policies and agreements. Prior to joining Licks Attorneys, she gained invaluable insight into the Brazilian judiciary by clerking for judges. Later on, she worked in a law firm specialised in intellectual property, advocating for leading corporations in litigation related to patents, trade marks, and conflicts over unfair competition, and contributing to assessments on domain name disputes.

Licks Attorneys

Rua George Ohm, 230
Tower A CJ 112/113
Sao Paulo SP
04576-020
Brazil

Tel: +55 11 3033 3700
Fax: +55 21 3956 9444
Email: info@lickslegal.com
Web: www.lickslegal.com

In 2024, several events occurred that set the stage for major developments in life sciences and pharma IP litigation in Brazil in the coming years. Some of the key events are detailed below.

Restrictive Amendments to Patent Application Claim Charts Allowed

The 1ª Specialized Panel of the Federal Court of Appeals for the Second Circuit (TRF-2) in Brazil issued a relevant precedent regarding the interpretation of Article 32 of the Brazilian Patent Statute (BPS – Law # 9.279/96), especially for the life sciences and pharmaceutical research and development industries. For the first time in an invalidity lawsuit, the court confirmed the legality of making restrictive amendments to a patent application claim chart, whether voluntarily or in response to a BPTO (Brazilian Patent and Trademark Office) order, even after a request for examination has been submitted to the BPTO – provided these amendments are included in the patent application as filed. The court has also confirmed that BPTO Ordinance # 93/2003, which regulates this matter, is legal and does not violate any prior legal precedent (namely, Case # 0513584-06.2003.4.02.5101). This precedent is still subject to appeals to the superior courts, but it is relevant, since generic industry often mentions the judgment of Case # 0513584-06.2003.4.02.5101 to argue against the possibility of restrictive amendments after the request for examination. This decision provides greater legal certainty, aligns with what the BPTO has already established on the matter, confirms the provisions of the TRIPS Agreement, and sets the standard for how such cases will be analysed going forward.

Invalidity As a Defence in Infringement Lawsuits

Brazil has a bifurcated judicial system, where patent infringement lawsuits are judged by the state court, while invalidity cases are handled separately by the federal court, with the BPTO as a party. Although this structure is expressly provided by the BPS and remains in force, the Superior Court of Justice (STJ) confirmed in 2024 that defendants in infringement lawsuits have the right to present patent invalidity arguments in their answer to a complaint. This decision was rendered in the judgment of Appeal # 1,332,417/RS, where the STJ gathered two panels with divergent interpretations of this legal matter, and established this unified understanding that must be followed hereafter.

In recent years, there has been considerable debate on whether the accused in a patent infringement could bring an invalidity defence in cases before the state court, especially considering that patent invalidity cases are to be tried before the federal courts as a matter of jurisdiction. Until this STJ decision, state courts had been ruling on a case-by-case basis, leading to different approaches, depending on the jurisdiction or judge handling the infringement case. The STJ precedent clarifies this scenario, providing patent owners and stakeholders with legal certainty, and allowing them to be prepared with accurate procedural, legal and technical strategies.

Developments After ADI # 5,529 and the Patent Term Adjustment-Like Lawsuits

After the trial by the Brazilian Supreme Federal Court (STF) of ADI # 5,529, owners with patents facing substantial reduction in terms of protection, sought compensation for the BPTO's delay in examination through patent term adjustment-like (PTA-like) lawsuits.

In May 2021, the STF declared that the sole paragraph of Article 40 of the BPS was unconstitutional (ADI # 5,529). Previously, the law assured patent protection of up to 20 years from the filing date, with at least ten years of protection after the granting, due to a possible backlog at the BPTO. From 12 May 2021 onwards, all patents granted, no matter the BPTO delay, are valid for 20 years from the date of the deposit. In addition, the decision immediately determined that certain granted patents would lose the ten-year period of protection after the granting, namely: (i) patents under discussion in invalidity lawsuits filed up to 7 April 2021; and (ii) patents related to pharmaceutical treatments and products.

Until the end of 2024, it was possible to identify 64 PTA-like lawsuits:

- Among these cases, 26 had requests for preliminary injunctions (PIs) – four PIs were granted and three are still in force (in one, the PI was granted at trial court level but was revoked in an appeal filed by the Brazilian National Health Surveillance Agency (*Agência Nacional de Vigilância Sanitária*, or Anvisa) after the original term of protection reinstated by the PI expired) and 22 PIs were denied.
- So far, 21 cases have been decided on the merits at trial level, all of which received unfavourable decisions rejecting the PTA-like claims. The plaintiffs filed appeals against 18 of these decisions. The Federal Court of Appeals for the First Circuit (TRF-1) has decided two appeals on the merits and upheld the trial-level decisions. Both appellate decisions were challenged, and the appeals are pending before the superior courts.
- Several constitutional complaints on the ADI # 5,529, filed by the BPTO and/or life sciences and pharma companies, pending before the STF, discussed the PIs granted by the federal courts, all of them deciding against granting compensation in patent terms due to delays in the BPTO's examinations.
- On this same matter, with Bill # 2,056/22, Congress proposes to amend Law # 5,648/1970 (which established the BPTO) to foster better management and governance practices at the BPTO, and to amend the BPS to:
  (a) allow divisional applications after the decision that granted the patent application and, in case of rejection, until the final decision (including the appeal phase);
  (b) allow claim modifications until the end of the examination phase;
  (c) declare that the end of the examination phase includes the appeal phase; and
  (d) establish a PTA mechanism for BPTO delays.

São Paulo Court of Appeals Sets Precedent for Technical Examination in Pharma Patent Case

In an infringement lawsuit (Case # 1002787-10.2022.8.26.0100) a decision on the merits in 2023 focused on certain invalidity aspects of the patent raised by the defendant (with no court ratification in the appropriate proceeding) and ignored infringement issues, without any technical examination. In June 2024, the First Reserved Chamber of Business Law of the São Paulo State Court of Appeals voided the trial decision, reasoning that the synthesis of a chemical component within the human body involves significant complexity, which requires technical examination, with a knowledge of biochemistry or organic chemistry, to determine whether there is illicit activity.

The decision established a significant precedent for pharma patent owners, ensuring the

broad collection of evidence to prove infringement. It also confirmed that the appellate court can determine the technical examination to be performed, even if this was previously deemed unnecessary at the trial level. The panel decision can still be challenged before the superior courts.

Drug Advertising Rules Set by Anvisa Considered Illegal by the STJ

In deciding Appeal # 2,035,645/DF, the STJ recognised that Rule # 96/2008, issued by Anvisa, which regulated drug advertising, was illegal as it restricted dispositions set forth by the law. The STJ stated that Anvisa's authority is limited to controlling, supervising and monitoring the advertising and publicity of products subject to health surveillance, in accordance with the existing health legislation (Law # 9,294 of 1996), but the agency does not have the legislative authority to issue new limitations rules on companies' advertising for pharmaceuticals, against what is provided by law.

The case was filed against Anvisa by a pharmaceutical company, which argued that it could not be subject to sanctions from the agency based on the mentioned rule, as it created prohibitions that exceeded Anvisa's regulatory authority. For instance, Rule # 96/2008 prohibited:

- indirect advertising in scenic contexts, performances, movies, radio programmes, or other types of electronic or printed media, as well as the broadcasting of images of people using drugs;
- required the inclusion of warning clauses, indicating the substances contained in the medication, especially those causing sedation or drowsiness; and
- prohibited the use of certain expressions, like "scientifically proven" or "demonstrated in clinical trials", in the advertising of over-the-counter drugs.

The STJ decision highlighted a legislative gap on the subject and officially notified the Ministry of Health and the National Congress about it, to initiate discussions on the matter within the legislative sphere. This topic may therefore come up for discussion in the coming years.

Productive Development Partnerships (PDPs) Are Back

In 2012, the federal government established Productive Development Partnerships (PDPs), bringing together public institutions (PIs) and private entities (PEs), with the latter transferring their expertise in producing active pharmaceutical ingredients (APIs) to the former. In summary, these are technology transfer agreements, including the supply of the product by the PEs. The aim is to reduce the importation of APIs and boost the country's economic-industrial complex, to ensure Brazilians have access to essential drugs and health products through the Brazilian public health system (*Sistema Único de Saúde*, or SUS), supplied at a lower price to the Ministry of Health (MoH), and thereby protect the treasury's coffers.

Over the last few years, PDPs have sparked intense debates about APIs under their scope that were still under patent protection, and the infringement acts involved in this. This discussion will possibly arise once more in 2025, as:

- between June and October 2024, several PIs, such as Fiocruz, Bahiafarma and the Butantan Institute, conducted public calls to start new PDPs;
- the MoH received 147 PDP proposals; and
- in December 2024, the MoH published SECTICS/MoH's Rule # 1/2024, which approved

the new internal regulations for this project, including the creation of a scoring system for PDP proposals, to serve as the criteria for analysing and classifying them (although it is still not clear what parameters will be applied to score each of the criteria).

Agrichemical Company Wins Unfair Competition Case, Halts Sale of Professional Solutions Products for Agricultural Use and Obtains Damages

Following an extensive investigation, an agrichemical company obtained evidence that another party was selling professional solution products containing a compound duly registered with Anvisa to farmers as agricultural pesticides. Not only is this regulatory fraud (misuse of a product), but the agrichemical company and its licensees were the only companies in Brazil authorised by the Ministry of Agriculture and Livestock (*Ministério da Agricultura e Pecuária*, or MAPA) to produce and sell pesticides containing this compound. In addition, the seller of the professional solution products engaged in comparative advertising, claiming that their products were identical to the original pesticides, also making use of the registered trade marks of the original product.

A lawsuit was filed, grounded on the trade mark violation and unfair competition before the State Court of São Paulo (Case # 1004858-48.2023.8.26.0100). At the trial, the final decision on the merits recognised the unfair competition act and ordered the defendant to refrain from making any statement that encouraged and/or taught third parties to use their professional solution products as agricultural pesticides and/or compare them to the originals. It also ordered the defendant to pay damages. In April 2024, the Second Reserved Chamber of Business Law confirmed the reasoning of the trial court decision.

This case shows that chemical product misuse in the agricultural market – unfortunately an issue in Brazil – can be associated with intellectual property violations beyond patents and regulatory subjects. This shows that IP title-holders must remain watchful.

Leading Cases in Agrichemical Data Protection Litigation: Preventing Unfair Competition

In 2021, in a preliminary injunction decision, the Fifth Chamber of TRF-1 recognised that merely receiving and processing – not only examining or granting – applications for the registration of equivalent technical products or formulated products based on equivalent technical products (generic agrichemicals) submitted by unauthorised third parties during the term of regulatory data protection of the reference molecule, constitutes misuse of the regulatory dossier (regulatory data) by the authorities in charge of agrichemical registration in Brazil (MAPA, Anvisa and IBAMA – the latter being the Brazilian Environmental Protection Agency or *Instituto Brasiliero do Meio Ambiente e dos Recursos Naturais Renovaveis*) and violation of Article 4, I of Law # 10.603 of 2002 (the Regulatory Data Protection Law or RDPL). As a result, the queue of cases waiting to be analysed by the Administration is to be reorganised, as applications submitted after the expiration of their term have to be placed in the position of applications filed after the expiration of protection.

According to the TRF-1, the document check performed when the application for registration of an equivalent technical product is submitted already represents misuse of the reference molecule's regulatory dossier (regulatory data), which

corresponds to the act of processing the application prohibited by the RDPL, leading to unfair advantage on the part of the applicant and violating the principle of equality. In a fair competitive environment, third parties would not be in a privileged position compared to others who wait for the expiration of the regulatory data protection period before submitting their applications. Accepting the early submission of applications gives those applicants an advantage, which is unfair competition practice.

In a similar case, in 2024, the Seventh Federal Court of the Federal District rendered a preliminary injunction on the same grounds and with reference to the above TRF-1 decision. The trial court decision ordered MAPA, Anvisa and IBAMA to refrain from processing, analysing and/or approving any formulated and/or equivalent technical product applications that referred to the regulatory data of the reference molecule under regulatory data protection. The order applies to registration requests pending in the analysis queues, as well as those submitted before the expiration of the regulatory data protection. The final decisions on the merits of these cases are expected in 2025.

Superior Court of Justice Validates Medicinal Cultivation of Cannabis by Companies

In November 2024, the First Section of the STJ ruled it legally possible to grant sanitary authorisation for the planting, cultivation and commercialisation of industrial hemp – a type of Cannabis sativa with a tetrahydrocannabinol (THC) content of less than 0.3% – by legal entities, for exclusively medicinal and pharmaceutical purposes (Case REsp # 2024250/PR).

The STJ highlighted that the cultivation must follow regulations – to be written in six months, by Anvisa and the federal government. With this ruling, the court issued a precedent that must be observed by all Brazilian trial courts and appellate courts.

As industrial hemp has a low THC content, there are no psychoactive effects, making it different from marijuana and other variations of cannabis used for drug production. As a result, industrial hemp is not subject to the prohibitions in the Law # 11.343/2006 and can be cultivated in Brazil, as ruled by the STJ.

The rapporteur also explained that this ruling does not encompass the possibility of importation or cultivation of industrial hemp by individuals, nor does it discuss uses of the product other than medicinal and pharmaceutical applications. Although Brazil currently authorises the use and commercialisation of cannabis-based medicines, the national production of the elements necessary for their preparation is prohibited.

Decisions Regarding the Supply of High-Cost Medicines by the Government

In 2024, the STF ruled on new guidelines for the judicial provision of drugs by the government, editing Topic # 6 and Topic # 1,234.

Topic # 6 (RE # 566,471)

This has been under discussion since 2020. The STF decided that the government is not obliged to provide high-cost medicines requested in court, when they are not provided for in the list of the SUS Exceptional Drug Dispensation Programme, nor registered with Anvisa.

Currently, the criteria for exceptions are under discussion before the STF, for circumstances in which the state may be required to provide high-cost medicines not available in the system, provided that the following are verified:

- the scarcity of resources and efficiency of public policies;
- the equal access to health and respect for technical and technical expertise; and
- the evidence-based medicine.

Topic # 1,234 (RE # 1,366,243)

The STF decided that claims related to drugs not incorporated into SUS public policy are within the jurisdiction of the federal courts, when the value of the specific annual treatment of the drug or active ingredient is equal to or greater than the value of 210 minimum wages (currently approximately BRL300,000 or USD50,000).

Non-incorporated drugs are those that are:

- not included in SUS lists;
- provided for in official clinical protocols for other purposes;
- not registered with Anvisa; and
- used off-label without a clinical protocol, or not part of lists of the basic component.

A special commission was created for debates with representatives of federative entities and civil society, culminating in the ratification by the STF of agreements signed between the federal government, the states, the federal district and the municipalities. These agreements include the competence of the federal courts to judge cases that deal with the supply of medicines not incorporated by the SUS, as well as the reimbursement to be made by the federal government to satisfy such demands.

The STF also determined the need to create a national platform to gather data on every lawsuit in which plaintiffs seek the supply of drugs, and to facilitate the management and monitoring of responsibilities between the federal government, states and municipalities, in addition to improving the performance of the judiciary in this matter.

This topic is relevant to the life sciences and pharma industry in relation to market dynamics, strategic planning of pharmaceutical companies, pricing strategies, reimbursement policies and potential alterations to the regulatory landscape.

Battling Counterfeit Seeds in Brazil: an Ongoing Struggle in the Agricultural Sector

As Brazilian agribusiness exports break records every year, the country faces a serious problem regarding seed counterfeiting. The agribusiness sector estimates that 30% of the seeds on the market are of unknown and illegal origin, putting the economy at significant risk. This is particularly concerning for those investing in cultivars and genetic improvement of seeds, protected by patents. As there are no criminal provisions in the Plant Varieties Law (Law # 9,456/1997), all actions against counterfeiters related to cultivars have only civil implications.

As an example of actions in this area, CropLife Brazil, a non-profit civil association that represents R&D companies in the sectors of germplasm, biotechnology, agrichemical and bio inputs, has been leading an investigation and litigation project against soybean seed counterfeiters, which has resulted in significant outcomes. For example, in 2024, CropLife was able to seize over 1.488 million kilograms of illegal seeds, thereby preventing the return of what is estimated to be more than BRL8 million's worth of illegal seeds to the Brazilian market.

Class Action Filed by ABPI Regarding the BPTO's Funds and Efficiency

The Class Action filed by the Brazilian Association of Intellectual Property (*Associação Brasileira da Propriedade Intelectual*, or ABPI) that

questions the allocation of 10% of the revenue earned by the BPTO to the BPTO itself, in view of understaffing and backlog issues, is pending analysis before the Appellate Court for the Federal Second Circuit (TRF-2), with the trial session expected to happen in 2025 (Case # 5095710-55.2021.4.02.5101).

In 2022, the trial court rendered a decision on the merits determining that the federal government should structure a report on the inefficiency of and need for the BPTO, and allocate financial resources to the IP authority to enable the development of activities and reduce the backlog.

Given the sensitive issues raised by life sciences and pharma IP cases, the sector would benefit from the success of this public civil action, as the incomings would allow the BPTO to improve the quality and delivery time of its services to applicants. Accurate and expedited analysis by BPTO examiners could prevent the need for lawsuits challenging BPTO actions.

The BPTO Joins the Global Patent Prosecution Highway

In July 2024, the BPTO joined the Global Patent Prosecution Highway (Global PPH or GPPH) programme, aiming to speed up the prosecution of patent applications by sharing examination results from any of the 35 participating offices, including those obtained under the Patent Cooperation Treaty (PCT), that indicate patentable subject matter.

For 2025, the BPTO issued Ordinance # 48 on 29 November 2024, which:

- establishes Phase V of the PPH Pilot Project, regulating the Global PPH;
- expands the participation limit to 3,200 PPH requests per year, with a maximum of 1,000 requests for the same section of International Patent Classification (IPC); and
- accepts substantive examination results indicating patentable subject matter from all Global PPH participating authorities, including those examined under the PCT.

This initiative may enhance Brazil's contribution to global protection for the pharmaceutical and life sciences industries in 2025, as it encompasses faster patent prosecution by leveraging examination results, while being cost effective.

Also aiming to reduce the BPTO's backlog, Bill # 2210/2022 proposes amendments to the BPS, to:

- create a provisional patent application;
- devise mechanisms for the BPTO to benefit from searches of technical examinations published by other patent offices and international organisations; and
- eliminate the automatic 36-month term required for applicants to request the examination of the patent application, and restrict the capability of amending the application only until the beginning of the technical examination.

This proposal of restriction limits the possibility of amending the patent application and favours the conclusion of the analyses of applications in Brazil before other jurisdictions, aiming to address backlog issues at the BPTO. A new proposal, including a PTA mechanism, was presented to the Senate in July 2024. The ongoing discussion in Congress must be closely monitored, particularly regarding the term to request examination and the possibility for the BPTO to consider searches from other patent offices.

CHINA

Law and Practice

Contributed by:
Hans She, Muran Sun, Andy Zhu and Ray Cao
Fangda Partners

Contents

Fangda Partners is one of the earliest private partnership law firms in China, and currently has over 700 lawyers, based in five offices in the major commercial hubs of Shanghai, Beijing, Shenzhen, Guangzhou and Hong Kong. It is a general practice law firm, with emphasis on complex litigation involving IP and competition matters. The firm is best known for its extensive experience in handling IP litigation in China, especially including life sciences and pharma IP litigation. Its team members have backgrounds in various technical fields, enabling them to communicate efficiently with clients in different industries. The team also includes former judges and patent examiners, and the firm has advised Watson Pharmaceuticals, Novartis, Wilmar Schwabe, Boehringer Ingelheim, Sucampo Pharmaceuticals and Leo Pharma in high-profile IP litigation and administrative proceedings.

Authors

Hans She joined Fangda Partners in 2005 and subsequently became a homegrown partner. He graduated with master's degrees from top Chinese and American law schools, is admitted to practice in the PRC, and received business management education at a prestigious European business school. He has represented dozens of foreign IP holders in various legal proceedings in China, including patent infringement lawsuits, patent invalidation proceedings, trade mark infringement lawsuits, trade mark administrative proceedings, unfair competition litigation, copyright lawsuits, domain name disputes, and trade secret protection lawsuits.

Muran Sun focuses her practice on IP litigation and licensing, especially those involving complex technical questions and cutting-edge legal issues. With broad experience in different technical standards and licensing models based on her practice for more than a decade, Ms Sun's expertise also lies in SEP-related disputes and licensing negotiations. Her practice further covers competition law disputes. Ms Sun has also successfully represented clients in licensing negotiations and other non-contentious IP matters.

Andy Zhu graduated from Guanghua School of Law, Zhejiang University, and joined Fangda Partners in 2017. Andy Zhu is a senior associate in the firm's IP group, with his main practice area covering IP litigations in relation to trade secrets, copyright, trade marks and unfair competition disputes, as well as non-contentious legal advice on IP issues. Andy Zhu has provided legal services for domestic and international clients from various fields, including life sciences, diagnostics, applied chemical markets and the manufacturing industry.

Ray Cao is an associate of Fangda Partners. Having received her master's degree at Koguan Law School, Shanghai Jiaotong University, she joined Fangda in 2022, and has since dedicated herself to IP practice – in particular, regarding IP dispute resolution and cross-border IP cases. She is soon to be admitted to practice in the PRC. To date, she has handled cases involving patent infringement, trade mark infringement and administrative proceedings, copyright infringement and unfair competition disputes, including those in the fields of cosmetics and pharmaceuticals.

Fangda Partners

24/F
HKRI Centre Two
HKRI Taikoo Hui
288 Shi Men Yi Road
Shanghai 200041
China

Tel: +86 1356 400 4915
Fax: +86 21 5298 5599
Email: hshe@fangdalaw.com
Web: www.fangdalaw.com

FANGDA PARTNERS
方達津師事務所

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Who Can Be the Plaintiff for Bringing a Patent Infringement Lawsuit?

The patentee and relevant interested parties are entitled to initiate a patent infringement lawsuit. These interested parties encompass the patent licensee and the heir of the original patent holder.

Under PRC law, both the patentee and the exclusive licensee possess the independent right to file patent infringement lawsuits in court. The sole licensee is empowered to file a lawsuit jointly with the patentee or independently, provided it can furnish evidence that the patentee has expressly waived legal action or refrained from filing a lawsuit due to awareness of the infringement.

Furthermore, a non-exclusive licensee is authorised to file patent infringement lawsuits in its own name after obtaining explicit authorisation from the patentee. Notably, there is no mandatory requirement for the registration or recording of a licensee to bring legal action. The licensee can substantiate its rights towards the patent by providing the contract with the patentee.

In situations where the licensee can independently file the lawsuit, if the patentee does not consent to being a plaintiff, it shall not be joined as a defendant either.

Who Can File a Nullity/Revocation Action?

Any party or individual who contends that the granting of the patent right does not align with the applicable provisions may petition to the China National Intellectual Property Administration (CNIPA) to declare the patent right invalid.

If any party is unsatisfied with the decision of patent invalidation or adjudication of patent infringement made by the relevant administrative authority, such party is entitled to file administrative litigation against such decision/adjudication.

1.2 Defendants/Other Parties to an Action

Defendants Involved in Life Sciences/Pharma Patent Infringement Cases

According to the PRC's Patent Law, unauthorised entities or individuals are prohibited from manufacturing, using, selling, offering to sell or importing patented products or employing patented methods without the patentee's permission for business purposes. This implies that suppliers, manufacturers, local distributors/wholesalers, pharmacists, doctors and hospitals could potentially face patent lawsuits as defendants. However, in practice, few pharmaceutical patentees sue doctors, hospitals or other health providers in China.

Notably, healthcare regulatory authorities (HRAs) and intellectual property offices (IPOs) also do not form part of infringement proceedings. However, if dissatisfied with an IPO's decision on patent application or invalidation, a party can file an administrative lawsuit against such IPO, with the IPO listed as the defendant.

1.3 Preliminary Injunction Proceedings

Preliminary Injunction Proceedings

Under PRC law, if a patentee or interested party possesses evidence demonstrating that another individual is currently infringing or is expected to infringe upon a patent, or is engaging or expected to engage in actions hindering the realisation of rights by the patentee or interested party, and such infringement could result in irreparable harm to the lawful rights and interests of the patentee or interested party if not promptly halted,

the patentee or interested party has the option of seeking a preliminary injunction from the court. This injunction may include measures under the law such as:

- attaching property;
- directing specific conduct; or
- prohibiting particular actions.

Upon receipt of an application, the court, in urgent circumstances, is obliged to issue a ruling within 48 hours. If the court decides to grant the preliminary injunction, its execution is immediate.

During the examination of a preliminary injunction application, the court is mandated to take into account several factors, including:

- the factual and legal basis of the applicant's request, encompassing the stability of the intellectual property's (IP) validity under consideration;
- the potential for irreparable damage to the legitimate rights and interests of the applicant if the preliminary injunction is not granted, as well as the impact on the enforcement of the eventual ruling or any other resulting harm;
- weighing of the damage caused by the failure to grant a preliminary injunction against the harm caused by granting it to the respondent;
- consideration of whether the granting of a preliminary injunction would adversely affect public interests; and
- consideration of any other relevant factors.

Most preliminary injunctions are ordered based on ex parte application. However, if needed, the court has discretion to hold an inter parte hearing over the application for preliminary injunction.

Requirements Before a Preliminary Injunction Request

The patentee or interested party can apply for a preliminary injunction only for granted patents. Patent applications or translations are not eligible as a legal basis for either infringement lawsuits or preliminary injunctions.

Quia timet relief is available in certain circumstances. The law sets forth the following that shall be considered as an "urgent situation":

- where trade secrets of the applicant are to be illegally disclosed;
- where the applicant's right of publication or privacy and other personal rights are to be infringed;
- where the IP in dispute is to be illegally disposed of;
- where the applicant's IP is being or will be infringed during a time-sensitive occasion such as a trade fair;
- where a time-sensitive popular show is being or will be infringed; and
- other situations requiring immediate preservation measures.

There are no specific procedural rules for patent litigation in life sciences cases. The same civil procedural rules apply to applications for preliminary injunctions in pharmaceutical patent cases.

How Is the Alleged Infringer Notified of a Preliminary Injunction Request?

Upon ruling to enact preservation measures or reject an application, the court is obligated to serve a ruling on both the applicant and the respondent. If delivering the ruling to the respondent might impact on the adoption of preservation measures, the court may serve the

ruling on the respondent no later than five days after implementing said measures.

The court, relying on the applicant's submission, may decide on granting a preliminary injunction, occasionally notifying the alleged infringer post-implementation of preservation measures and thereby limiting their chance to present evidence during the court review. Nevertheless, the alleged infringer retains the right to apply to the same court for the reconsideration of the preliminary injunction post-decision. In instances of preservation errors, a claim for damages is permissible.

Notably, Chinese law lacks a "protective letter" doctrine akin to that in Europe. However, as previously mentioned, the alleged infringer can seek reconsideration of the preliminary injunction ruling, affording them the opportunity to pursue compensation for any inaccuracies in the application process.

1.4 Structure of Main Proceedings on Infringement/Validity

Infringement and Validity Proceedings

In China, patent infringement and validity proceedings follow a bifurcated structure. Patent infringement matters are adjudicated through litigation processes before the civil court, while patent invalidation procedures are submitted to the CNIPA via administrative channels.

In cases where the defendant requests to challenge the validity of a patent during the defence period in a dispute involving the infringement of an invention patent accepted by the court, or in a dispute concerning the infringement of a utility model or design patent that has been reviewed and upheld by the CNIPA, the court may proceed with the litigation without suspension. It is noteworthy that the patent invalidity examination typically takes approximately eight months, which is far less than the time period of a civil infringement lawsuit. Consequently, by the time the court renders a judgment, the CNIPA's examination decision is usually already concluded.

Nullity Proceedings

In China, a nullity proceeding can only be filed against a patent after it has been granted by the CNIPA.

1.5 Timing for Main Proceedings on Infringement/Validity

Proceedings Regarding the Infringement Case

The statutory timeframe for initiating legal action against patent infringement spans three years, commencing from the date when the patentee or interested party becomes aware or should have reasonably become aware of the infringement and the infringer.

In the course of an infringement proceeding, the court is responsible for serving the complaint to the alleged infringer. Within five days of docketing a case, the court is obliged to provide the defendant with a copy of the written complaint. The date affixed to the service acknowledgment by the recipient signifies the official date of service. Electronic means, such as email or SMS, are now widely used in China for court's service. Following receipt, the defendant must submit a written statement of defence within 15 days. For parties without domicile within the territory of the PRC, the court may employ special methods, such as service based on international treaties, diplomatic channels or other legally specified manners.

In practical terms, the initial judgment in the first instance typically takes between one year and

one-and-a-half years for the court to deliver. Prior to the hearing, the court may arrange pre-hearing sessions to facilitate the delivery of parties' preliminary opinions and the examination of evidence by the involved parties. There has been no mechanism of discovery in Chinese litigation; a party may apply to court for evidence investigation and collection, if such evidence is closely related to the facts to be proved but is in the possession of the opposite party.

Proceedings Regarding Patent Invalidity

From the moment the CNIPA grants a patent right until its expiry, any entity or individual holds the right to petition for invalidation before the CNIPA. The CNIPA, upon receiving a written request for patent invalidation and accompanying documents, forwards these to the patent holder, prompting them to express their views within a stipulated timeframe. At the discretion of the involved party or as dictated by case requirements, the CNIPA may opt to conduct an oral hearing for the invalidation request. The final decision declaring the patent invalid is typically rendered approximately six to eight months within the filing of the petition for invalidation.

1.6 Requirements to Bring Infringement Action

The optimal time to initiate a primary infringement action is upon the granting of a patent, supported by preliminary evidence indicating the alleged infringer's engagement in actions that violate the patent rights. This includes making, using, promising the sale of, selling or importing the patented product, or utilising the patented process. These activities should be conducted for production or business purposes.

In instances of patent infringement disputes related to utility model patents or design patents, the court or CNIPA may request the patentee or interested party to furnish a patent evaluation report generated by the patent administration. This report, derived from searching, analysing and evaluating the relevant utility model or design, serves as evidential support for the trial and resolution of the patent infringement dispute.

In light of the reversal of the burden of proof, in disputes involving a patent for the invention of a manufacturing process for a new product, the entity or individual manufacturing the identical product is obligated to furnish evidence demonstrating the distinctions in their manufacturing process from the patented one.

1.7 Pre-Action Discovery/Disclosure

Pre-action discovery/disclosure is not available in China.

1.8 Search and Seizure Orders

In a civil infringement lawsuit, a patent holder or concerned party has the option of petitioning the court for evidence preservation if there is a risk of evidence destruction or loss, or difficulty in obtaining it later. Once the petition for evidence preservation is granted, court judges, together with bailiffs, may search and seize infringing products or other related evidence at the defendant's premises.

In cases involving suspected patent counterfeiting, when a patent holder initiates an administrative complaint for infringement, the administrative authority is empowered to decide on sealing or impounding products proven to bear a counterfeit patent based on evidence.

1.9 Declaratory Relief

Only a declaratory judgment of non-infringement is available under Chinese law.

If a right-holder gives a warning of patent infringement to another person, and the person warned or an interested person reminds the right-holder in writing of exercising their right to sue and the right-holder neither withdraws the warning nor files a lawsuit within one month after receipt of the written reminder or within two months after the written reminder is sent, such person can then file a lawsuit to request a confirmation that their act does not infringe the patent.

In China, there is no legal concept equivalent to "Arrow Declaration".

1.10 Doctrine of Equivalents

Equivalence infringement, or the doctrine of equivalents, was officially introduced into Chinese patent legislation in 2009, through the implementation of the Chinese Supreme Court's judicial interpretation. Chinese courts have since developed a three-step method for determining equivalence infringement, which is conveniently referred to by the Chinese legal community as the "three (basically identical) plus one (obviousness)" approach.

The "three plus one" approach includes:

- step 1 – ascertaining the distinguishing features;
- step 2 – comparing the distinguishing features and the patent, to assess whether they use basically identical means to achieve functions which are basically identical and which result in basically identical effects; and
- step 3 – determining obviousness for replacement.

1.11 Clearing the Way

There is no obligation to "clear the way" ahead of a new product launch. However, when sued for patent infringement, Freedom to Operate (FTO) reports can be used to prove unintentional infringement to avoid punitive damages.

1.12 Experts

In China, it is not uncommon for experts to be involved in civil lawsuits, particularly in patent infringement cases, such as those involving life science patents. These experts fall into two categories: expert witnesses and expert assistants.

Expert witnesses are typically responsible for endorsing the appraisal report, attending court sessions and providing testimony.

Expert assistants actively contribute to the trial process, participating in entire court hearings, posing questions to the opposing party, and responding to queries from the judges.

Moreover, if the case concerns complex technical issues, the court may appoint technical investigators to participate in pre-hearing sessions or court hearings; the technical investigator may ask questions of the parties, expert witnesses and expert assistants about the technical issues (in relation to the patent at issue), and may conduct investigations.

Theoretically, expert evidence is permissible in patent infringement proceedings, though this is not common in China.

1.13 Use of Experiments

Experiments are permissible for establishing or refuting infringement or validity in terms of life science patents. For instance, the court has the authority to carry out comparisons and experimentation directly within the court session for evidentiary purposes.

1.14 Discovery/Disclosure

Discovery/disclosure is not available in China.

1.15 Defences and Exceptions to Patent Infringement

In patent infringement litigation, besides the non-infringement defence, common defences include:

- prior use defence;
- prior art defence;
- patent exhaustion defence;
- Bolar exception defence;
- scientific research purpose defence;
- temporary transit defence;
- non-production and operation purpose defence;
- abuse of patent right defence; and
- legitimate source defence.

The legitimate source defence does not assume liability for compensation.

1.16 Stays and Relevance of Parallel Proceedings

Generally, patent infringement lawsuits will not be stayed due to patent invalidation procedures. However, the litigation period is generally longer than for administrative procedures. Therefore, administrative decisions can in fact also affect court rulings. For example, if an administrative decision declares a patent invalid, the court typically rejects the lawsuit.

1.17 Patent Amendment

Patents cannot be amended during litigation, though they can be amended during patent invalidation proceedings.

1.18 Court Arbiter

In pharmaceutical and life sciences cases, judges, rather than juries, preside over civil proceedings. Both preliminary injunctions and main actions in patent infringement disputes fall under the jurisdiction of the court in the location of infringement or the defendant's domicile, allowing forum shopping. Differences between courts primarily arise from judges' experience and case trial durations, though the legal foundation for court rulings remains consistent, resulting in no significant overall deviation.

2. Generic Market Entry

2.1 Infringing Acts

According to Article 11 of the PRC's Patent Law, unless otherwise specified, exploiting a patent without the patentee's permission for production or business purposes, or making, using, offering for sale, selling or importing patented products, is prohibited. This applies to small-molecule pharmaceutical products as well.

In Chinese practices, a marketing authorisation application or grant is typically considered exempt from patent infringement as a pre-launch activity. However, actions such as reimbursement, pricing, listing applications or tender submissions (which in principle would not be available on the public record) may be deemed patent infringement.

Article 18 of the 2020 Amendment to Several Provisions of the Supreme People's Court on Issues Concerning the Application of Law in the Trial of Cases on Patent Disputes defines the offer to supply or sell as declaring the intention to sell through advertising, shop displays or exhibitions. Offering for sale without authorisation remains an independent act of patent infringement under the PRC's Patent Law.

Further, an administrative punishment decision by the Shanghai Intellectual Property Office (Case No [2019] 2) illustrated that a disclaimer stating "Products under patent are not offered

for sale until patent expiry in the relevant countries" could not justify an infringement of offering for sale under the PRC's Patent Law.

Regarding infringement, current laws or regulations in China do not provide special consideration for second medical-use patents, skinny labelling, etc.

Regarding parallel imports, Article 75(1) of the PRC's Patent Law is usually interpreted as an exemption for patent infringement for parallel importation activities, regardless of country of origin.

2.2 Regulatory Data and Market Exclusivity

Current Chinese laws lack specific provisions for data and market exclusivity related to orphan drugs, paediatric formulations, new indications or combinations. For generic chemical drugs, only the first applicant successfully challenging a listed patent and obtaining the first marketing approval receives a 12-month exclusivity period.

On 9 May 2022, the National Medical Products Administration of the PRC released a draft revision of the Implementation Regulations of the Drug Administration Law of the PRC for public comments. Notably, Article 28 proposes a 12-month market exclusivity for the first approved paediatric new variety, dosage form or specification, and for those with new indications, usage or dosage. Article 29 suggests a seven-year market exclusivity for new orphan drugs, contingent on the drug marketing authorisation holder's commitment to ensuring drug supply. It is important to monitor the status of this draft for any formal approval updates. That said, the newly revised Implementation Regulations of the Drug Administration Law issued in December 2024 has not adopted the aforesaid draft provisions.

2.3 Acceptable Pre-Launch Preparations

Article 75(5) of the PRC's Patent Law is often viewed as the country's Bolar exemption, permitting the production, use or importation of patented drugs or medicinal equipment for the purpose of obtaining administrative approval or providing required information. It also excludes the production or importation of such items from patent infringement, specifically for the applicant.

Similarly, Article 76 of the PRC's Patent Law, after its fourth amendment, is considered the country's Hatch-Waxman Act, as it establishes an early dispute resolution system for generic market entry.

2.4 Publicly Available Drug and Patent Information

The National Medical Products Administration (NMPA) and the CNIPA jointly issued the Implementation Measures for the Early Settlement Mechanism of Drug Patent Disputes on 4 July 2021. According to Article 3, the China Patent Information Registration Platform for Marketed Drugs (the "Platform for Marketed Drugs", akin to the Orange Book), is managed by the Centre for Drug Evaluation, NMPA.

On this platform, the drug marketing authorisation holder is obliged to disclose various information, including:

- drug details;
- related patents;
- patent status; and
- contact information (Article 4).

Generic drug applicants must notify the marketing authorisation holder via paper or email, with the declaration being publicly accessible on the platform (Article 6).

Given the absence of specific timing requirements in current regulations, regular monitoring of the Platform for Marketed Drugs is advised for drug marketing authorisation holders.

2.5 Reimbursement and Pricing/Linkage Markets

China's Patent Linkage System

China's patent linkage system for generic drugs is primarily governed by three legal frameworks:

- the Implementation Measures for the Early Settlement Mechanism of Drug Patent Disputes (for Trial Implementation) jointly issued by the Centre for Drug Evaluation, NMPA and CNIPA (the "Implementation Measures");
- the Administrative Adjudication Measures for Early Resolution of Drug Patent Disputes issued by the CNIPA (the "Administrative Adjudication Measures"); and
- the Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Patent Disputes Related to Drugs Applied for Marketing Authorisation (the "Provisions of the SPC").

As outlined in Article 5 of the Implementation Measures, pertinent patents for chemical drugs encompass:

- the compound patent of the pharmaceutical active ingredient;
- the composition patent containing active pharmaceutical ingredients; and
- the medical indication patent.

The Mechanism

Under Chinese law, a drug marketing authorisation holder must register essential information within 30 days of obtaining the drug registration certificate. This includes details such as:

- drug name;
- dosage form;
- specifications;
- marketing authorisation holder;
- related patent information; and
- contact details.

The Platform for Marketed Drugs, managed by the Centre for Drug Evaluation, NMPA, makes this information publicly available.

Generic drug applicants must, upon submitting a marketing authorisation application, declare one of four options regarding listed patents. Within ten working days of application acceptance, the Centre for Drug Evaluation, NMPA publicly discloses the application details and corresponding declarations. Simultaneously, the generic drug applicant informs the marketing authorisation holder via paper and email.

In the case of objections to a Type (4) declaration, the patentee or interested party may file a lawsuit with the Beijing Intellectual Property Court or seek administrative adjudication with the CNIPA within 45 days of the Type (4) declaration being disclosed on the platform. If litigation or administrative adjudication is initiated, the Centre for Drug Evaluation, NMPA imposes a non-renewable nine-month stay period on the generic drug registration application (Article 8).

Marketing approval suspension for the generic drug occurs only if the court judgment or administrative adjudication decision determines that the application falls within the scope of protec-

tion of the listed patent. This suspension applies throughout the entire marketing approval process, whether within or beyond the nine-month stay period.

3. Biosimilar Market Entry

3.1 Infringing Acts

Lawsuits concerning biologics and biosimilar patents will follow the same procedural rules as indicated in **2.1 Infringing Acts**.

3.2 Data and Regulatory Exclusivity

The details discussed in **2.2 Regulatory Data and Market Exclusivity** will not differ in relation to biologics and biosimilars, except that there will be no 12-month market exclusivity period for biosimilar applicants.

3.3 Acceptable Pre-Launch Preparations

The details discussed in **2.3 Acceptable Pre-Launch Preparations** do not differ where the litigation concerns biologics or biosimilars.

3.4 Publicly Available Drug and Patent Information

The details discussed in **2.4 Publicly Available Drug and Patent Information** will not differ where the litigation concerns biologics or biosimilars.

3.5 Reimbursement and Pricing/Linkage Markets

The details discussed in **2.5 Reimbursement and Pricing/Linkage Markets** will not differ where the litigation concerns biologics or biosimilars, except that there will be no nine-month stay period for marketing approval in the scenario of litigation or administrative adjudication for applications of biosimilars.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

In China, the availability of a patent term extension for pharmaceutical products is specifically governed by Article 42.3 of the Patent Law. This provision allows the patent administrative department of the State Council to grant an extension, not exceeding five years, upon the request of the patentee. The purpose is to compensate for the time required for the assessment and approval of a new drug's marketing. The total effective term of the patent, after approval for marketing, must not exceed 14 years.

Invention patents related to new drugs include new drug product patents, preparation method patents and pharmaceutical use patents that meet specific requirements found in the Patent Examination Guidelines (2023). The application for the extension should be filed by the patentee; and if the patentee is inconsistent with the holder of the drug marketing authorisation, the written consent of the holder of the drug marketing authorisation should be obtained. For a patent to be granted the extension, it is also a prerequisite that it has not been granted an extension previously. According to the newly amended Detailed Rules for the Implementation of the Patent Law (2023) and the Patent Examination Guidelines (2023), for different products but the same patent, the applicant can only apply for extension for one drug product. For one product protected by a number of patents, the patentee can only apply for extension for one patent. Where the patent(s) belong(s) to multiple patentees, and no patent agency has been engaged, the application shall be handled by their representative.

Additionally, another patent term extension scheme is provided in Article 42.2 of the Patent Law, which is available for all invention patents and mainly applies to circumstances where there is unreasonable delay in the patent grant procedure. According to this provision, patents eligible for extension include invention patents granted four years from the application filing date and three years from the date of filing the request for substantial examination. In such circumstance, the patent administrative department of the State Council shall, at the request of the patentee, provide patent term extension for unreasonable delay in the patenting process for the invention, except for unreasonable delay caused by the applicant.

4.2 Paediatric Extensions

To date, there have been no special rules for paediatric extensions, though this can be included in the patent term extension scheme.

4.3 Paediatric-Use Marketing Authorisations

To date, there has been no special rule for paediatric-use authorisation similar to PUMA in China.

4.4 Orphan Medicines Extensions

In the draft revision of the Implementation Regulations of the Drug Administration Law of the PRC for public comments, Article 29 suggests an up to seven-year market exclusivity for new orphan drugs. That said, the newly revised Implementation Regulations of the Drug Administration Law issued in December 2024 has not adopted the aforesaid draft provision.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

Firstly, the PRC's Civil Procedure Law mandates that a plaintiff is required to post a bond when applying for a preliminary injunction. The bond serves the purpose of compensating the adversely affected party if the preliminary injunction is erroneously granted and enforced. In practice, plaintiffs often secure an insurance policy instead of the bond, with assistance from an insurance company.

Preliminary injunctions become enforceable upon issuance of decisions. The courts follow the same procedural steps for serving preliminary injunction orders as they do for civil complaints.

In China, enforcing preliminary injunctions mirrors the process of enforcing judgments. Non-compliance by the affected party prompts the court to enforce it compulsorily.

The primary procedures for preliminary injunctions encompass:

- the application (when initiated by the applicant rather than at the court's discretion);
- court decision;
- decision enforcement;
- decision review; and
- injunction termination.

Generally, a court should render a decision within 48 hours of the application. Enforcement follows immediately, and if the applicant does not initiate litigation or arbitration within 30 days, the court may terminate the injunction.

As previously noted, the patentee must furnish a bond for a preliminary injunction, with the court determining the amount at its discretion. The patentee is obligated to file litigation or arbitration within 30 days of enforcement, and no further actions are required to enforce or sustain the injunction. However, the injunction typically remains in force only until the judgment or awarding of the litigation or arbitration takes effect.

Lastly, there is no provision for staying a preliminary injunction pending appeal in China.

5.2 Final Injunctive Relief

In China, a prevailing plaintiff receives a final judgment that includes a final injunction directing the defendant to cease and desist from any infringement. Final judgments are served using the same procedural steps as civil complaints, typically through mail to representative lawyers.

If the infringer fails to comply with the judgment's obligations, the enforcement procedure involves initiating enforcement, either by the patentee or the court, within six months of receiving the application. The completion of enforcement does not have a specific time limit. The application for enforcement can be made within two years from the last day of the designated period for performing the obligation in the judgment.

Unlike preliminary injunctions, the patentee is not required to provide a bond or prepay enforcement fees before initiating enforcement proceedings for a final judgment in China.

In very rare circumstances, such as when the underlying judgment is under retrial, the enforcement proceeding may be stayed.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

A Chinese court does have the discretion to award damages instead of an injunction. According to the Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law to the Review of Intellectual Property Dispute Preservation Cases, the court considers factors such as proportionality and/or public interest when deciding on an injunction. This principle holds true in life sciences and pharmaceutical patent litigation cases.

Additionally, the Interpretation of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Patent Infringement Disputes stipulates that, considering national and public interests, the court may order the defendant not to cease the alleged infringement but rather to pay appropriate, reasonable fees.

5.4 Damages

In China, methods of calculating damages include considering the following:

- the actual loss suffered by the right-holder due to the infringement;
- the benefits obtained by the infringer from the infringement;
- where it is difficult to determine both the above, the damages shall be reasonably determined by reference to the multiple of the royalty; or
- where it is difficult to determine all three of the above, the court can determine discretionary damages as not less than CNY30,000 and not more than CNY5 million.

The methods are electable by the plaintiff.

The right-holder's actual loss is typically calculated by the decreased sales profit due to the infringement, and the infringer's benefits are typically calculated by the sales profit of the infringing products (such as the sales volume multiplying the profit per product).

Reasonable royalty is typically calculated by precedent licence contracts between the right-holder and third parties. Discretionary damages are calculated based on the type of the patent and the nature and circumstances of the infringement.

As for transfer pricing, there are no specific rules on its impact on assessment of damages, but it may be considered as a factor for lifting/reducing the damages.

It is hard to say what a typical award of damages is in the pharma/biopharma/medical device industry, as each case involves its own facts. That said, the PRC's Patent Law provides punitive damages in cases where the infringement is wilful and serious. In such circumstances, the damages may be determined as not less than one and not more than five times the amount calculated by the right-holder's actual loss, the infringer's benefits or the reasonable royalty.

Generally, damages accrue when the infringement starts. However, if the right-holder brings a suit after three years from the infringement and the infringer is known, and if the infringement continues and the patent is still valid at the time of filing the litigation, the damages shall be calculated three years in advance from the date of filing the litigation. The law does not specifically provide for whether interest is payable, though there are rare cases where interest is awarded, especially when the court adopted a discretionary amount of damages.

Usually, damages are awarded together with technical trials in the final judgment. However, it is possible for a quantum hearing to be held separately if the court deems it necessary. Interim awards are also possible, though not very common.

As indicated in **5.1 Preliminary Injunctive Relief**, in cases where the preliminary injunction is wrongfully granted and enforced, the applicant should pay damages to the respondent. Specific considerations include:

- that the applicant does not bring a lawsuit or apply for arbitration within 30 days;
- that the patent rights requested for protection are declared invalid; and
- that the enforceable judgment finds that the respondent's actions do not constitute infringement.

Such claims are relatively rare and not frequently raised. It is hard to say whether such claims are easily settled.

Only a plaintiff to a lawsuit may claim for damages. Third parties are not entitled to claim for damages in a civil lawsuit.

5.5 Legal Costs

According to Article 71 of the PRC's Patent Law, the prevailing plaintiff in a patent infringement litigation is entitled to recover reasonable legal expenses, covering:

- attorney fees;
- notarisation fees; and
- related costs, such as evidence investigation and preservation fees.

It is essential to note that these legal costs are not automatically granted – the plaintiff must for-

mally request recovery, specifying the amount and providing supporting documents such as invoices.

In the case of a favourable judgment for the plaintiff, where the defendant is held responsible for patent infringement, the court will order compensation for the plaintiff's justifiable legal costs. Interim payment orders are rarely issued in Chinese litigation, making this practice uncommon.

The court has discretionary authority to award legal costs either in full or in part, considering the reasonableness of the amount claimed and the adequacy of supporting evidence. Distinct from legal costs, court fees in Chinese litigation are the plaintiff's responsibility and must be paid upfront. These fees are later apportioned between the parties based on the level of support for the plaintiff's claims, as determined in the court judgment (refer to Chapter V on the Bearing of Litigation Costs in the Measures on the Payment of Litigation Costs).

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

Like many other jurisdictions, there is prescription of action in Chinese civil litigation. For patent infringement cases, generally speaking, the prescriptive period is three years commencing from the date when the claimant/plaintiff knows or should have known of the infringement and the infringer (refer to Article 74 of the PRC's Patent Law). Therefore, the claimant's/plaintiff's delay in bringing proceedings may induce reduction or even withholding of monetary relief.

However, as Chinese laws do not require that the claimant/plaintiff engage in pre-action correspondence before initiating actions, the court will not withhold or reduce relief if the claimant/plaintiff directly files civil actions with the court.

Also, since there is no mandatory requirement for the registration or recording of a licensee to bring legal action, there is no penalisation on relief to exclusive licensee claimants not named on the Patent Register.

6. Other IP Rights

6.1 Trade Marks

Quite a few trade mark disputes occur in the life sciences and pharma sector in China, whether between local practices or between local and foreign entities.

The main source of law concerning trade mark disputes in the life sciences and pharma sector is the PRC's Trade Mark Law, while the PRC's Unfair Competition Law also regulates passing off or free-riding activities relating to unregistered marks.

Given the above, restrictions on naming, issues around confusion and anti-counterfeiting for pharma/medical device marks will follow the general rules under the PRC's Trade Mark Law and the PRC's Unfair Competition Law.

For restrictions on naming, based on the general principle that a generic name may not be registered as a trade mark, Article 29 of the PRC's Medicinal Product Administration Law further clarifies that the names of medicinal products listed in the national medicinal product standards shall be the generic names of medicinal products and should not be used as trade marks.

6.2 Copyright

Copyright disputes do occur in the life sciences and pharma sector in China.

Product labels, instructions for use, research articles or reports, software programs and other objects in the life sciences and pharma sector, originally created, may be protected as works under the PRC's Copyright Law; the scope of protection is limited to expressions and will not extend to any idea, procedure, function, process, method of operation, concept or discovery.

The main sources of law include:

- the PRC's Copyright Law;
- administrative regulations, such as the Regulations for the Protection of Computer Software and the Regulations for the Implementation of the Copyright Law; and
- judicial interpretations, such as the Interpretation of the Supreme People's Court Concerning the Application of Laws in the Trial of Civil Disputes Over Copyright.

6.3 Trade Secrets

Trade secrets disputes are common in the life sciences and pharma sector in China.

Common issues with respect to trade secrets disputes include, without limitation:

- whether the information claimed by the plaintiff is not known to the public, well protected through reasonable confidential measures and has commercial value, and thus meets the threshold of trade secret protection;
- whether the defendant has access to the plaintiff's trade secret;
- whether the technology/information used by the defendant is the same as or substantially similar to the plaintiff's trade secret; and
- how to determine and calculate the compensation amount.

Moreover, as the infringer's disclosure activities may cause the trade secret to become open to the public and to no longer be protectable, it is not uncommon for the plaintiff to seek interim injunction from the court.

The main sources of law include:

- the PRC's Unfair Competition Law; and
- judicial interpretations such as the Provisions of the Supreme People's Court on Several Issues Concerning the Application of Law in the Trial of Civil Cases Involving Infringements Upon Trade Secrets.

7. Appeal

7.1 Timeframe to Appeal Decision

Appeal Regarding Preliminary Injunction

In China, the party affected by the preliminary injunction can apply to the same court that issued the injunction for reconsideration, which is of the party's right. The court is obligated to render a reconsideration decision within ten days of receiving a petition for reconsideration. Throughout the reconsideration, the preliminary injunction order maintains its full force and effect.

Appeals Regarding Patent Infringement Cases

According to the PRC's Civil Procedure Law, a party can appeal a first-instance judgment within 15 days of receiving the written judgment. If a party resides outside the PRC, it can file an appeal against a judgment or ruling of a first-instance court within 30 days of receiving the written judgment or ruling.

During the appeal process, the second-instance court typically conducts a hearing session to hear the case. If, after reviewing the case files,

conducting investigations and questioning the involved parties, no new facts, evidence or reasons are presented, the court may deem holding a hearing session unnecessary. The second-instance court is required to complete the trial of an appeal case within three months after it is docketed. Any extension of this period due to special circumstances requires approval from the court president. In the second instance, the court primarily assesses whether there were errors in factual determination or legal application during the first-instance court's trial. Practically, the second instance of a patent infringement lawsuit usually takes between nine months and one year.

Appeals Regarding Patent Validity Cases

If any party disagrees with the CNIPA's decision on patent invalidation or maintenance, they have a three-month window from the date of receiving the notification to file a lawsuit in court requesting a judicial review. During the legal proceedings, the court notifies the opposing party from the invalidation request procedures to participate in the litigation as a third party. The judicial review is a two-instance administrative lawsuit, which may take between one year and one-and-a-half years in total.

Release of the Preliminary Injunction

In China, a preliminary injunction is tied to a specific lawsuit. Therefore, once a patent is declared invalid, as per PRC laws and regulations, the patentee is required to withdraw the lawsuit. If not, the court will dismiss the lawsuit, rendering the underlying lawsuit non-existent. In such cases, the preliminary injunction becomes invalid, and the court issues an order to lift the previous preliminary injunction. Simultaneously, the defendant retains the right to apply for the release of the preliminary injunction. The court will assess the application and make a ruling accordingly.

7.2 Appeal Court(s) Arbiter

The Panel of Judges for Patent Litigation Appeals

In China, the Supreme Court hears the vast majority of second-instance patent infringement cases. That said, according to the latest regulations, appellate cases for utility model patents and design patents shall be heard by the provincial Higher People's Court rather than the Supreme Court.

A collegial panel encompassing entirely judges shall be formed to adjudicate a second-instance infringement lawsuit. The members of a collegial bench must be in an odd number. In some patent cases, as in first-instance proceedings, a "technical judge" will be present during the hearing besides the collegial panel.

7.3 Special Provisions

In patent litigation, the general provisions of the PRC's Civil Procedure Law are applicable. Additionally, there are certain specific provisions in IP litigation, such as:

- the Several Provisions on Evidence in Intellectual Property Civil Litigation; and
- the Several Provisions of the Supreme People's Court on the Application of Law in the Trial of Patent Dispute Cases.

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

In the context of life sciences and pharma IP litigation, additional forums or avenues for dispute resolution involve:

- initiating platform complaints;
- submitting administrative reports; and
- managing customs detentions.

When dealing with life sciences and pharma IP infringement on internet platforms, the right-owner has the option to file complaints or reports with the platforms selling the infringing or counterfeit products. They may also choose to submit administrative complaints to competent IP administrations in lieu of pursuing civil litigation. In China, customs detention serves as an administrative measure for combating infringement and counterfeiting during the importation and exportation processes. The PRC's Regulation on the Customs Protection of Intellectual Property Rights is specifically designed to facilitate customs protection of IP rights.

9. Alternative Dispute Resolution

9.1 ADR Options

Alternative dispute resolution (ADR) options for life sciences disputes in China encompass arbitration, administrative determination and mediation.

Arbitration is chosen pre-emptively for its advantages in confidentiality, procedural flexibility and the selection of arbitrators with relevant expertise. Although traditionally a common ADR option, its adoption in life sciences disputes, particularly in infringement cases, is less frequent compared to litigation.

Administrative determination, outlined in the PRC's Patent Law, serves as an alternative for patent disputes related to drug registration and is known as the "early resolution mechanism". Recognised for its efficiency, it is increasingly utilised in life sciences disputes, nearly as frequently as litigation. In 2021, the NMPA and the CNIPA released the Implementation Measures for the Mechanism for Early Resolution of Drug Patent Disputes, for better implementation of administrative determination in drug application disputes.

Mediation can be employed concurrently with litigation, arbitration and administrative determination to achieve amicable resolution. As it can be integrated into other ADR options when parties intend to settle cases amicably, mediation is widely utilised.

ADR is not mandatory during court proceedings; the court in particular has no power to require the parties to engage in arbitration, since arbitration can be conducted only with parties' consent. However, in practice, the court will usually strongly encourage the parties to engage in mediation/settlement discussion as a friendlier approach to resolving the dispute; this is common in Chinese judicial practice.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

In Chinese civil litigation, as in many other jurisdictions, a prescription of action exists. For patent infringement cases, the prescriptive period is generally three years from the date when the claimant/plaintiff becomes aware or should have known about the infringement and the infringer (see Article 74 of the PRC's Patent Law). Consequently, any delay by the claimant/plaintiff in initiating proceedings may lead to a reduction or even withholding of monetary relief.

Notably, Chinese laws do not mandate that the claimant/plaintiff engage in pre-action correspondence before initiating legal actions. There-

fore, the court will not withhold or reduce relief if the claimant/plaintiff opts to directly file civil actions. Furthermore, since there is no requirement for the registration or recording of a licensee to bring legal action, there is no penalisation on relief for an exclusive licensee claimant not named on the Patent Register.

11. Collective Redress

11.1 Group Claims

In China, group claims are available in civil litigation but are not common in the life sciences/pharma sector.

Article 56 of the PRC's Civil Procedure Law provides that, where the parties on one side of a joint action are numerous, such parties may appoint a representative or representatives to participate in the action, and the litigation conduct of such representatives shall bind all the parties represented. However, to modify or relinquish any claims, admit any claims of the opposing party or reach a settlement, such representatives must first obtain consent from the parties represented.

Article 57 addresses cases where the subject matter of action for each party is of the same kind and the parties on one side of an action are numerous, but the exact number of such parties is uncertain when the action is instituted; here the court may publish a notice to describe the case and claims, and may notify right-holders to be registered with the court within a certain period of time. The right-holders that have been registered with the court may appoint a representative or representatives to participate in the litigation; if no representative is appointed, the court may determine a representative or representatives in consultation with the right-holders that have been registered with the court.

Additionally, the litigation conduct of such representatives shall bind all the parties represented; however, to modify or relinquish any claims, admit any claims of the opposing party or reach a settlement, such representatives must first obtain consent from the parties represented. The judgment or ruling issued by the court shall bind all right-holders that have been registered with the court, and shall also apply to actions instituted during the time limitation by rights-holders that have not been registered with the court.

Trends and Developments

Contributed by:
Binxin Li, Guangzhen Shang and Sally Wang
LeanWill Law Firm

LeanWill Law Firm is a distinguished expert in intellectual property (IP). Its team has vast experience in providing tailored services to leading global enterprises across various industries. LeanWill provides comprehensive IP legal services, including regular consultation, strategic planning, prosecution/registration, enforcement, transactions, and related compliance and risk management. LeanWill is committed to delivering visionary and pragmatic IP protection solutions, maximising the value of intangible assets, and effectively managing IP-related risks for its clients. The firm's overarching goal is to safeguard society's innovations and creations, and to uphold clients' collective efforts. Several cases represented by LeanWill team members have been selected as typical cases by the Supreme People's Court and its lower courts, which demonstrates the firm's commitment to the rule of law. Many team members have received recognition from industry-leading ranking organisations, including Chambers and Partners.

Authors

Binxin Li brings over 16 years of extensive experience in the IP field. He possesses a deep understanding of his clients' business landscapes and challenges, both in China and overseas. Offering practical and comprehensive solutions, he assists clients in maximising the value of their IP assets while effectively mitigating potential IP-related risks. Over the years, Mr Li has advised both multinational and domestic companies across diverse industries, including healthcare, mechanical, telecommunications, energy and entertainment. His expertise encompasses complex IP issues, covering enforcement, filing, portfolio management and technology transfers.

Guangzhen Shang specialises in patent litigation, trade mark and brand protection, trade secret litigation, and other areas of IP dispute resolution and consultation. As an attorney at law and patent attorney, Mr Shang has represented many well-known domestic and international companies spanning industries including pharmaceuticals, chemistry, machinery, communications and consumer goods, with great success in relevant IP litigation. Some of the cases he has handled have been selected as typical cases by the Supreme People's Court and local IP courts/tribunals.

Sally Wang is an expert with extensive experience in the soft IP field. Drawing from profound experience in both in-house counsel and private practice, Ms Wang has tremendous experience in all aspects of soft IP practice in China and overseas, from both a commercial and legal perspective. Her expertise extends to advanced IP management systems, strategic IP planning, and the complex regional and global IP portfolio management of leading multinational companies. Ms Wang's understanding of both domestic and multinational clients enables her to offer efficient and practical solutions for safeguarding soft IP in China and overseas.

LeanWill Law Firm

Unit 902, Tower A
Dawning Center
500 Hongbaoshi Road
Changning District, Shanghai
PR China 201103

Tel: +86 21 52867968
Email: mail@leanwill.com
Web: www.leanwill.com

LEAN WILL
领为律师事务所

Intellectual Property Litigation Development and Trends in China's Life Sciences and Pharmaceuticals Industry

The life sciences and pharmaceuticals sector in China has been undergoing an innovation transformation, re-shaping its position in the global market, driven by the advancing of technology and increasing market value. China ranks 11th in the Global Innovation Index 2024 issued by WIPO, and emerges as the country with the largest number of science and technology clusters. With the innovation transformation, intellectual property (IP) litigation has become a key battlefield in which the boundaries of IP legislation and judicial protection are being tested and clarified, thereby profoundly affecting the growth of China's life sciences and pharmaceuticals sector.

This article aims to provide a brief overview and analysis of the IP litigation landscape and trends within China's life sciences and pharmaceuticals industry, exploring legislative changes, regulatory amendments, judicial system advancements and landmark cases. These factors play a pivotal role in shaping the development of IP protection in this vibrant industry. Each section below will explore critical aspects that relate to or impact on IP litigation in this industry, and will offer insights on key issues that garner wide attention and concern in this sector in China.

A Glance at the Development of the Life Sciences and Pharmaceuticals Industry

China's life sciences and pharmaceuticals industry is on an upward trajectory, with innovation transformation being propelled by strong research and development (R&D) capabilities as well as a fast-growing patient population. Some recent statistics underscore this growth and transformation:

- the total market capitalisation of the top five listed pharmaceutical and biological companies surged from RMB550 billion in 2018 to RMB1.1 trillion in 2024;
- the income of the healthcare sector increased from RMB8 trillion in 2021 to RMB9 trillion in 2024;
- China's innovative drug market scale exceeded RMB100 billion in September 2024, and China's share of new drug R&D is close to 30% of the global share; and
- the scale of licensing-out deals in China was close to RMB250 billion in 2024.

The thriving of the industry has prompted a proportional rise in IP litigation. In particular, in light of the improving IP protection environment, IP litigation continues to rise in both amount and complexity. This escalation reflects the intricate nature of the industry and the competitive forces at play.

IP Litigation Statistics in China

A close examination of the IP litigation statistics in China reveals a compelling narrative. The White Paper on China's IP protection reported an annual growth rate of 14.73% for first-instance patent infringement civil cases, reaching a staggering 44,711 cases in 2023. Furthermore, in 2023, the Annual Report of the IP Tribunal of the Supreme People's Court (the "SPC IP Tribunal") disclosed that the volume of cases involving strategic emerging industries pertaining to the pharmaceuticals sector increased to 1,582, with an annual increase rate of 18%.

Trade secret misappropriation notably caused by employee departures constitutes 84% of all trade secret disputes, according to a report issued by the Beijing IP Court. Trade secret protection remains a critical issue, and demands

more attention from healthcare companies operating in China than ever before.

The White Paper also indicated that the volume of trade mark-related first-instance infringement civil cases demonstrated a significant 16.82% increase in 2023 compared to 2022, reaching a total of 131,429 cases. At the same time, copyright-related cases dropped slightly by 1.57%, while competition cases grew by 8.97%.

Legislation and Regulatory Developments

The IP landscape in the life sciences and pharmaceuticals sector continues to evolve, influenced by legislative and regulatory changes. Several noteworthy developments include the following.

Patent term extensions

Patent term extensions (PTEs), along with detailed implementing rules and regulations (effective as of 20 January 2024), bring extra protection to innovations in the industry.

The issue around the "new drug" classification has now been clarified by a China National Intellectual Property Administration (CNIPA) decision, in which the CNIPA ruled that a drug under Class 5.1 is not eligible for a PTE – ie, the "new drug" qualifying for a PTE refers to one that has not been approved globally, which also reflects China's current position and intention to encourage early entry of drugs into the Chinese market.

In addition, a number of the CNIPA's decisions rejecting the granting of a PTE owing to formality issues – including no submission of a drug registration certificate and no PTE application within three months after drug market approval – highlight the need for patentees to pay attention when preparing and filing proper PTE applications in time, so as to utilise the mechanism.

Judicial interpretation on civil antitrust action

On 24 June 2024, the Supreme People's Court of China (SPC) released a new judicial interpretation, *Judicial Interpretation of Several Issues Concerning the Application of Law in the Trial of Civil Disputes Over Monopoly* (the "New Judicial Interpretation"). This became effective on 1 July 2024 and replaced the one released in 2014.

The New Judicial Interpretation mainly covers the following five aspects:

- procedural matters – mainly including definitions, case acceptance, jurisdiction, ascertaining of evidence, public interest action, and suspensions of proceedings;
- determination of the relevant market – mainly including the principal requirements for defining the relevant market, burden of proof, analytical methods and other facts to be considered;
- monopoly agreements – mainly stipulating synergistic behaviour, drug patent reverse payment agreements, algorithmic agreements, and cross-platform most-favoured treatment in horizontal monopoly agreements;
- abuse of dominant market position – mainly providing the definition of dominant market position, and the analysis and determination of various types of abuse of dominant market position behaviour; and
- civil liabilities – mainly relating to civil liabilities, loss determination, behaviour effects and the statute of limitations.

Reverse payment agreements in the pharmaceutical industry were specifically addressed in the New Judicial Interpretation, and could lead to antitrust violations if occurring without proper justifications. Companies in the life sciences and pharmaceuticals sector should be aware of

potential legal risks of related agreements under the New Judicial Interpretation.

"Case Law" in China

The SPC officially launched the "People's Court Case Database" on 27 February 2024, aiming to improve the "Case Law" mechanism in China and providing reference/guidelines for adjudication of similar cases. On 7 May 2024, the SPC released *Work Procedures for the Construction of a People's Court Case Database* to guide the application of the "Case Law" mechanism in practice, mainly covering:

- selection of guiding cases and reference cases;
- searching and utilisation of cases in the database; and
- adjustment of cases in the database.

By the end of 2024, the People's Court Case Database had collected 4,710 cases, among which 781 cases related to IP and anti-unfair competition. In light of the promotion of the People's Court Case Database by the SPC, more cases will be selected for the database, and improvement to the transparency and predictability of IP litigation could be expected.

Centralisation of the IP judicial system

By the end of 2024, there were 28 IP tribunals and four IP courts located across the country, with one appellate court (ie, the SPC IP Tribunal).

Wide discussions and legislative proposals took place regarding the establishment of a national IP court during the National People's Congress and Chinese People's Political Consultative Conference of 2024. In addition, in a recent press conference held by the SPC, the Deputy Chief Justice of the SPC also indicated that establishing a national IP court based on the current SPC IP Tribunal is a feasible approach.

Priority processing of innovative drug MA applications

Starting from 1 November 2024, innovative drug marketing authorisation (MA) applications can enjoy priority acceptance service in accordance with a notice issued by the Centre for Drug Evaluation (CDE) of the NMPA, with the aim of stimulating the R&D of innovative drugs and accelerating the launch process of innovative drugs.

The priority service relates to regulations, procedures and required documents, but does not involve technical review-related issues.

The Trade Mark Law to be amended

In January 2023, the CNIPA published the Draft Amendments to the Chinese Trade Mark Law for public opinion, and received over 3,400 comments from more than 400 entities. Based on extensive public consultation and feedback, the CNIPA has revised the draft to focus on six key areas:

- supporting high-quality economic development;
- safeguarding social fairness and justice;
- optimising the trade mark registration process;
- strengthening the trade mark use obligation;
- enhancing trade mark protection and enforcement; and
- deepening trade mark supervision and management.

The CNIPA has developed refined draft amendments and is actively progressing the legislative process. The amendment of the Trade Mark Law was included in the legislative agenda of the 14th National People's Congress Standing Commit-

tee published in May 2024, although the timeline for implementation has not yet been disclosed.

To complement the amendments to the Trade Mark Law, the CNIPA issued the Draft Regulations on the Evidence Standards for Trade Mark Administrative Enforcement and the Draft Measures for Calculating Illegal Business Revenue in Trade Mark Infringement Cases for public opinion, in December 2023 and April 2024 respectively, aiming to provide guidance for trade mark administrative protection. The authors expect that, once these two regulations come into effect, the criteria for trade mark administrative enforcement will be further unified and standardised, and the transparency and predictability of administrative penalties will be significantly enhanced.

Furthermore, the CNIPA published the Draft Amendments to the Measures for Rapid Examination of Trade Mark Applications for public opinion at the end of November 2024, to address the issue of rapid examination of trade mark applications involving national interests, public interests or major regional development strategies, and to innovate examination models and improve examination procedures. This may help to accelerate trade mark prosecution for healthcare and pharmaceutical products.

Draft Amendments to the Regulations for the Implementation of the Copyright Law

In response to the new landscape brought about by the rapid development of technological revolution and industrial transformation, and to strengthen copyright protection in China, the Director of the National Copyright Administration recently disclosed that the Draft Amendments to the Regulations for the Implementation of the Copyright Law will be published for public opinion in the near future.

Pilot programme for data IP registration

In December 2022, the State Council of China issued the *Opinions on Establishing Fundamental Data Systems to Better Leverage the Role of Data as a Production Factor*, setting forth the general direction that data is a factor of production. Under this guidance, the CNIPA launched the local pilot programme for data IP registration. By November 2024, a total of 17 provinces were participating in the programme and successively promulgating local regulations on data IP registration. The pilot programme has received more than 18,000 applications for data IP registration and issued over 10,000 registration certificates. The registration of data in the life sciences and pharmaceuticals sector could further benefit R&D in the industry.

Judicial and Administrative Practice Developments

Patent linkage litigation

Patent linkage enforcement remains a hot battlefield in which more legal issues have surfaced in civil and administrative cases, addressed by courts and the CNIPA. From July 2021 to June 2024, the CNIPA processed 171 patent linkage administrative cases, closing 162 cases, with an average closure period of 162 days. By the end of 2023, the SPC IP Tribunal closed 17 patent linkage appellate cases.

Certain puzzling issues have been further clarified by the courts and the CNIPA. Notably, in the case of Warner-Lambert v Qilu, the SPC confirmed that a generic drug applicant should make a patent linkage statement against a brand drug with different dosage, if no brand drug with identical dosage is available. In Pfizer v Yunnan Sincere, the CNIPA directly ruled that a generic drug falls within the scope of protection of the listed patent, as the submission order for rel-

evant technical documents for the generic drug was refused by the generic drug manufacturer.

However, combo use patents, among other complex issues, remain a challenge faced by the pharmaceuticals sector. Further, antitrust judicial review on settlements between brand and generic drug owners is another critical issue to watch.

Conventional patent infringement litigation

Beyond patent linkage, conventional patent infringement litigation remains crucial for resolving disputes, and the following highlights stand out in China's life sciences and pharmaceuticals sector.

The synchronous collaborative handling of patent infringement cases and related patent invalidation cases adopted by the SPC could unify claim construction in two separate proceedings, and save time and costs. In Nanjing Sanhome v Hunan Warrant, the SPC formed an identical panel to handle two patent infringement appeal cases and two related patent invalidation administrative appeal cases, so as to conduct synchronous review and trial of patent validity, claim construction and infringement; finally, it efficiently closed all cases. In another patent infringement case relating to a medical device patent, in the first instance, the Shenzhen IP Tribunal co-operated with the CNIPA in conducting a joint hearing for the infringement case and the related invalidation case – ie, with the first section being the invalidation oral hearing held by the CNIPA and audited by the handling judges, and with the second section being the court hearing for the infringement case; finally, the CNIPA invalidated the patent at issue, and the court dismissed the complaint (it took around three months to close the infringement case).

The acceptance of supplementary data/post filing data is a critical issue leading to wide discussion in the life sciences and pharmaceuticals industry. In University of California v the CNIPA, the SPC further clarified that it is reasonable and allowable for the patentee to submit supplementary data developed by the same test method described in the patent to support the technical effects asserted in the patent, unless the supplementary data is used to supplement the inherent defects of the patent.

Prodrug-related patent infringement appears to be an interesting and disputed topic in China. Whether supply of a prodrug constituted indirect infringement was not addressed by the SPC in Gilead v Kawin, due to case withdrawal by Gilead; nonetheless, in the first instance, the court ruled that manufacturing and selling the prodrug of a patented compound constituted neither direct infringement nor contributory infringement.

Patent infringement relating to government central procurement/volume-based purchase remains a hot topic following the benchmark case of Sandoz v Hansoh, in which the SPC confirmed that filing an application for drug procurement constitutes infringement of offering for sale. However, in MSD v Hec, relating to the National Drug Reimbursement List (NDRL), the SPC held that filing an application for listing in the NDRL does not constitute infringement of offering for sale.

Punitive damages

After being introduced into IP judicial practice in China, punitive damages have led to strong deterrence and attracted wide discussions.

According to the White Paper on IP protection, in 2023 there were a total of 319 IP civil cases in

which punitive damages were applied, with an annual growth of 117%; the punitive damages awarded reached RMB1.16 billion, three and a half times that in 2022.

The life sciences and pharmaceuticals sector normally involves a large scale of investments, high uncertainty and long-term return periods, meaning that sufficient and effective IP protection is needed. In Hunan Changsheng v Hunan Huize, a trade secret misappropriation case in the life sciences and pharmaceuticals sector closed by the SPC in January 2024, one and a half times punitive damages were applied. As a powerful mechanism, it is expected that punitive damages could be applied in more IP cases in the life sciences and pharmaceuticals industry in China.

Administrative patent enforcement

The CNIPA continues to promote this enforcement channel, through the release of relevant regulations and guidelines, providing systematic training to staff and setting up local IP protection centres. The administrative enforcement channel continues to be attractive for patent infringement disputes resolution. In 2023, 680,000 patent disputes were handled via administrative channels (an 18.8% increase compared to 2022), among which 180 closed cases involved foreign parties.

In the life sciences and pharmaceuticals sector, some patentees have started to enforce their patents via administrative channels – eg, in Boehringer Ingelheim v HEC. Although no damages are awarded in the administrative enforcement channel, administrative enforcement may still provide for injunctions, a quite important remedy for patentees in the life science pharmaceuticals sector.

Trade secret enforcement

Trade secret protection is quite vital in the life sciences and pharmaceuticals industry, given the intensified competition and flow of talent (both domestically and internationally). Notably, approximately 84% of trade secret misappropriations are attributed to employee departures, according to a report issued by the Beijing IP Court.

Following the digitalisation of certain critical R&D assets, trade secret misappropriation via digital channels – eg, unauthorised transfer of confidential technical information via email, USB and/or WeChat – has recently emerged in China, requiring rights-owners to establish a systematic trade secret protection mechanism to mitigate risks and enforce their trade secrets efficiently and effectively.

Encouraged by favourable outcomes in recent trade secret misappropriation cases in other industry sectors, and by improvement of the legal framework for trade secret protection, companies in the life sciences and pharmaceuticals sector are gaining confidence in enforcing their rights in China. Given that patents and trade secrets constitute crucial components of IP assets for these companies, trade secret misappropriation cases often intertwine with patent ownership or patent infringement disputes, adding complexity to the disputes in this sector.

Copyright and data

Amidst the swift evolution of AI technologies, the widespread industrial applications of generative AI have sparked increasing disputes and heated discussions relating to data and AI-generated content (AIGC). This emerging industry presents substantial avenues for exploration within the existing IP protection system in China. Over recent years, the Chinese courts have conclud-

ed several infringement cases related to AIGC and datasets.

Regarding copyright protection, Chinese courts generally recognise the protectability of AIGC under the Copyright Law, such as in:

- the first AIGC text-to-image case of Yunkai Li v Yuanchun Liu;
- the first AIGC service provider case of SCLA v YouthGPT; and
- the first AI virtual digital figure case of XMOV v Hangzhou Sihai.

The authors expect that the copyrightability of AIGC may be further discussed and clarified in future cases or legislation, such as regarding human contributions versus AI contributions.

Data is increasingly demonstrating its value in the digital economy, particularly in the AI era. Data that meets originality requirements may be protected as copyrightable works, non-public data may be protected as trade secrets, and public data that confers a competitive interest to the owner may seek protection under the Anti-Unfair Competition Law. Data IP registration can serve as preliminary evidence of data ownership and legitimacy of data sources in litigation, as recognised by the Beijing IP Court in Yinmu v DataTang.

As society becomes more digitalised, interconnected and open, AI and data-related disputes are becoming increasingly prominent. A notable trend is AI and data-related cases often being highly complex, involving overlapping issues such as open-source, software, AIGC and data; some cases involve a combination of topics, including copyright, trade secrets and unfair competition, as seen in Yinmu v DataTang (open-source data protection case) and XMOV v Hangzhou Sihai (AIGC protection case for virtual digital figures). The life sciences and pharmaceuticals industry, known for its intensive data processing, is not exempt from this trend, and related players are advised to prepare for potential disputes.

Moreover, with the introduction and enforcement of laws such as the Personal Information Protection Law and the Data Security Law, companies handling sensitive information within the life sciences and pharmaceuticals industry – including personal data, medical data and genetic data – can expect significant changes in their daily compliance practices. Recently, the Shanghai Cyberspace Administration issued a warning and imposed a fine on a Chinese medical company for failing to meet the data protection standards set by the Data Security Law, resulting in personal data leaks. Therefore, companies in the life sciences and pharmaceuticals industry should pay close attention to data compliance issues, including data collection, storage, use and cross-border data flow.

Abuse of IP rights

With the substantial expansion of IP enforcement, concerns surrounding the abuse of IP rights have become prominent in China, and cases related to malicious IP enforcement have emerged in recent years. The number of accepted cases regarding malicious IP enforcement across the country surged from 74 in 2022 to 152 in 2023, with an increase rate of 105.41%.

The SPC has addressed this issue by incorporating a clause into its judicial interpretation, empowering courts to compel parties to disclose information regarding ownership, infringement and prosecution disputes related to the asserted IP rights; it has also provided guidance through representative cases.

Conclusion

As the life sciences and pharmaceuticals industry in China continues to evolve, stakeholders must navigate the complex terrain of IP litigation. Legislative vigilance, regulatory compliance and strategic enforcement strategies will be pivotal in safeguarding IP in this dynamic and promising sector.

GERMANY

Law and Practice

Contributed by:
Dr. Clemens Tobias Steins, Dr. Michael Pfeifer,
Dr. Daniel Grohs and Dr. Bianca-Lucia Vos
Hoffmann Eitle

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Hoffmann Eitle is one of the largest intellectual property law firms in Europe, with a market-leading, strong presence of 150+ highly qualified, specialised and experienced patent attorneys working across all technical fields. We were one of the first to create a one-stop IP boutique providing outstanding quality services in all areas of intellectual property. No other European firm is entrusted with more EPO opposition cases. HOFFMANN EITLE's forceful team of passionate litigators has profound experience in patent disputes in all relevant industries, including pharma and other life sciences, medical devices, telecommunication, automotive, etc. A further strength is our vast expertise in international coordination of multi-jurisdictional disputes, advising our clients regarding their overall European litigation strategy. With offices in Munich, London, Dusseldorf, Hamburg, Milan, Madrid, Barcelona and Amsterdam, we are taking the truly European approach, and our attorneys from Japan, the US, China and Korea add a broader international perspective.

Authors

Dr. Clemens Tobias Steins is an attorney-at-law, UPC representative, and partner in HOFFMANN EITLE's Patent Litigation and Contracts group. After working in technology law and M&A, Tobias has specialised in patent litigation since 2007. He represents predominantly Japanese and US clients in large-scale patent litigation projects, mainly in the fields of pharma/biotech and electronics. He is an experienced coordinator and is known to develop a thorough understanding of the technical aspects of a case. He has represented large and medium-sized pharmaceutical and biotech companies in main and provisional injunction proceedings both before German national courts and before the Unified Patent Court.

Dr. Michael Pfeifer is an attorney-at-law, UPC representative, and partner in HOFFMANN EITLE's Patent Litigation and Contracts group. Since joining Hoffmann Eitle in 2017, Michael's work has focused on litigation in pharmaceutical and biotechnology matters, in addition to medical devices and food products, before the German courts. He has been involved in high-stakes UPC litigation from the very first day of the new court. With an academic background in Japanese law, Michael is fluent in Japanese and regularly advises Hoffmann Eitle's Japanese clients on all IP-related matters, including employee invention law.

Contributed by: Dr. Clemens Tobias Steins, Dr. Michael Pfeifer, Dr. Daniel Grohs and Dr. Bianca-Lucia Vos, **Hoffmann Eitle**

Dr. Daniel Grohs is a German and European patent attorney, an expert in patent litigation and a UPC representative. He is a partner in HOFFMANN EITLE's Chemistry practice group. For two decades, he has been representing and advising clients from various technical fields, including pharmaceuticals, microorganisms, food products, organic chemistry, functional polymers, and filter technology. His main area of work concerns opposition and appeal proceedings before the European and the German Patent Office, validity proceedings before the Federal Patent Court and the Federal Court of Justice, opinion work and patent prosecution. Daniel has extensive litigation experience before the German civil courts.

Dr. Bianca-Lucia Vos is a patent attorney and a UPC Representative. She is a partner in HOFFMANN EITLE's Chemistry practice group and an expert in supplementary protection certificates (SPCs). She has gained extensive experience in the prosecution of patents in examination and opposition/appeal proceedings before the EPO and has been involved in nullity proceedings before the German Federal Patent Court. She specialises in the prosecution of SPCs and is responsible for advising clients on their SPC strategy, including the filing strategy for the underlying patent. Bianca also coordinates the international filing of SPC applications for biopharmaceuticals and drugs containing chemical compounds and examination and appeal proceedings before national courts and patent offices in Europe and countries outside the EU.

HOFFMANN EITLE

Arabellastr. 30
81925 Munich
Germany

Tel: +49 89 91 40 90
Fax: +49 89 91 83 56
Email: pm@hoffmanneitle.com
Web: www.hoffmanneitle.com

Contributed by: Dr. Clemens Tobias Steins, Dr. Michael Pfeifer, Dr. Daniel Grohs and Dr. Bianca-Lucia Vos, **Hoffmann Eitle**

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Patent Infringement Actions

Generally, only patent proprietors and exclusive licensees have standing to sue for patent infringement. Nevertheless, others may also be granted the authority to assert certain claims under specific conditions and limitations.

Patent Proprietors

A patent proprietor, including a co-owner, has standing to sue for patent infringement. In this regard, depending on the particular claim of relief being requested, it is the formal registration as proprietor which is decisive, rather than the substantive ownership:

- the claims of relief of cease-and-desist, recall and destruction of infringing products may only be asserted by the person registered as proprietor in the register of the German Patent and Trademark Office (GPTO); and
- for the claims of damages and rendering of accounts, the person(s) registered in the GPTO patent register as proprietor is presumed to have been the proprietor(s) over the time of their registration, but the defendant may challenge this; if the challenge is successful, the plaintiff must request the rendering of accounts on behalf of the actual owners and the damages to be paid to them.

Co-owners may generally request a cease-and-desist order and the recall and destruction of infringing products on their own, ie, without the involvement of the other co-owner(s), unless stated otherwise in their agreement. With respect to damages, a co-owner must request the rendering of accounts and payment to all co-owners.

Exclusive licensees

An exclusive licensee also has standing to sue with respect to all available claims of relief, provided the infringing product and activity is within the scope of the licence.

It is not necessary to register the licence with the GPTO.

Others

Persons other than proprietors and exclusive licensees do not have their own standing to sue but may be empowered to assert certain claims by a proprietor or exclusive licensee.

Claims for damages and unjust enrichment are generally assignable and may, therefore, be asserted by an assignee.

Third parties with their own interest in stopping the infringer may seek injunctive relief and the recall and destruction of infringing products if the patent proprietor or exclusive licensee has authorised them to assert these claims on their behalf (*Prozessstandschaft*). Non-exclusive licensees typically have such an interest if the infringing activities affect their sales.

Joinders

In an infringement action brought by an exclusive licensee, involving the patent proprietor(s) is generally unnecessary since the infringement court cannot invalidate a patent.

There may, however, be other reasons for joining a third party in the litigation, and the German Code of Civil Procedure (GCCP) allows for such joinders.

Nullity Actions and Oppositions

In nullity proceedings, anyone has standing to sue, at least for as long as the patent is in force.

The plaintiff must demonstrate a legal interest in the action if the patent has expired or lapsed.

The same applies to opposition proceedings before the European Patent Office (EPO) and the GPTO. However, the latter has little practical relevance in the field of life sciences. It is very rare, at least so far, to file an application for a German national patent for life science inventions.

Depending on the future experience with the Unified Patent Court (UPC), applicants may, however, wish to retain the possibility to litigate life science patents nationally by filing (also) nationally after the option to opt-out of newly filed European patent applications from the competence of the UPC has expired (probably in 2030).

1.2 Defendants/Other Parties to an Action

German courts cast a wide net when it comes to patent infringers. Anyone who facilitates infringing activities in Germany, such as manufacturing, offering and putting the infringing product on the market, can be considered an infringer.

In the life sciences field, defendants are primarily the manufacturers or importers who hold the marketing authorisation. Wholesalers and others may be addressed in warning letters but are rarely joined as defendants.

A particularly interesting position in the German pharmaceutical market is held by a company called IFA GmbH. It is an information service provider for the pharmaceutical market. Specifically, it maintains a database of all pharmaceuticals distributed through pharmacies in Germany. The database, updated twice a month, is the basis (indirectly via providers of specialised software for pharmacies and other users) for all pharmacies' transactions with their customers and the pharmaceutical wholesalers who supply them. IFA is, therefore, a gatekeeper in the German pharmaceutical market. It regularly finds itself under pressure from (generic) manufacturers on the one hand and patent proprietors on the other, including as a defendant in provisional injunction proceedings.

1.3 Preliminary Injunction Proceedings

Although main infringement proceedings in Germany are relatively fast by international standards (see below), provisional injunctions play an important role in life sciences litigation, especially in the case of a generic launch in the presence of pertinent patents (launch at risk). The reason for this is the immediate and irreversible impact of generic competition on the originator prices in Germany and other countries that refer to the price in Germany.

The provisional measures that can be requested are a cease-and-desist order and a seizure of infringing products.

Requirements for a Provisional Injunction

To obtain a provisional injunction, the petitioner must make it credible to the court that the patent is being infringed and that it would be unreasonable for the petitioner to be deferred to main proceedings. The latter is a comprehensive assessment including the patent's validity, urgency, and the parties' respective interests.

Infringement

In practice, there are no particular differences between the provisional injunction and main proceedings with respect to infringement. The court must be convinced that the patent has been infringed or that the infringement is imminent. The experienced patent panels, especially in Dusseldorf and Munich, are used to handling

even technically complex cases if duly supported by the explanations in the petitioner's written submissions.

Validity

The standard for determining patent validity has been a topic of significant debate in recent years. Generally, most courts require that validity be confirmed beyond just the initial grant of the patent. This confirmation may come from the fact that the patent has withstood inter partes proceedings, such as an opposition, or has faced challenges from third-party observations during the prosecution phase. However, there have always been exceptions to this rule, especially in the context of early generic market entry. A panel of the Regional Court (Landgericht) Munich sought to challenge the prevailing practice by referring questions for a preliminary ruling to the Court of Justice of the European Union (CJEU). The CJEU ruled that the practice of rejecting provisional injunction requests when the patent's validity has not been confirmed in inter partes proceedings is contrary to EU law (judgement of April 28, 2022, C-44/21), and argued, inter alia, that European patents enjoy a presumption of validity upon grant. This judgement did not do much to resolve the differences. The Munich Regional Court sees it as confirmation of its more liberal approach. Other judges criticise that their practice was misrepresented to the CJEU, resulting in a decision not addressing actual practice.

Urgency

After becoming aware of the infringement and the infringer, the petitioner must promptly file their request for a provisional injunction without undue delay. A period of about four weeks is not considered an undue delay, but any significantly longer period requires a reasonable justification, such as the need for experiments, which must also be conducted expeditiously.

If, in the specific scenario, a confirmation of validity is required, a decision in inter partes proceedings, eg, by the Opposition Division, may start a new urgency clock.

Procedure

Requesting a provisional injunction to be granted ex parte

The petitioner may request that the provisional injunction be granted ex parte, ie, without hearing the respondent, but must justify that there is exceptional time pressure.

The court must consider this request in light of the respondent's constitutional right to procedural equality of arms. In principle, the respondent must be heard, but there are exceptions. Exceptions are, for example, cases of exceptional urgency or if the petitioner has sent a warning letter.

An ex parte injunction is often issued within one to two working days.

The court may also hear the respondent in writing before issuing a cease-and-desist order, which may take about two weeks.

Enforcing an ex parte injunction

The petitioner must execute the provisional injunction by serving it on the respondent.

The court may make the execution conditional on the respondent being provided security for their claim to be compensated for the harm incurred due to the enforcement of the provisional injunction, should the provisional injunction be lifted later. Such security is usually provided in the form of a bank guarantee from a German bank.

If the provisional injunction is not executed in the manner described above within one month of its issuance, the respondent may request that it be lifted on this ground alone. It will normally not be possible to apply for a new provisional injunction because of the lack of urgency.

Protective briefs

A protective brief is a common instrument to ensure that one is heard before the court considering an ex parte injunction. A protective brief is an anticipatory defence brief that is filed when one is concerned about an ex parte injunction, eg, before launching a product or attending a trade fair in Germany. The brief is filed with an online repository accessible only to the German courts.

Should a provisional injunction request be filed, the court would search the repository for a protective brief and decide how to proceed. A provisional injunction is still possible, namely when the protective brief fails to convince. If the court decides against issuing the provisional injunction, the court may contact the petitioner and recommend that they withdraw their request. If this is not done or the petitioner refuses, the court will proceed to inter partes proceedings (see e) below).

The protective briefs are valid for six months but can be renewed.

Objection by the respondent against an injunction order

If a respondent is faced with an injunction order, they can – at any time – file an objection with the court, which will cause the court to schedule a hearing, as set out below.

Oral hearing in provisional injunction proceedings

If the provisional injunction is not requested ex parte or if the court does not follow the request, the court will serve the provisional injunction request on the respondent and schedule an oral hearing, typically to be held about two to three months later.

The same applies if the respondent objects to a provisional injunction order.

The parties can make submissions up to the end of the oral hearing; there is no preclusion, and the other party must react, if necessary, on the spot unless the court finds that an assertion has been held back to blindside the other party. The hearing must, therefore, be prepared, taking into account all eventualities. Thus, potential witnesses and party experts should be present at the hearing.

Upon the hearing, the court would issue a judgment. Also, this judgment is merely provisional and can be challenged by the defendant at any time.

Relation to main proceedings

Provisional injunction proceedings are independent of a main action in Germany. Respondents can request the court to set a deadline for commencing a main action, but in practice, they rarely do so.

1.4 Structure of Main Proceedings on Infringement/Validity

Patent infringement proceedings in Germany are bifurcated. The infringement courts are not permitted to hold that a patent is invalid.

Parallel invalidity proceedings must be pending to argue the patent's invalidity in the infringement

action. These proceedings can have been initiated by the defendant or by a third party. They can be an opposition at the EPO or GPTO or a nullity action filed at the Federal Patent Court (Bundespatentgericht). Oppositions can only be filed within nine months after the grant. A nullity action is admissible when this opposition period ends, and no opposition is pending.

In the infringement proceedings, upon the main oral hearing, if:

- the requirement of parallel invalidity proceedings is met; and
- the infringement court should conclude that the patent is infringed,

the court may, in its discretion, order a stay of the infringement proceedings pending a decision in the parallel invalidity proceedings. In exercising this discretion, the court must balance the interest in non-contradictory decisions with the plaintiff's interest in a timely decision on infringement. Defendants should, therefore, not wait too long before commencing a nullity action.

1.5 Timing for Main Proceedings on Infringement/Validity

First-instance Infringement Actions

An infringement action can be commenced at any time. As long as infringing activities are ongoing, the cease-and-desist claim will not be statute-barred. The claim can be considered waived, but not without the defendant taking steps that can be construed as a waiver. Claims for damages and unjustified enrichment can become barred by statute of limitation, even if infringements are ongoing.

To initiate an infringement action, the plaintiff must file a complaint with any of the regional courts (*Landgericht*) that have competence for patent matters and pay the court fee. German proceedings are front-loaded, so the complaint must substantiate the infringement and offer evidence.

The court will serve the complaint on the defendant. If service is outside the EU, it is served pursuant to the Hague Service Convention.

With the service, the court sets the defendant two deadlines, the first for an attorney-at-law to assume representation and the second for submitting the statement of defence.

After the initial exchange of complaint and statement of defence, the parties are free to exchange further briefs; one or two more rounds of briefs are typical.

While the burden of proof for infringement is initially on the plaintiff, if the plaintiff sufficiently substantiates their case, the defendant must dispute it at a matching level of substantiation. In this regard, the parties are prohibited to lie or mislead. It is, therefore, usually not sufficient for the defendant to merely dispute that the attacked embodiment is construed or operates according to the claim; the defendant must specify the allegedly non-infringing construction or operations. In this way, German courts largely manage without the need for document disclosure or discovery. A legal instrument to request disclosure of a specific document under certain conditions is available but rarely used. Discovery is not available.

The presiding judge can exercise more or less control over this stage of the proceedings, eg, by:

- setting time limits for further briefs;
- scheduling an early court hearing; or

• written guidance orders.

In patent infringement proceedings, all of those are rather uncommon as of late.

Eventually, the court will schedule the main hearing, usually about nine to 12 months after service.

If the court deems it necessary, it can call witnesses proposed by a party to be present at the hearing for questioning, predominantly by the court. This is, however, also rare in patent infringement proceedings.

To prepare for the hearing, the reporting judge writes a preliminary opinion based on the written submissions. This opinion is then discussed internally with the presiding judge and the third judge, resulting in the court's preliminary opinion. At the outset of the hearing, the presiding judge presents this preliminary opinion to the parties involved. The attorneys then have an opportunity to respond to the court's preliminary opinion. The entire hearing typically lasts about two to three hours.

Upon the hearing, unless the court finds that their decision hinges on a factual issue on which evidence must be taken, the court will issue a judgment within typically four to six weeks. If the decision favours the plaintiff, the plaintiff can provisionally enforce the judgment upon providing security.

First-instance Nullity Actions

As with infringement actions, the plaintiff initiates the action by filing a complaint with the Federal Patent Court (*Bundespatentgericht*) and paying the court fee. The complaint must set out all validity attacks in sufficient detail for the court to decide on this basis alone, should the defendant not dispute it.

A nullity action can be served on either the proprietor or the representative, as recorded in the GPTO patent register.

With service, the court will set the defendant a one-month deadline to declare whether they intend to object to the request for invalidation and a deadline of a further month (extendable to two months if sufficient grounds are given) to substantiate the grounds for the objection.

Within six months from service, the court shall issue a preliminary opinion.

The parties can exchange further briefs, and the court can set further deadlines to guide this process.

The main hearing is typically scheduled about 18 to 24 months after service, and a judgment is issued, usually about two months later.

Considering that the nullity action is usually prepared and filed as a reaction to being served an infringement action, ie, at least one or two months later, and the overall longer duration, the infringement court regularly decides on infringement, and a potential stay, before the nullity court has heard the case. The above-mentioned (early) preliminary opinion has been introduced to assist the infringement court in deciding whether to stay.

1.6 Requirements to Bring Infringement Action

While an infringement action can be filed before a patent grant, a cease-and-desist order (in main or provisional injunction proceedings) requires that the mention of the grant has been published.

If a patent applicant wishes to stop infringements before the grant, an option may be to spin off a utility model from the pending application. A cease-and-desist order can be based on such a utility model after a few days or weeks, as only registration is required. Utility models are available for product claims, include medical use claims, and have a term of ten years (if spun off from a patent application, calculated from the application date of the patent).

The plaintiff bears the burden of proof regarding the infringement. In the case of a manufacturing process, this can be challenging. The German Patent Act (GPA), however, reverses the burden of proof if the patented manufacturing process creates a new product.

1.7 Pre-Action Discovery/Disclosure

Under German law, there is no pre-action discovery or disclosure.

1.8 Search and Seizure Orders

Inspection orders are available under Section 140c GPA. While the requirements in the books have been mostly aligned with procedures known in other European jurisdictions following the implementation of the EU Enforcement Directive 2004/48, inspection proceedings in Germany still have their own procedural particularities.

To obtain an inspection order, (i) the patentee or an authorised person is required to demonstrate that (ii) infringement is sufficiently likely, ie, that there are concrete indications for infringing acts by the defendant or another person, whereas (iii) the inspection into specific objects or documents assumed with the defendant (iv) is necessary for the applicant for establishing its claims. The court will then assess the proportionality of issuing such an order. In essence, an inspection order has the best chance of being granted if the applicant has collected all pieces for establishing infringement except for certain facts that are otherwise inaccessible to the applicant. Inspections can be sought in preliminary proceedings (Section 140c(3) GPA) and granted ex parte, provided that are is a sufficient reason (eg concerns that the purpose of the inspection may be frustrated if the defendant had advance knowledge of the request) and, according to some courts, urgent action of the applicant.

In order to ensure the confidentiality of the results while also fulfilling the proportionality requirement and permitting use of the obtained evidence in main proceedings, inspection requests are frequently combined with an evidence preservation procedure, as detailed in Section 485 of the Code of Civil Procedure. This process, known as the Düsseldorf procedure (Düsseldorfer Verfahren), involves a court-appointed expert conducting the inspection according to the tasks specified by the court. The applicant's outside counsel will accompany the expert and must adhere to a strict confidentiality order.

The process concludes with the expert providing a written report, after which the court will decide on the release of an unredacted version, having considered the parties' arguments. This final stage is generally completed within six months of the initial application.

Per Section 493 Code of Civil Procedure, the expert report may be utilised in subsequent infringement or unrelated proceedings (Section 411a Code of Civil Procedure).

1.9 Declaratory Relief

Under German law, declaratory actions require the plaintiff to demonstrate a specific legal interest in the declaration being sought for the action

to be admissible. Requests for declarations of non-infringement thus typically depend on a particular behaviour exhibited by the defendant, such as claiming entitlement to certain rights in a warning letter. A negative declaratory action is considered subsidiary to and thus does not bar a full action for performance.

"Arrow declarations", ie, requests for a declaration stating that a specific embodiment is neither novel nor obvious in light of certain prior art (and thus cannot fall under the scope of protection of a patent granted later), have so far not been granted by a German court.

In contrast, infringement actions typically contain merely a declaratory request that the defendant is obliged to reimburse the plaintiff for any damage suffered from the infringement. As a result, German patent litigation typically consists of two phases: the first focuses on the infringement itself, while in the second phase the amount of damages may be subject to a separate action (see **5.4 Damages**).

1.10 Doctrine of Equivalents

The claims of a patent define the scope of protection of a patent, and due account shall be taken of any element equivalent to an element specified in the claim (cf Protocol on the Interpretation of Article 69 EPC). Based on the understanding of the claims, the courts assess whether the skilled person could find the modified means used in the challenged embodiment to be equally effective for solving the problem underlying the invention, referring to three questions (cf FCJ, X ZR 168/00 – *Schneidmesser I*):

- Does the attacked solution have essentially the same effect, ie, does it achieve the same results and advantages as the claimed invention in essentially the same way?
- Was it obvious to the skilled person at the time of priority that the concerned solution had essentially the same effect?
- Orientation by the wording of the claims: Would the skilled person find the modified means used in the challenged embodiment equally effective for solving the problem underlying the invention with the aid of his specialised knowledge?

For striking a fair balance between the patentee's interest in covering equivalent solutions and legal certainty, the third question is of particular importance. Case law assesses each feature in the context of the description as a whole. A limitation of the claims to a particular example from the description may result in pledging alternatively disclosed embodiments to the public (FCJ, X ZR 16/09 – *Okklusionsvorrichtung*). Courts may turn to the patentee's submissions in the grant proceeding to assess whether an amendment was indeed meant to limit the subject matter of the patent, ie, to distinguish the claimed invention from the prior art, or merely to overcome formal objections (FCJ, X ZR 29/15 – *Pemetrexed*).

A court must not find equivalent infringement if the claimed solution was not novel or inventive over the relevant prior art (so-called Formstein defence, cf FCJ, X ZR 28/85). The rationale behind this defence is that the patent owner could not secure patent protection for an invention that was already in the public domain when filing the application. It follows that these known solutions or embodiments cannot constitute a patent infringement.

1.11 Clearing the Way

Under German law and practice, there is no obligation to clear the way before launching a product, and failing to do so is not a factor consid-

ered by the court when decision on whether to grant an injunction. However, a defendant must submit their validity challenge early – well before the oral hearing date in preliminary proceedings – if they want the infringement court to consider the likelihood of the patent being invalidated in its decision on an injunction.

1.12 Experts

Expert evidence plays only a limited role in German proceedings, as courts prefer to decide a dispute based on the parties' written submissions. Questions of claim interpretation and validity of a patent are considered legal questions for the court to decide.

In infringement proceedings, parties often rely on statements and reports of private experts to verify and support the credibility of their assertions. Such evidence is, however, given no other procedural status than regular submissions by representatives unless the parties' experts are proposed and summoned as witnesses. Party experts are not subject to particular duties and obligations to the court. Intentionally false statements and misleading the court can have consequences under general criminal law rules.

Upon request of the parties or its own assessment, a court may appoint a neutral expert as formal evidence for answering any specific factual question it considers relevant for deciding the dispute (Section 402 et seqq. Code of Civil Procedure). Court-appointed experts are required to maintain impartiality and to respond to the specific question posed by the court. Selecting experts, as well as preparing and discussing the expert report, typically in further oral proceedings, considerably delays a decision on the dispute. In preliminary proceedings, the court relies entirely on the parties' submissions; court-appointed experts are not used.

1.13 Use of Experiments

Experiments are not treated differently than other forms of factual assertions. Parties may introduce the results of experiments into the proceedings in the form of written (expert) reports. The individuals who conducted the experiments may also be called to give witness evidence if disputed by the other side.

Further, court-appointed experts may be requested to conduct certain experiments to answer the questions referred to them.

1.14 Discovery/Disclosure

As stated in **1.7 Pre-Action Discovery/Disclosure**, there is no pre-action discovery or disclosure, and neither is there in the proceedings.

It is the plaintiff's burden to substantiate and offer evidence for the facts underlying its legal claim. On the other hand, a party may utilise information from a variety of sources. Even information obtained illegally may, in principle, be used. In principle, even illegally obtained information may be used. Courts apply only limited exceptions, eg, if the manner in which the information was unlawfully obtained violated a person's constitutionally protected fundamental rights. Moreover, the burden on the defendant to respond at a matching level of substantiation and not to lie and mislead in practice compensates for the lack of pre-action discovery or disclosure.

The GCCP allows a party to request the court to compel the opposing party to produce a specific document that is essential for the requesting party. However, this process requires a high degree of specificity, often proving unhelpful in practice.

1.15 Defences and Exceptions to Patent Infringement

Patent infringement proceedings typically evolve along diverging views on understanding the patent's scope of protection. In addition, the defendant may rely on a number of defences:

- *Permitted uses:* Section 11 GPA enumerates the permissible uses of a patent (eg, private action, acts of experimental use and Bolar exemption, see **2.3 Acceptable Pre-Launch Preparations** and **3.3 Acceptable Pre-Launch Preparations** below).
- *Private prior use before the priority date (Section 12 GPA):* While a prior use right is limited to the undertaking at which the prior use occurred, courts have come to accept scaling up and amending the concerned embodiment unless the intrusion into the scope of protection is intensified (FCJ, X ZR 95/18).

Declaration of Willingness to Grant Licences

Section 139(1)3 GPA, in theory, also allows the defendant to rely on third-party (patient) interests for arguing that an injunction would have disproportionate effects but plays little role in practice due to a very high bar.

- *Positive right to use:* If the defendant is the proprietor of a patent with an earlier priority date, whereas the plaintiff has a later priority date, the former may be deemed the rightful owner of the patent. The defendant's own patent precludes any infringement of the younger patent.
- *Unlawful extraction:* If the plaintiff has extracted the intention from the defendant in an unlawful manner, the defendant is not deemed to have infringed the patent.
- *Exhaustion:* If the product in question has been put on the market within the EU or the EEA with the patentee's consent, the patent protection in question shall be deemed to have lapsed for the concerned embodiment. As a transitional provision, EU law foresees a specific mechanism for the parallel import of pharmaceuticals from later-acceded member states in consideration of the diverging level of protection available at the time of application.
- *Statute of limitations:* See **1.5 Timing for Main Proceedings on Infringement/Validity** above.

If the DoE is applicable, the Formstein defence may be invoked (see **1.10 Doctrine of Equivalents** above)

Due to Germany's bifurcated system, a defendant can only indirectly assert the invalidity of the patent concerned, namely by requesting a stay of the infringement proceedings in view of the success chances of a pending validity attack before the EPO or the federal courts (see below).

1.16 Stays and Relevance of Parallel Proceedings

Stay Because of Parallel Invalidation Proceedings

As explained under **1.4 Structure of Main Proceedings on Infringement/Validity**, the infringement court can stay the action in view of parallel German or EPO opposition proceedings or a German nullity action regarding the patent in suit.

Stay Because of Parallel CJEU Proceedings

Moreover, a court may also stay the infringement proceedings because of pending proceedings at the CJEU, eg, for a preliminary ruling, if the infringement court's decision hinges on the outcome of the CJEU proceedings.

Stay Because of Lis Pendens

If proceedings involving the same cause of action between the same parties have been brought at another EU court, the German court must stay its proceedings according to Article 29 Brussels Regulation I (recast) until the court seized first has determined whether it has jurisdiction. If the proceedings are merely related, the court that has been seized later has discretion on whether to request a stay (Article 30 Brussels Regulation I (recast)).

No Discretionary Stay – Taking Foreign Judgements Into Consideration

The court, however, has no discretionary powers to stay the infringement proceedings, for example, to await a foreign decision in scenarios other than the one mentioned above. However, sometimes, a court's use of its discretionary scheduling powers can appear as if it was done to await a certain event.

In principle, German courts must take decisions by a foreign court on another national part of the same European patent into consideration and, if the court comes to a different decision, explain why the court diverges. However, decisions from the USA or other overseas courts are not of much relevance since these courts' practices are seen as being too different.

1.17 Patent Amendment

A patent can only be amended in opposition or nullity proceedings, not infringement proceedings.

In infringement proceedings, the plaintiff cannot amend the patent. However, a patent can be asserted in limited form (eg, to reduce the risk of a stay). This may also be done initially in the form of so-called "in particular" claims – that is, claims where the plaintiff substantiates that certain dependent claims or features from the description are also realised by the attacked embodiment – without limiting their broadest request for a cease-and-desist order. This allows the plaintiff to potentially limit the asserted claim later in the proceedings (ie, if the patent is upheld in such amended form).

1.18 Court Arbiter

The plaintiff may commence infringement proceedings or provisional injunction proceedings regarding a patent at any of the twelve regional courts with specialised patent panels, at least as long as infringing acts are conducted or imminent in the court's territory. In practice, this gives the plaintiff freedom to forum-shop between these courts. As plaintiffs usually choose an experienced court, the Regional Courts Dusseldorf and Munich handle almost all infringement actions in the field of life sciences.

As set out under **Requirements for a Provisional Injunction** (Validity), above, these courts have developed a somewhat distinct practice related to the patent's validity standard in provisional injunction proceedings, albeit it has no significant relevance in the early generic entry cases.

2. Generic Market Entry

2.1 Infringing Acts

Under German law, different acts regarding a generic market entry can constitute a patent infringement, as outline below.

- Offering or advertising on trade fairs despite patent protection.
- Listing in the Lauer-Taxe: This research device contains all available drugs and other medicinal devices in Germany. It is also suf-

ficient if there is a listing in another database, such as physicians' software.
- Announcement of market entry: A serious and unambiguous specific announcement of intended market entry is generally sufficient for an imminent threat of infringement.
- Entering into a rebate agreement with a public health insurance company.

However, the following acts do not constitute a patent infringement:

- Grant of a market authorisation as well as trials and studies in preparation thereof (see 2.3 Acceptable Pre-Launch Preparations below).
- Application for reimbursement.
- With respect to second medical use patents: Skinny labelling (cf Article 11 Directive 2001/83/EC) – unless the plaintiff can establish that the defendant exploited an existing prescription practice in the protected use (cf HRC Dusseldorf, 2 U 27/18).

2.2 Regulatory Data and Market Exclusivity

The originator is responsible for submitting data regarding the initial market entry. The data will be protected for a period of eight years from the date of submission of this application for MA. During this period, the generic company is not permitted to access these documents.

Following the eight-year period, the originator is granted a two-year exclusivity period in the market. This indicates that a generic company is permitted to apply for an MA and may be granted such a status but must refrain from sales activity until the application is approved. The originator may request an extension of the market exclusivity period by one year if a new use is authorised within the first eight years and this new use provides additional value.

In total, the periods are described as "8+2+1".

An exception is made for orphan drugs. Orphan drugs are granted a period of ten years of market exclusivity, which can be extended by a further two years.

2.3 Acceptable Pre-Launch Preparations

The experimental use exemption under Section 11(2) GPA exempts any acts directed at gaining insights into the invention, including proof of function. Following the clinical trial decisions (FCJ, X ZR 99/92 and X ZR 68/94), such exempted experimental use may ultimately also be motivated by commercial interests.

In addition, the German legislator has opted for a broad implementation of the Bolar exemption in Section 11(2b) GPO, extending the exemption to all studies and tests and the resulting practical requirements undertaken to obtain a marketing authorisation, ie, not limited to generics and also applying to acts undertaken for obtaining non-EU, eg, FDA approval. It is the position of the German courts that third-party suppliers may also benefit from their customer's exemption under the Bolar and experimental use exemption under strict requirements. A reform of the underlying EU legislation, which may provide for full harmonisation among the EU member states, is under discussion.

2.4 Publicly Available Drug and Patent Information

The Federal Institute for Drugs and Medical Devices publishes a monthly updated anonymised list of pending applications for marketing authorisations; granted MAs are compiled and publicly accessible in the AMIce database. No notice or other information will be given to the MA holder.

Marketed pharmaceuticals are included in the Lauer-Taxe, updated twice a month, with updates visible a few days before becoming effective.

2.5 Reimbursement and Pricing/Linkage Markets

MAs and reimbursements are granted without consideration of the patent status (no patent linkage system). The private company IFA is entrusted with issuing tag numbers for pharmaceuticals (PZN) and compiles the data on commercialised pharmaceuticals (which is then published, eg, in the Lauer-Taxe) and is at least partly acting as a gatekeeper against generic launch (see Germany Trends and Developments for details).

Public health insurers may, at least in theory, resort to indication-specific tendering as generic bidding on unlimited tenders may constitute an act of infringement if use patents still cover certain indications.

3. Biosimilar Market Entry

3.1 Infringing Acts

There are no differences between biosimilars and generics in terms of infringement (see **2.1 Infringing Acts** above).

3.2 Data and Regulatory Exclusivity

There are no differences between biosimilars and generics in terms of data and regulatory exclusivity (see **2.2 Regulatory Data and Market Exclusivity** above).

3.3 Acceptable Pre-Launch Preparations

The Bolar exemption under German law also covers biosimilars (see **2.3 Acceptable Pre-Launch Preparations** above).

3.4 Publicly Available Drug and Patent Information

There are no differences between biosimilars and generics in terms of publicly available drug and patent information (see **2.4 Publicly Available Drug and Patent Information** above).

3.5 Reimbursement and Pricing/Linkage Markets

There are no differences between biosimilars and generics in terms of reimbursement and pricing/linkage markets (see **2.5 Reimbursement and Pricing/Linkage Markets** above).

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

In Germany, supplementary protection certificates (SPCs) are available for patents relating to active ingredients of medicinal products as well as plant protection products. The holder of a patent for a new medicinal product or plant protection product must refrain from placing it on the market until it has received the necessary authorisation. This reduces the period of effective protection of the patent. SPCs have been established to partly make up for this loss of exclusivity.

German SPCs for medicinal products are governed by Regulation (EC) No 469/2009, which has been translated into national law. Relevant provisions can be found in Section 16a and Section 49a GPA.

Any active ingredient or combination of active ingredients protected by a patent and subject matter prior to being placed on the market as a

(human or veterinary) medicinal product may be the subject matter of an SPC.

Article 3 of Regulation 469/2009 sets out the requirements for obtaining an SPC for a medicinal product. The product (ie, the active ingredient or combination of active ingredients of the approved medicinal product) must be "protected" by a basic patent in force (Article 3(a)). There is no limitation to certain types of patents; a suitable basic patent may be a patent protecting the product, a process to obtain the product, or an application of the product. However, to be "protected" by the basic patent, the product must be "specifically identifiable" in the patent based on the disclosure of the patent, the common general knowledge and the prior art. Furthermore, the product must have received a valid authorisation to be placed on the market as a medicinal product for human or veterinary use (Article 3(b)). Each patent holder may only obtain a single SPC for a particular product (Article 3(c)) on the basis of the first authorisation for placing the product on the market (Article 3(d)). In other words, the holder of several patents must select one patent of the patent portfolio as the basic patent of the SPC. While it is possible to file several SPC applications, once an SPC is granted, it will prevent the granting of a further SPC to the same patent holder and the same product.

The SPC application must be filed in the name of the patent holder. It is often the case that the marketing authorisation holder and the patent holder are not identical. The current proposal for an amended SPC Regulation contains a provision according to which the patent holder may not obtain an SPC without the MA holder's consent.

If the originator (the MA holder) and a third party both hold separate patents (and provided that both firms are unrelated entities), SPCs may be granted to both parties.

The circumstances under which an SPC for a combination of active ingredients can be obtained after an SPC for a single product has already been granted based on the same patent were the subject of the recent Court of Justice of the European Union (CJEU) decision on joined cases C-119/22 and C-149/22. At present, an SPC for the combination may be granted if there is a separate patent that specifically protects that combination.

Regulation (EU) No 2019/933 amends Regulation (EC) No 469/2009 and introduces the so-called manufacturing waiver for SPCs. This means that, despite the SPC, companies based in the EU can manufacture a generic or biosimilar product either solely for export to a country outside the EU ("third" country) where the product is not protected by a patent or SPC or during the last six months of the SPC term for placing it on the market in the EU once the SPC has expired (stockpiling).

4.2 Paediatric Extensions

The SPC term may be extended by 6 months if clinical studies of an agreed paediatric investigation plan (PIP) have been completed (see Article 13 No 3 of Regulation No 469/2009).

The paediatric extension of the SPC term was established as an incentive or reward for pharmaceutical companies for the investment and effort put into clinical studies testing the safety and efficacy of a medicinal product in the paediatric population.

4.3 Paediatric-Use Marketing Authorisations

Special MAs are possible for the paediatric use of a medicine that already has an MA for adults. These medicines must no longer be covered under a patent or an SPC and, furthermore, may not be developed specifically for children. As mentioned (see **4.2 Paediatric Extensions** above), the paediatric use has to follow the PIP.

With a paediatric-use MA (PUMA), data protection is established for eight years and two subsequent years of market exclusivity. This topic is governed by Regulation (EC) No 1901/2006.

4.4 Orphan Medicines Extensions

For the time being, an extension of the SPC term is not available for orphan drugs. However, an orphan drug has the advantage of a ten-year orphan exclusivity (see Article 8 of Regulation No 141/2000). This period can be extended by up to two additional years if clinical studies in accordance with an agreed PIP are completed. There are plans to reform the EU pharmaceutical legislation, which are likely to result in changes in the regulatory exclusivity periods.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

Instead of a preliminary injunction in main proceedings, German law provides for a right to commence provisional injunction proceedings separately from main proceedings. We have addressed the relief available in those proceedings under **1.3 Preliminary Injunction Proceedings** above.

5.2 Final Injunctive Relief

A first-instance judgment in favour of the plaintiff may include an order to cease and desist from undertaking certain specified activities (final injunctive relief) as well as further claims of relief, such as the recall and destruction of infringing products.

The enforcement of a first-instance judgment that is not (yet) final requires the plaintiff to provide security (often in the form of a bank guarantee) for the defendant for the damages incurred due to the enforcement, should the judgment be set aside upon an appeal. The amount of security is within the court's discretion but is usually set at the same level as the value in dispute on which the court fees and reimbursement claims are based (see **5.5 Legal Costs** below).

To enforce the cease-and-desist order, the plaintiff must indicate to the defendant that the judgment is enforced by serving a copy of the judgment and the aforementioned security.

The defendant can petition the appeal court to stay the enforcement, but this is granted only in exceptional cases.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

German law provides for an action for a compulsory licence, which can be filed with the Federal Patent Court. To prevail in this action, the applicant must demonstrate that:

- they have unsuccessfully tried to obtain a use right from the proprietor on reasonable terms; and
- the public interest calls for the grant of a compulsory licence.

A public interest exists in cases where the use right is required to provide a medicament for a serious illness that has either higher efficacy or fewer side effects than can be achieved with any other available medicament.

Besides this specific provision, a court must generally consider whether circumstances exist under which the injunction would lead to hardship for the infringer or third parties, which is disproportionate to the plaintiff's interest in excluding those based on the intellectual property right granted to him. German courts apply this only in very exceptional cases, and in principle, it cannot replace the above action for a compulsory licence.

5.4 Damages

It is common practice in German infringement proceedings only to request a declaration that damages are to be compensated and that the defendant must render accounts. Upon obtaining the rendering of accounts, the plaintiff can commence a follow-on lawsuit, claiming payment of a specific amount of damages.

Those damages can be calculated under German law according to the methods of:

- lost profits;
- infringer's profit; and
- reasonable royalty.

The plaintiff has discretion regarding the applied calculation method and can even apply different methods to different periods.

Damages are only meant to compensate for a loss suffered, not to penalise. In general, German courts are conservative regarding the amount of damages awarded.

It very rarely comes to a follow-on action on the amount of damages because the parties reach an out-of-court settlement once infringement has been established in a final decision or earlier because of a threatened or enforced injunctive relief. Therefore, the case law on the amount of damages is limited, so no industry-specific conclusion can be drawn.

5.5 Legal Costs

In its decision, the court will also decide which party will bear the legal costs of the case or, if the costs are to be shared, which share of the costs. The legal costs include, in particular, the court fees (advanced by the plaintiff) and the attorney fees of the adversary. Both depend on the value of the dispute, which the court also determines on the basis of the parties' submissions or the court's own findings of facts.

In principle, the losing party pays the legal costs. However, a plaintiff must bear the legal costs of litigation if:

- the defendant's conduct did not give justified cause to resort to litigation; and
- the defendant immediately acknowledges the claim.

The plaintiff can avoid this risk by sending a warning letter, but it is necessary to decide on a case-by-case basis:

- how likely an immediate acknowledgement is?
- is such a quick win potentially worth bearing the legal costs?
- what risks does sending a warning letter bring in a specific situation?

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

German courts have no discretion to reduce or withhold relief because of a plaintiff's conduct unless the plaintiff holds a dominant position and if the conduct constitutes an abuse of that dominant position under competition law (Article 102 TFEU).

6. Other IP Rights

6.1 Trade Marks

There are no special rules for trademarks relating to pharmaceuticals or life sciences, so any trademark must not be misleading or cause confusion with a pre-existing trademark.

In the life science field, trademark disputes are most common regarding repackaging pharmaceuticals for parallel import.

6.2 Copyright

It is currently unknown if there are any copyright disputes in the life sciences and pharma sector in Germany.

6.3 Trade Secrets

Trade secret disputes are so far not very common in Germany in the pharma and life sciences sector.

7. Appeal

7.1 Timeframe to Appeal Decision

Main infringement judgements and judgements in provisional injunction proceedings can be appealed at the higher regional courts. A further appeal at the Federal Court of Justice (FCJ) on a point of law is possible only in main infringement proceedings.

In nullity proceedings, the FCJ is the appeal instance so that the bifurcated tracks of the German system converge at the FCJ.

7.2 Appeal Court(s) Arbiter

The higher regional courts and the FCJ also have specialised patent panels.

7.3 Special Provisions

Patent infringement proceedings are subject to the same rules as any other civil procedure case.

Special provisions only apply to nullity proceedings.

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

The Unified Patent Court (UPC) has made a promising beginning, with cases from the life sciences and pharmaceuticals sector being presented at the UPC. However, national litigation continues to play a more significant role in this field, and this trend is likely to continue for the foreseeable future.

9. Alternative Dispute Resolution

9.1 ADR Options

Mediation and other forms of alternative dispute resolution are available and may be suggested by the court under Section 278a GCCP, but they require the consent of both parties. The parties are also free to agree on any alternative approach to resolving their dispute, eg, through an expert determination. The parties may agree on such ADR once a dispute has arisen or in advance, as often is the case in IP contracts.

Objective statistics that provide a clear picture of the use of ADR to resolve disputes in life sciences are not available. Seemingly, ADR does play a role, either based on contractual dispute resolution clauses or agreed at the time of the dispute, but it is extremely rare compared to litigation.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The EU Commission, as the competent antitrust authority for the entire European Union, is closely monitoring the pharma and life sciences sector, both in terms of abuses of dominant positions and agreements that violate competition law. The EU Commission has been particularly critical of settlements that limit generic entry and include a value transfer to the generic company.

11. Collective Redress

11.1 Group Claims

Group claims are only available regarding unfair practices against consumers. They can be brought by consumer advocacy organisations and are designed to assist consumers who have suffered minor damages and are unable to pursue their own legal action. They are not very relevant in the life sciences and pharma sector.

Trends and Developments

Contributed by:
Dr. Peter Klusmann, Gregor König, Dr. Dirk Schüßler-Langeheine and Dr. Lasse Christian Weinmann
Hoffmann Eitle

Hoffmann Eitle is one of the largest intellectual property law firms in Europe, with a market-leading, strong presence of 150+ highly qualified, specialized and experienced patent attorneys working across all technical fields. We were one of the first to create a one-stop IP boutique providing outstanding quality services in all areas of intellectual property. No other European firm is entrusted with more EPO opposition cases. HOFFMANN EITLE's forceful team of passionate litigators has profound experience in patent disputes in all relevant industries, including pharma and other life sciences, medical devices, telecommunications, automotive, etc. A further strength is our vast expertise in international coordination of multi-jurisdictional disputes, advising our clients regarding their overall European litigation strategy. With offices in Munich, London, Dusseldorf, Hamburg, Milan, Madrid, Barcelona and Amsterdam, we are taking the truly European approach, and our attorneys from Japan, the US, China and Korea add a broader international perspective.

Authors

Dr. Peter Klusmann is a German and European patent Attorney and partner in HOFFMANN EITLE's chemistry practice group. He has represented small, medium-sized and large clients in all aspects of chemistry and beyond for more than two decades. His technical areas range from foods to forest products and from polymers to pharmaceuticals. For the most part, Peter handles contentious matters, particularly opposition and appeal cases before the European Patent Office and revocation actions. Peter has been involved in hundreds of oral proceedings and is very active in patent prosecution and litigation procedures.

Gregor König is one of the leading German patent attorneys in litigation and validity proceedings and will be joining HOFFMANN EITLE as a partner in February 2025. During his many years of litigation practice, he has developed special approaches and tools to maximize exclusivity and maintain long-term protection. Gregor represents national and international market leaders in the fields of molecular biology, pharmaceuticals, medical devices, and mechanical engineering. He is currently teaching pharma/biotech-Patent-patent law at the University of Dusseldorf. He also taught medical engineering patent law at the University of Aachen from 2005 to 2015.

Contributed by: Dr. Peter Klusmann, Gregor König, Dr. Dirk Schüßler-Langeheine and Dr. Lasse Christian Weinmann, **Hoffmann Eitle**

Dr. Dirk Schüßler-Langeheine is a qualified attorney-at-law in Germany, UPC Representative and Business Mediator. He is a partner and co-leader of HOFFMANN EITLE's patent litigation and contracts practice group. Dirk specializes in patent litigation, with a special focus on life sciences, and is frequently acting as German lead counsel and coordinator of pan-European pharma patent enforcement projects for originators. He also advises on licensing and other IP agreements as well as IP-related aspects of competition law. With his special expertise in the Japanese language and culture, he is regularly involved in the resolution of international disputes involving Japanese companies.

Dr. Lasse Christian Weinmann is a patent attorney and partner in HOFFMANN EITLE's biotech and pharma practice group and specializes in German nullity proceedings, multinational invalidity and infringement disputes, EPO opposition/appeal cases, the UPC, as well as FTO and invalidity opinions and due diligence work. His areas of scientific expertise include therapeutic proteins such as antibodies and blood factors, CAR T-cells, diagnostic methods, sequencing technologies, vaccines, and small RNA-based drugs.

HOFFMANN EITLE

Arabellastr. 30
81925 Munich
Germany

Tel: +49 89 91 40 90
Fax: +49 89 91 83 56
Email: pm@hoffmanneitle.com
Web: www.hoffmanneitle.com

Contributed by: Dr. Peter Klusmann, Gregor König, Dr. Dirk Schüßler-Langeheine and Dr. Lasse Christian Weinmann, **Hoffmann Eitle**

The German FCJ on a Reasonable Expectation of Success – Good Times for Patentees?

In the past decade, the concept of a reasonable expectation of success has gained considerable relevance for patent litigation in Germany. According to the established case law of the German Federal Court of Justice (FCJ), in assessing whether it would have been obvious from the prior art to solve a technical problem in a particular way, it may be relevant whether this would have been associated with a reasonable expectation of success, which is generally similar to the EPO's Boards of Appeal case law. However, the FCJ's specific approach is different from that of the EPO, as it is performed for each individual step on the skilled person's path to the invention, rather than assessing the outcome, ie, the claimed invention directly (as at the EPO).

In 2023 and 2024, the FCJ further refined this case law. In particular, in its decisions X ZR 77/23 - "Testosterone ester", FCJ X ZR 83/21 – "Sorafenib tosylate", and "X ZR 92/23 - "Mirabegron", the FCJ denied such a reasonable expectation of success and held that the claims were inventive. These decisions have already impacted German and UPC patent litigation practice, particularly in the field of pharmaceuticals and their medical uses.

The framework of the earlier FCJ case law

In its earlier case law, the FCJ had already established the basic criteria for assessing a reasonable expectation of success. According to these criteria, the courts shall determine, with due regard to the technical field in question, the extent of incentives for the skilled person, the effort required for adopting and pursuing a particular approach, and the alternatives in question, if applicable, as well as their respective advantages and disadvantages (eg, FCJ X ZR 59/17 - "Fulvestrant", FCJ X ZR 24/19 - "Phytase", FCJ X ZR 150/18 - "Pemetrexed II", and FCJ X ZR 65/18 – "Tadalafil").

After these criteria had been formulated by the FCJ in the Fulvestrant case, they initially proved to be a challenging hurdle for owners of some pharmaceutical formulation and dosing patents because the skilled person was seen to take a stepwise approach on their way from the prior art to the claimed invention. In other words, the reasonable expectation of success only needed to suffice for the next step rather than for the claimed subject matter as under the EPO's problem-solution approach.

In the Fulvestrant case, the FCJ specifically asked whether the skilled person would have had a reasonable expectation of success in performing animal experiments as the first step to identifying the claimed pharmaceutical formulation. The FCJ held that a reasonable expectation of success, and hence obviousness, can already result from the skilled person's incentive to test the efficacy and tolerability of a formulation in an animal experiment with sufficient predictive value for therapeutic use in humans. Thus, according to the FCJ, a claimed teaching may be obvious without requiring or even considering clinical tests.

In the Tadalafil case, the FCJ again asked whether the skilled person would have had a reasonable expectation of success to proceed stepwise, ie, to perform each individual step in pre-clinical and clinical development in order to arrive at the (surprisingly) low dosage of tadalafil. The outcome from the first step then provided an incentive to perform the further steps until the claimed subject matter was reached. The fact that the dosage was surprisingly low played no role, contrary to the EPO's assessment. The

FCJ considered that results of clinical trials in the prior art were not required for a reasonable expectation of success. Instead, mere in vitro data were considered sufficient to motivate the skilled person to conduct the next step in the development if there was a reasonable expectation of success only for such next step, and the outcome of this step triggered the remaining steps all the way to the claimed invention.

Recent developments and the testosterone ester case

Following the above decisions (that were unfavourable for owners of pharmaceutical dosing and formulation patents), the FCJ has now provided (counter-)examples of cases in which medical use or composition claims were found to be inventive.

In the Pemetrexed II case, which concerned a combination treatment involving pemetrexed, vitamin B12 and optionally folic acid, the FCJ held that there was no reasonable expectation of success in relation to using vitamin B12, inter alia because, firstly, it would have been necessary for the skilled person to deviate from the previous folic acid-based path of pre-clinical and clinical studies. Secondly, the skilled person would have had to return to an earlier development stage and perform studies for the claimed additional ingredient, vitamin B12, in animals and humans (see rec. 114-118). The FCJ was of the opinion that there was an imbalance between the incentive for deviating from the already promising path with only folic acid, on the one hand, and pursuing the additional effort required for the folic acid/vitamin B12 combination (that would have led to the claimed invention), on the other hand. As a result, the FCJ decided that there was no reasonable expectation of success, so the claimed combination was inventive.

The FCJ decision in the Testosterone ester case seems to expand further on this approach. The claims concerned a composition containing a testosterone ester and a vehicle comprising castor oil in a concentration of 25-45 vol.% and a co-solvent. There were hints in the prior art that the claimed concentration of castor oil would result in an advantageous property of the composition (lower viscosity). At the same time, there was a risk of losing the composition's long-term depot effect. The FCJ considered that the expected advantage provided only a weak incentive for the skilled person and that a disproportionate amount of effort— including clinical studies requiring considerable time and financial resources — would have been needed to identify the effect on the required sustained release. The FCJ thus found that the claims involved an inventive step due to the lack of a reasonable expectation of success.

This seems to be generally in line with the Sorafenib tosylate case, where the FCJ acknowledged an inventive step for a specific salt of sorafenib (the tosylate salt) in an oral dosage form. The FCJ found sorafenib tosylate as such to be obvious in view of the prior art (disclosing sorafenib as an orally effective compound with anti-cancer activity) since the skilled person would have found and identified the usefulness of the tosylate salt in a routine "preformulation screen". The FCJ determined that the salt was inventive when claimed in "an oral dosage form." This conclusion stemmed from a specific problem related to the salt's usefulness in this context: both the free base of sorafenib and the tosylate salt exhibited very low solubility. The FCJ thus concluded that the measures routinely employed in a pre-formulation screen would not have worked, and it had not been obvious or predictable that non-routine measures would have resulted in a better outcome. While the pri-

or art was found to have justified an increased likelihood of success that there must be some form of sorafenib suitable for oral administration, this did not provide a sufficient guarantee that the tosylate salt would belong to "the group of the investigated substances" (the sorafenib forms to be tested for oral administration suitability). In other words, it was not "obvious to try" testing the suitability of the tosylate since there was no reasonable expectation of success to justify considering this compound as a possible candidate.

In the Mirabegron case, the FCJ acknowledged an inventive step for a second medical use of mirabegron in the treatment of overactive bladder. In the prior art, mirabegron had been known to be a selective β3-adrenoceptor agonist and had been suggested for use in, eg, preventing obesity and hyperglycaemia. It has also been known that an active ingredient having β3-adrenoceptor agonist properties can cause alleviation of the symptoms associated with an overactive bladder. The FCJ found the definition of the technical problem crucial, dismissing the lower court's definition ("finding new fields of use or indications for mirabegron") as containing elements of the solution. The FCJ confirmed its earlier case law (eg, FCJ X ZR 41/13 – "Quetiapin") that the technical problem must be formulated in such a general and neutral manner that the question of what suggestions the skilled person obtained from the prior art in this respect only arises when assessing obviousness. Regardless of the starting point in the prior art (ie, on the one hand, the effect of β3-adrenoceptor agonists on overactive bladder symptoms or, on the other hand, the use of mirabegron for the treatment of other diseases), the FCJ saw the problem as "providing an effective remedy for the treatment of an overactive bladder". The claimed solution was not obvious. The FCJ reasoned that while it may have seemed possible in the prior art that mirabegron could have the properties necessary for preventing and treating overactive bladder, there was no sufficient expectation of success in this regard, especially given the complexity shown in tests with other substances. Although many β3-adrenoceptor agonists were known in the art, this also could not establish a sufficient expectation of success, for it was known that not every one of these substances is equally suitable for the treatment of bladder dysfunctions and that a high β3-adrenoceptor selectivity was a necessary, but not a sufficient condition in this respect. The claimed second medical use was thus found to be non-obvious.

A patent-friendly trend?

While the recent FCJ case law seems promising for patent owners, this may not necessarily be a new trend in the sense of a departure from the previous case law. Rather, the FCJ has further supplemented its existing case law with individual cases in which applying the previously developed criteria has resulted in a finding of inventive step.

In particular, the FCJ's reasoning in the Pemetrexed II, Testosterone ester and Mirabegron cases provides concrete examples of situations in which the balancing of the criteria for a reasonable expectation of success, including, eg, the incentives and the required effort, led to a favourable outcome for the patentees. Patent owners may look for similar arguments for their own cases. It may be helpful, for instance, to demonstrate that the skilled person needed to deviate from a previous path and/or that a considerable and unnecessary effort for the skilled person outweighs a small incentive.

Possible future interplay with the UPC

Historically, the concept of the reasonable expectation of success was introduced by some of the earlier decisions of the EPO's Boards of Appeal, such as T 2/83 and T 149/93, and it was developed further by numerous further decisions of the EPO. The concept was eventually adopted by the German courts, albeit in a modified way, ie, not applying it to the claimed invention directly, but to the next step to be performed by the skilled person. If there are multiple steps on the path to the invention, each step is assessed in this way, using the outcome of the previous step as an incentive (in contrast to the EPO's "problem-solution" approach).

Against this background, it will be interesting to see whether and how the case law of the German courts and the EPO, on a reasonable expectation of success, will influence the UPC and vice versa. While the UPC appears to have accepted this concept in principle, it has not (yet) defined a set of criteria for assessing a reasonable expectation of success.

In the Nanostring v 10x Genomics case (UPC CoA 335/2023) relating to provisional measures, the Court of Appeal (CoA) of the UPC held that "problems that regularly arise" in the technical field at issue would not have prevented a skilled person from carrying out the relevant tests (see p. 33). This approach of the CoA is consistent with the notion that – in accordance with EPO and German practice – certainty of success is not required.

Further, in the Sanofi v Amgen case (UPC 1/2023), the UPC Central Division (Section Munich) held that "The absence of a reasonable expectation of success (or more in general: non-obviousness) does not follow from the mere fact that other ways of solving the underlying problem are also suggested in the prior art" (headnote 4). Again, this notion is generally consistent with the case law of the EPO and the German courts, according to which the selection of one out of several obvious alternatives cannot establish an inventive step.

Accordingly, it appears that the UPC applies the concept of a reasonable expectation of success in a way that reflects a "common ground" of the approaches taken by the EPO and the German courts. Further cases will show whether the UPC's approach is closer to the EPO or the German courts.

In this regard, it is interesting to note that, unlike the EPO, the UPC currently requires only a "realistic starting point" in the prior art but does not adhere to the concept of selecting a "closest prior art" document for the assessment of inventive step, suggesting that the UPC does not apply the EPO's problem-solution approach strictly (see UPC 1/2023, headnote 3). This approach taken by the UPC resembles that of the German FCJ. The similarity between these courts' views on inventive step may help to promote a further interplay between the case law of the UPC and the FCJ on inventive step in the future.

Divisional Applications in the Focus of Competition Law

Patent disputes, particularly major ones, often involve several members of the same patent family. EPO practice allows the applicant to branch off divisional applications as long as an application is pending (Article 76 EPC) and is traditionally little concerned with questions of double patenting, albeit in cases where the patent claims at issue cover the same, ie, identical, subject matter (c.f. EBoA, G 4/19). In consequence, unless literally identical, a patentee may file actions based on multiple patents cov-

ering almost the same subject matter against the same defendant.

The authorities have recently become more willing to intervene if they perceive a misuse of the option to obtain and rely on multiple patents of the same patent family protecting the same product. Following a dispute on patents covering the MS drug Copaxone (API glatiramer acetate), the European Commission (EC) issued a fine exceeding EUR460 million against Teva in October 2024 for abuse of its dominant market position (Article 102 TFEU). Teva was found to have created and enforced a "web of secondary patents" with similar content, which it strategically withdrew "to avoid a formal invalidity ruling, which would have set a precedent threatening other divisional patents to fall like dominos". According to the EC, Teva thereby artificially prolonged legal uncertainty on the validity of its patents, potentially hindering the entry of competition (EC, Press Release re AT.40588). As early as 2020, the Regional Court of Munich issued a first-of-its-kind injunction, preventing the patentee from dropping a patent that had been enforced to prevent a (negative) decision on such patent's validity (7 O 1456/20).

While the facts underlying the Copaxone investigation are specific and also involved commercial activities of Teva "disparaging" their competitors, which were not patent-related, the EC's decision is of high relevance for the filing and enforcement strategies of patentees with a dominant position on their respective (pharma) market when relying on divisional applications and patents deriving therefrom with largely overlapping scope of protection.

IFA's Responsibility for Listing Pharmaceutical Products in their Databases

In recent years, it has become common practice in Germany for patent holders to enforce patents not only against the pharmaceutical companies responsible for manufacturing, offering and launching an infringing generic product on the German market but also against IFA GmbH. IFA is an information service provider for the pharmaceutical market, collecting information from pharmaceutical companies and processing it into databases, which are essential for marketing pharmaceutical products in Germany. Among others, the Lauer-Taxe relies on information provided by IFA. For a long time, case law in Germany has established that the inclusion of an infringing product in the Lauer-Taxe qualifies as an infringing offer by the pharmaceutical company having applied for the product to be listed.

There have been numerous disputes, however, to what extent IFA can be held responsible for (contributing to) patent infringement by including infringing products in their databases. There has been case law holding IFA responsible for checking whether any products listed in their databases were infringing and preventing the inclusion of such infringing products in their databases when they had a reason for a corresponding check. IFA would be required to exclude an infringing product from their databases upon receipt of a corresponding provisional injunction against the supplier of the relevant drug or upon receipt of a notification by the patentee informing IFA about the (threat of) infringement. In many cases, the infringement would be obvious, for example, if there is compound patent protection and it is clear to IFA already from the active pharmaceutical ingredient that the attacked product falls within the scope of patent protection.

Contributed by: Dr. Peter Klusmann, Gregor König, Dr. Dirk Schüßler-Langeheine and Dr. Lasse Christian Weinmann, **Hoffmann Eitle**

In Germany, there is no pre-warning of an infringing product launch, such as certain post-grant regulatory or other pre-launch steps which would have to be undertaken by a generic competitor prior to launch. As a clearing instance for pharmaceutical databases, IFA, therefore, plays a key role in the effective pre-emptive prevention of market disturbance by the offering and launching of an infringing generic product.

For patentees, it has thus been of particular interest to what specific remedies they are entitled against IFA in relation to (infringing) products which have not been published yet in the Lauer-Taxe, but for which IFA has obtained a request for inclusion in their databases. On the one hand, a (pre-emptive) provisional injunction against IFA can effectively prevent offer (and launch) of the infringing product from the outset. On the other hand, an obligation of IFA to inform the patentee about a request for having an infringing product listed in their databases would yield information useful for seeking a provisional injunction directly against the pharmaceutical company offering the infringing product.

Against this background, a provisional injunction of the Regional Court (RC) Munich I issued in March 2024 for Bayer against IFA in relation to the (prevention of the) listing of generic rivaroxaban products attracted a lot of interest. The RC held IFA responsible for checking whether infringement was obvious, stating that patent infringement should have been obvious for IFA even in relation to the case at hand where the infringement allegation was based on infringement by equivalent means. Most remarkably, the RC also ordered IFA to inform Bayer about any request for the listing of an infringing generic product.

However, as the Higher Regional Court (HRC) Munich was about to reverse the RC's decision on IFA's appeal, Bayer withdrew the request for a provisional injunction so that the RC's decision lost its effect. In the introduction of the oral hearing in the appeal proceedings on 5 December 2024, the HRC took the preliminary view that patent infringement was not obvious and that the HRC would not concur with the RC's position on the extent of IFA's responsibility to examine and assess the patent situation.

As Bayer withdrew the request for a provisional injunction after hearing the HRC's preliminary view, there is no written decision based on the court's reasoning. It remains to be seen what position other German courts will take on the extent of IFA's responsibilities, given that there is no recourse to the FCJ in provisional injunction proceedings and there may be deviating approaches taken by different Higher Regional Courts.

Liability under German Patent Law for Damages Incurred after Patent Expiry or Abroad

In two recent decisions, the FCJ developed the concept that a patentee is generally entitled to claim any damages resulting from patent infringement, even if the relevant damage occurs only after patent expiry or outside the territory of patent protection. While the underlying cases do not concern life science patents, the rationale behind the FCJ decisions can be highly relevant for calculating damages in cross-border life science patent disputes.

The general idea underlying the FCJ's decisions is this: An act of infringement deprives the patentee of business opportunities associated with the patent. As a result, the patentee should be entitled to claim all profits resulting from the

patent infringement, irrespective of where and when they materialize. It would be unfair if profits resulting from patent infringement would remain with the infringer.

In the first case decided by the FCJ in 2023 (FCJ X ZR 30/21 - "Upholstery conversion machine"), the infringer did not only sell the protected machine but also had agreements in place with their customers on maintenance and supply of use materials for the machine. The patent holder claimed damages not only for the sale of the protected machine but also for the additional services and supplies, irrespective of whether such services or supplies were conducted before or after patent expiry.

The FCJ stated that the patent owner might claim all infringer's profits resulting from the infringing act (ie, sale of the protected product) unless (exceptionally) the attribution of the relevant profits to the infringement would be unjustified. Such an exception would only apply in rare cases, for example, if the infringer made additional profits by reinvesting the profits caused directly by the infringement.

Based on such reasoning, the FCJ ruled that the infringing sales of the machine caused both the sale of maintenance contracts and the sale of used materials. The market opportunities incorporated in the patent covering the machine also included the profits made by selling additional services. According to the FCJ, the damages claim for these additional services is not limited to the duration of the patent but rather includes the profits made with additional services after patent expiry as long as these sales were also caused by the infringing sale of machines during the duration of the patent.

In the second case decided by the FCJ in 2024 (FCJ X ZR 104/22 - "Evaporation dryer system"), an offer for the sale of a machine protected by a patent in force in Germany was made from Germany, while the subsequent sale of the machine took place in Sweden where the parallel patent had already expired. The patentee also claimed damages for the profits resulting from the sale in Sweden. The FCJ confirmed that the profits made by the sale in Sweden resulted from the infringing offer in Germany. The profits made in Sweden were associated with the market opportunity reserved for the patentee, who may, therefore, in principle, claim the infringer's profits made in Sweden.

However, as only the offer took place in Germany, the patentee is only entitled to a fraction of the infringer's profit, which can be attributed to the infringing offer. The FCJ sent the case back to the Higher Regional Court to assess the relevant facts of the case and determine the appropriate contribution factor, ie, to what extent it was relevant for the profit generation that the offer was conducted from Germany.

In patent disputes in the life sciences, there are numerous cases and constellations where certain acts of infringement or elements relevant for infringement are conducted in a country with patent protection and while a patent is in force (eg, manufacture and/or final batch release of an infringing product, or customization of a product for a patent-protected use), while subsequent activities resulting in significant commercial profits (eg, sales of the relevant product) are conducted in a country without patent protection or after patent expiry. The recent FCJ decisions strengthen the patentee's position for claiming full damages resulting from patent infringement.

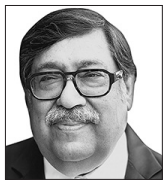
INDIA

Trends and Developments

Contributed by:
Pravin Anand, Vaishali R Mittal and Gursimran Singh Narula
Anand and Anand Advocates

Anand and Anand Advocates is a full-service intellectual property law firm providing all-around IP solutions; its forte is the development of precise ways to navigate the grey areas of new laws. Its principal office is in New Delhi, with other offices in Noida, Mumbai, Chennai, and Bengaluru. The firm provides a comprehensive IP service encompassing protection, enforcement, advisory, licensing and litigation for patents, designs, trade marks, copyrights, trade secrets, domain names, geographical indications and more. It is also committed to the development of a responsible AI domain and has a dedicated Digital group. Credited with lawsuits that have transformed the IP landscape in India, the firm's litigation arm has decades of unmatched experience in dispute resolution. It has maintained a patent grant rate of over 93%, while its trade mark team also has to its credit over 3000 successful trade mark oppositions in two years.

Authors



Pravin Anand is Anand and Anand's managing partner and head of litigation. Presented with the AIPPI Award of Merit and INTA's President's Award and recognised as the "Most Innovative Lawyer" for Asia-Pacific by the Financial Times, Pravin has appeared in more than 3,000 cases in over 45 years of practice as an IP lawyer. He has been involved in lawsuits transforming the Indian IP enforcement regime and has engendered many original facets of IP. He is the author of "Halsbury's Laws of India on Intellectual Property" and has contributed to the India chapter in "Trade Secrets Throughout the World." He is also dedicated to promoting intellectual property awareness through the Raj Anand Moot.

Vaishali R Mittal is a partner on the litigation team at Anand and Anand. She is also one of the key strategists on some of the most path-breaking cases in the Indian IP jurisprudence. A go-to litigator decorated with the epithet of 'leading light' in SEP cases, in her career of over 21 years, Vaishali has led from the front in cases such as India's first judgement on product-by-process patent, the country's first Pro-tem security order in favour of Nokia, first anti-anti-suit injunction in InterDigital Corp & Ors v Xiaomi Corp & Ors and also nation's first final judgment on the issue of standard essential patents in Philips v. KK Bansal; Philips v. Rakesh Bansal.

Gursimran Singh Narula is a senior associate on the litigation team at Anand and Anand. He assists the firm in patent, copyright, trade secret and trademark litigation. He has been involved in contentious patent matters concerning pharmaceuticals, aviation, agriculture, and SEPs. Gursimran has played a significant role in key software patenting decisions at various courts in India. He is also an alumnus of IIT Kharagpur law school.

Anand and Anand

B-41, Nizamuddin East
New Delhi – 13
India

Tel: +91 997 169 3875
Web: www.anandandanand.com

ANAND & ANAND

Establishment of IPR Divisions in Different High Courts of India

Establishing the Intellectual Property Division (IPD) at the Delhi High Court became an essential step after the abolition of the Intellectual Property Appellate Board (IPAB) under the Tribunals Reforms Act, 2021. In response, the Delhi High Court created the IPD as a solution to manage the increasing caseload, forming a specialised division, albeit without specialised judges initially. The first year of the IPD's operations showcased the division's efforts in handling the significant number of cases transferred from the now-dissolved IPAB. In its second year, the IP Division continued to make strides in reducing the backlog of these transferred cases. Between January 2023 and June 2024, the division disposed of 1,217 IPAB-transferred cases. By June 2024, over 60% of the cases received from the IPAB had been successfully resolved. Additionally, the IP Division managed to clear 2,026 fresh cases, contributing to a decrease in the overall pendency of IP cases — from 3,799 cases in 2023 to 3,742 cases by June 2024.

The success of this model was widely recognised, notably by the 169th Report of the Parliamentary Standing Committee on Commerce, which recommended the replication of this model in other High Courts across the country. In response to this, several other High Courts, including those of Madras, Calcutta, and Karnataka, have followed suit, establishing their own dedicated IPR divisions. These divisions serve not only to streamline the adjudication process but also to address the growing complexity and volume of intellectual property litigation in India.

Following the dissolution of the erstwhile IPR tribunals, the Delhi High Court took the lead by setting up a specialised IPR division, an initiative that has proven to be highly successful – in its first year alone, this division resolved over 600 commercial IPR suits, setting a high standard for the expeditious handling of IPR disputes.

At the same time, legislative changes have been introduced to further enhance the functioning of India's patent system. Amendments to the Patents Rules, 2003, which came into effect in March 2024, aim to reduce procedural delays, simplify compliance for patent applicants, and align India's patent system with international best practices. This combination of judicial and legislative reforms is set to transform India into a more attractive destination for innovation and IP protection. This paper delves into the establishment of IPR divisions across Indian High Courts, the recent legislative changes, and key judicial rulings that have shaped the landscape of intellectual property law in India.

Legislative Changes

- The Government of India has passed key legislative amendments to the Patents Rules, 2003, effective March 15, 2024. The amendments aim to streamline patent prosecution and implement various court decisions in India, as outlined below.
- Reduced examination timeline: Requests for examination can now be filed within 31 months, down from the previous 48-month period, accelerating the examination process.
- Simplified submission process: Foreign patent submissions must be filed within three months of receiving the first statement of objections, with late submissions allowed if condoned by the Controller.
- Relaxed filing norms: Statements of working under Form 27 need to be filed only once every three financial years, simplifying compliance for patent applicants. Further, on August 26, 2024, the Indian Patent Office clarified the

rules for filing the statement of commercial working of patents. The key points are:

(a) First statement: Must be filed according to specific due dates.
(b) Subsequent Statements: Required every three financial years. For instance, if filed in 2024, the next is due by September 30, 2027.
(c) Last statement: Should cover the entire 20-year patent term or until the patent expires. The final statement period may be shorter, depending on the remaining term.

- Extensions: The filing deadline of September 30 can be extended up to three months with a fee of INR10,000 (approximately USD125) per month. A further extension of up to six months can be requested with a fee of INR50,000 (approximately USD600) per month.
- Amendment to pre-grant opposition Rules: The amendment mandates that if a pre-grant representation is filed, the Controller is required to examine if a *prima facie case* is made out by the opponent. Only upon determination of the prima facie case shall the patent applicant be notified about the representation.

Illustrative List of Case Laws

Interpretation of product-by-process claims

A division bench of the High Court of Delhi has resolved the contentious debate on the interpretation of product-by-process claims in India. In *Vifor (International) Limited & Anr v MSN Laboratories Pvt Ltd & Ors*, the Court sided with the UK and EP approach while recognising the unique nature of product-by-process claims. The case concerned infringement of Vifor's patent covering Ferric Carboxymaltose, used to treat iron-deficiency anaemia. The Court held that the claim relates to a novel product, ie, a water-soluble iron carbohydrate complex of iron and an oxidation product comprising one or more maltodextrins. The Court applied the rule of necessity, holding that product by process claims are the ones whose unique attributes are sought to be explained by reference to the manufacturing process. The Court clarified that product and process claims cannot be categorised in watertight compartments. Therefore, the mere fact the patentee chose to describe the invention more exhaustively by reference to process terms does not limit the patent to a specific process.

Infringement of species patent

A single judge of the Delhi High Court delivered an interim injunction in favour of Kudos Pharmaceuticals Ltd and held Natco Pharma Limited liable for patent infringement for unauthorised manufacture and distribution of a compound named Olaparib, an oral poly (ADP-ribose) polymerase (PARP) inhibitor, used for treating various forms of Cancer. The Court rejected the invalidity challenge raised by Natco in light of a genus patent. The Court held that the genus patent failed to provide an enabling disclosure about the claimed compound and was not a valid prior art for prior claiming. It was further held that Natco failed to raise the challenge due to a lack of inventive steps and the absence of any teaching from the genus patent and other prior arts towards the claimed compound, Olaparib. The Court discouraged an attempt by Natco for hindsight reconstruction to attack the validity of the species patent. In another litigation for the same compound, the Court ordered BDR Pharmaceuticals to earmark 20% of the net value from the sale of the infringing drug to protect the financial interest of Kudos, given that an interim injunction was possible due to the expiry of the patent during the case hearing.

Divisional patenting

A division bench of the Delhi High Court in *Syngenta Limited v Controller of Patents and Designs* clarified the Indian position on divisional patents, holding that a further application can be filed from the subject matter disclosed in provisional or complete specification already filed. The Court held that the divisional claims need not be restricted to the parent application's claims.

Antibody patenting in India

The Madras High Court in *Genmab A/S v Assistant Controller of Patents* set aside an order refusing a grant of a patent for antibody claims. The Patent Office had earlier rejected the grant of claims noting that the DNA and protein of claims were from *homo sapiens* as per the sequence listing. The High Court refused to apply Section 3(c), holding that the said provision is applicable only for the "discovery of a naturally existing molecule/substance" and not for a synthetic version of a non-living substance, especially a monoclonal antibody. The Court held that the claimed invention concerns Daratumubab, a monoclonal antibody that binds to human CD38. It was held that the annotation *homo sapiens* indicated that the antibody was developed from a transgenic HubMab Mouse platform based on human germline sequence. The High Court also allowed a separate appeal by *Immunas Pharma, Inc* against the application of Section 3(c) for an invention titled "Antibody Capable of Binding Specifically to A-beta Oligomer and Use Thereof".

Patents for diagnostic methods

The Madras High Court in *The Chinese University of Hong Kong v The Assistant Controller of Patents* has clarified the law on patent ineligibility for diagnostic methods in India.The Court held that the patentability prohibition proposed by Section 3(i) of the Patents Act is limited to inventions that are inherently and *per se* capable of identifying the disease, disorder or condition for treatment of the person. However, if the process cannot *per se* uncover the pathology, the same would not qualify as "diagnostic". The Court held that the claimed invention relates to a method for determining a fractional concentration of fetal DNA in a biological sample taken from a pregnant female subject, which *per se* was incapable of identifying the existence of a disease, a disorder or a condition and further testing is required for such purpose and thus was not barred from patenting.

Determining therapeutic efficacy for patentability

The Madras High Court in *Bristol Myers Squibb Company v Deputy Controller of Patents* set aside a refusal order by the Patent Controller denying the grant of a patent for a new formulation under Section 3(d) of the Patents Act. The Court held that bioavailability is relevant for therapeutic efficacy but may not be the sole criterion for patentability. Therapeutic efficacy under Section 3(d) is a unique provision for India and has previously been debated.

Post-filing of therapeutic efficacy data

The Delhi High Court in *Ischemix LLC v The Controller of Patents* has permitted the patent applicants to rely on post-filing of clinical trial data to determine therapeutic efficacy. The decision follows a similar position taken by the Calcutta High Court in *Oyster Point Pharma Inc v The Controller of Patents and Designs* and the Delhi High Court in *AstraZeneca AB and Ors v Intas Pharmaceuticals*. The Court reasoned that in the pharmaceuticals industry, the drug could be undergoing clinical trials for a new form at the time of filing of the patent application. Furthermore, given the complexities and lengthy nature of the process for drug development,

empirical evidence may not be readily available to the applicant at the time of filing a patent application. Therefore, the clinical trial data can be filed later only to support the stand taken by the applicant in the complete specification demonstrating enhancement of therapeutic efficacy.

Biochemical patents

A Single of the Madras High Court in *Novozymes v Assistant Controller of Patents* clarified the efficacy test for a biochemical patent application titled "Phytase Variants with Improved Thermostability". The Court observed that biochemical derivative forms are distinguishable from the derivatives of synthesised chemicals. It was held that the explanation clause of Section 3(d) is only applicable to synthesised chemicals and not to variants of phytase, ie, an enzyme/biochemical. The Court ruled that the efficacy of biochemicals is to be assessed based on the product's function, purpose or utility. The Court agreed with the appellant, noting that increased thermostability is a relevant factor that enhances the known efficacy of the enzyme for phytase.

Biosimilar litigations

Indian courts have currently witnessed an exponential rise in biosimilar litigation proceedings. A Single Judge of the Delhi High Court in *F Hoffman-La Roche Ltd & Ors v Drugs Controller General of India & Others* rejected applications filed by Cadilla Healthcare and Hetero Drugs against Roche's suit for restraining the said companies to manufacture a biosimilar version of "Trastuzumab" and "Bevacizumab", respectively. Roche has challenged the validity of marketing approval secured by the said companies and has a restraining order from representing those versions of drugs as biosimilars. Roche had alleged several irregularities in clinical trials carried out by Hetero and Cadilla, which is a mandatory requirement as per Biosimilar Guidelines. The Court held that a substantial part of the cause of action pleaded relates to non-compliance/violation of the Drugs and Cosmetics Act, 1940, Drugs and Cosmetics Rules, 1945 and Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India, 2012, and in any manner, these statutes do not exclude the jurisdiction of the civil courts.

Roche has also filed biosimilar infringement litigation against Zydus Lifesciences Limited for its patented drug Pertuzumab, a monoclonal antibody (MAb) biologic and first in a line of agents called "HER Dimerisation Inhibitors". In another suit, E.R Squibb and Sons have filed an infringement proceeding against Zydus for infringement of their patent pertaining to the pharmaceutical product "Nivolumab". These cases are pending adjudication before the Delhi High Court.

Directions for treatment of rare diseases

The High Court of Delhi decided a batch of writ petitions in *Master Arnesh Shaw v Union of India & Anr* pertaining to the treatment of patients suffering from rare diseases in India. The Court issued a slew of directions for all stakeholders, including the constitution of a National Fund for Rare Diseases (NFRD) with a budgetary allocation of at least INR 974 crores. The Court also directed pharmaceutical companies to ensure a proper distribution network to make available therapies and medicines for rare diseases in India. The companies involved in the import of rare disease therapies were also directed to prepare detailed plans for establishing local manufacturing or distribution facilities. Furthermore, the companies were directed to make the therapies available after reaching a price agreement with the National Rare Diseases Committee.

Maintainability of an infringement suit

The High Court of Delhi in *AstraZeneca Ab & Anr v Westcoast Pharmaceutical Limited* held that nothing in the Patents Act, 1970 precludes a patentee's right to institute an infringement suit even if a post-grant opposition proceeding is pending. The Court rejected Westcoast's argument that the patentee was required to wait for one year to have their patent rights crystallised. It was held that such an interpretation of an *orbiter dicta* from an earlier decision of the Supreme Court in *Alloys Wobben* was incorrect.

Ad interim injunctions for pharmaceutical patents

The High Court of Delhi has passed a series of ad-interim restraining orders in lawsuits filed by AstraZeneca AB for infringement of patented compound "Osimertinib". The orders were passed against several entities, including Westcoast Pharmaceuticals, BDR Pharmaceuticals, Azista Industries, Everest Pharmaceuticals, Beacon Pharmaceuticals, Zee Laboratories and MSN Laboratories.

Notably, AstraZeneca was also successful in post-grant oppositions filed by Natco Pharma Ltd and Sunshine Organics Pvt Ltd against the grant of a patent for Osimertinib. The claimed compound is an oral, third-generation epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) approved for the treatment of non-small cell lung cancer (NSCLC). The drug is being marketed under the brand Tagrisso in India and several other countries across the world.

The Delhi High Court also passed an ad interim injunction in *Helsinn Healthcare SA v Hetero Healthcare Limited,* restraining Hetero from infringing a formulation patent for an oral dosage of "Netupitant" and "Palonosetron hydrochloride". The infringing drug was being sold in an integrated combination of both salts.

Imposition of cost for causing delay in determining infringement

The Delhi High Court in *Bristol Myers Squibb Holdings v KM Swarnlatha* imposed a cost on one of the defendants who had launched the infringing drug but failed to appear before the Court, causing a delay in suit proceedings. Earlier, the Court issued *an ex parte* restraining order as the defendant launched a generic version of Dasatinib before the expiry of the patent.

Relevance of Opposition Board Recommendations

The Madras High Court in *Ashok Leyland Limited vs. The Controller of Patents* has ruled that while dealing with post-grant opposition, the Controller is duty-bound to decide on the qualitative merit of the Opposition Board Recommendations (OBR). The Court held that OBR is a foundational document during the post-grant stage, and the patent applicant shall be given an opportunity to illustrate the inadequacies of the OBR during the hearing.

Writ proceedings against pre-grant opposition decisions

A Division bench of the Delhi High Court in *Rich Products Corporation v The Controller of Patents & Anr* examined the issue of maintainability of a writ petition against the Controller's dismissal of a pre-grant opposition. The Court held that remedy under Article 226 of the Constitution is discretionary and shall not be used if there is an efficacious, alternate and statutory recourse available. The Court upheld the single judge's refusal to entertain a writ petition in view of the post-grant opposition remedy available for the opponent.

Territorial jurisdiction to adjudicate patent appeals

The High Court of Delhi in *Filo Edtech Inc v Union of India* ruled that an appeal arising from the Patent Office would lie with the appropriate High Court on the basis of the appropriate office having dominion over the patent application. The Court reaffirmed the decision of a coordinate bench in *Dr. Reddy's Laboratories,* stating that an appeal is a continuation of the original proceeding. Once the patent applicant has chosen the appropriate office when filing the application, it cannot be allowed to approach a different High Court to decide the appeal arising from the refusal of the patent application.

Conclusion

The establishment of IPR divisions in India's High Courts is a landmark development in the country's approach to intellectual property enforcement, signifying a move toward more efficient, specialised, and accessible IPR adjudication. These divisions not only expedite the resolution of IPR disputes but also create a focused platform for addressing the unique challenges associated with intellectual property law.

Complementing the judicial reforms are significant legislative changes, particularly the amendments to the Patents Rules, 2003, which aim to streamline the patent prosecution process, reduce delays, and enhance compliance. These changes reflect the government's commitment to creating a more efficient and transparent system for intellectual property rights in India, fostering innovation, and encouraging international collaborations. Judicial rulings have clarified and refined key areas of patent law, such as the patentability of antibody claims, divisional patents, diagnostic methods, and therapeutic efficacy. These rulings reflect an increasingly sophisticated approach to IPR issues, demonstrating India's readiness to address complex challenges in a globalised economy.

In sum, establishing IPR divisions across High Courts, along with the legislative amendments and key case law developments, positions India as a growing hub for innovation and intellectual property protection. These reforms not only enhance the legal landscape for domestic and international patent applicants but also provide a more streamlined and specialised system for enforcing and adjudicating IPR matters. As India continues to modernise its IPR regime, these initiatives promise to contribute significantly to protecting intellectual property, ultimately fostering an environment conducive to growth, innovation, and global competitiveness.

ISRAEL

Law and Practice

Contributed by:
David Gilat and Matan Kovacs
Gilat, Bareket & Co, Reinhold Cohn Group

Contents

Gilat, Bareket & Co, Reinhold Cohn Group is one of the leading intellectual property firms in Israel, specialising in litigation and legal counselling relating to intellectual property rights, including patents, patent term extensions, trade marks, designs, copyrights, trade secrets and plant breeders' rights, as well as litigation and legal counselling in IP-related fields. With years of professional experience, Gilat, Bareket & Co has been recognised for successfully litigating landmark cases and representing local and international clients. As part of the Reinhold Cohn Group, the firm works in close co-operation with the patent and trade mark attorneys of Reinhold Cohn & Partners, creating a unique and effective platform for maximising the value of IP assets and securing optimal protection.

Authors

David Gilat is an attorney-at-law, a patent attorney and a partner in the Reinhold Cohn Group, heading its legal practice. David has extensive professional experience in the various fields of intellectual property, including litigation, transactions, and general consulting on intellectual property issues. His main fields of expertise include technology (particularly chemistry, pharmaceutics, physics, and high-tech) and branding. Among other things, he has extensive professional experience in patent litigation and is involved in landmark cases. David has been recommended for several years by leading international guides, such as Chambers & Partners where he is ranked in Global: Intellectual Property.

Matan Kovacs is an attorney-at-law and a partner in the legal practice of the Reinhold Cohn Group. Practising intellectual property litigation for more than 12 years, he has gained a wealth of valuable experience representing leading multinational companies in all manner of intellectual property disputes, with particular focus on patent cases. Matan is regularly involved in complex, high-stakes litigation cases and appears before Israeli courts of all instances, local and international arbitration tribunals, and the Israeli Patent and Trade Mark Office. In 2024, Matan was noted as a "next generation partner" in the field of intellectual property disputes by a leading international guide.

Gilat, Bareket and Co, Reinhold Cohn Group

26A HaBarzel St.
Tel Aviv, 6971037
Israel

Tel: +972 356 720 00
Fax: +972 356 720 30
Email: info@gilatadv.co.il
Web: www.rcip.co.il/en/

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Infringement

An infringement action must involve, on the plaintiff's side, the patent owner or its exclusive licensee; and, on the defendant's side, the alleged infringer and any party involved in the infringement whose participation is necessary to efficiently decide all issues of the claim.

Where a patent is co-owned, each co-owner may file an infringement claim. If the other co-owners (or the exclusive licensee) do not join as plaintiffs, the suing co-owner must name them as defendants. This is also true where a patent owner does not join an exclusive licensee's claim and vice versa.

A patent owner is defined under the Patents Law as "the person registered in the Register as the person to whom a patent was granted or to whom ownership of a patent has passed"; an exclusive licence affords its holder the right to "[exploit the claimed invention] as if it was the owner of the patent" and "prohibits the owner of the patent from exploiting in Israel the invention that is the subject of the patent".

Revocation

Any person may submit a motion for revocation, without being required to show any particular interest.

1.2 Defendants/Other Parties to an Action

Under Israeli law, a plaintiff must join to its claim all those parties whose participation is necessary to efficiently decide all issues involved in the claim. Where life sciences/pharma cases are concerned, that usually means the manufacturers and/or importers of the infringing products (and/or those parties contributing to the alleged infringement). Other parties, such as health maintenance organisations (HMOs), which are known as "sick funds" in Israel, are not sued in practice, despite their involvement in the distribution of patented drugs. Doctors who prescribe drugs are not sued and they might be exempted under the rule de minimis non curiat lex or under the so-called private use exemption.

1.3 Preliminary Injunction Proceedings

Availability of Preliminary Injunctions and Timing of a Decision

A party bringing an infringement claim may move for the issuance of an interlocutory injunction against the alleged infringer, including ex parte.

The plaintiff-applicant would normally file such motion alongside the filing of the case-in-chief, or beforehand, in situations of urgency, on the condition that the case-in-chief would be filed up to seven days following the issuance of a decision in the motion for preliminary injunction.

In urgent matters, motion for a temporary injunction may be filed ex parte, and a decision may be issued without hearing the respondent, within a day or two at most, according to which a hearing would be set as soon as possible, and, in any case, within 14 days. If the court is disinclined to issue a temporary injunction ex parte, it will schedule a hearing as soon as possible, usually immediately after the defendant-respondent filed its response to the motion for interlocutory remedies. Under the Civil Procedure Regulations (CPR), the hearing will take one day and will include oral summations. The court will then issue its decision immediately after the hearing and, in any case, no later than 14 days following the hearing.

Considerations in Granting Preliminary Injunctions

A court with which a motion for a preliminary injunction has been filed must be convinced that the matter is urgent and will first consider whether the plaintiff-applicant has shown a prima facie case for infringement. While the defendant-respondent may argue non-infringement, they will not be able to challenge validity at that stage unless invalidity of the alleged patent – at a prima facie level – is abundantly clear and could be established without an in-depth review of the evidence.

In addition, the plaintiff-applicant must show that the balance of convenience tilts in its favour; namely, that the injury that would be caused to the plaintiff-applicant by non-issuance is more severe than the injury the defendant-respondent would suffer as a result of the issuance of the injunction.

Finally, the court will weigh considerations such as laches (namely, whether the plaintiff-applicant acted expeditiously enough to protect its rights upon learning of the need to do so) as well as good faith (namely, whether the plaintiff-applicant had acted in an equitable manner and disclosed all pertinent facts).

Prerequisites to Filing a Motion for a Preliminary Injunction

A claim for patent infringement and a motion for a preliminary injunction can only be filed with respect to a granted patent, and the plaintiff-applicant must be able to show that the defendant-respondent has exploited – or is immediately about to exploit – the claimed invention, with such exploitation being defined as either "production, use, offer for sale, sale, or import for purposes of one of the said acts". Quia timet reliefs are available, provided that a substantial danger of infringement is shown.

Effecting Service of Motions for a Preliminary Injunction

If a motion for a preliminary injunction was filed ex parte, and an interim injunction was issued, the plaintiff-applicant must serve it on the defendant-respondent immediately and, in any case, no later than three days from the day on which it was issued. Usually, the defendant-respondent will be instructed to file a response prior to the hearing taking place.

If no order was issued, or if the motion for a preliminary injunction was filed inter partes, the plaintiff-applicant must immediately serve it on the defendant-respondent. In most cases, the court will set short deadlines to file a response to

the motion, and, if no such deadline is provided, the defendant-respondent will have 20 days to file a response.

Both motion and response must be supported by an affidavit or affidavits detailing all those facts alleged by the parties.

1.4 Structure of Main Proceedings on Infringement/Validity

A defendant in an infringement claim may – in addition to arguing non-infringement – raise validity arguments in defence. This will not automatically lead to the proceedings' bifurcation: usually, both infringement and validity are heard concurrently, though the court has the discretion to instruct otherwise.

A defendant may also file a motion for the revocation of the patent with the Patent Office. In such case, the court hearing the infringement claim will decide which instances will hear the issue of validity – the Patent Office or the court itself – and the Patent Office will not hear the revocation motion unless authorised to do so by the court. Where the defendant instituted the revocation proceedings before the plaintiff's filing of the action with the court, the Patent Office will proceed with the hearing of the revocation, unless the court instructs otherwise. There is no rule that prohibits a person from filing revocation proceedings while there are pending revocation proceedings (oppositions in Israel are conducted before the patent grant, following patent examination).

1.5 Timing for Main Proceedings on Infringement/Validity

According to Section 179 of the Patents Law, an infringement action shall be brought only after the patent has been granted; however, once an action for infringement is brought, then the court may (i) award compensation for exploitation of an invention committed after the date of publication under Section 16A (basically, 18 months from priority date) and before the date of publication under Section 26 (publication for third-party oppositions after allowance), as well as (ii) grant relief for an infringement committed after the date of publication under Section 26.

Where granting compensation for exploitation committed before publication under Section 26, the court shall set a reasonable rate for royalties, such as the infringer would have paid had it been granted a licence to exploit the invention within the scope in which its aforesaid exploitation was committed, However, such compensation shall not be awarded unless the court finds that the exploitation constitutes an infringement of the patent as granted, and on the condition the invention claimed in the application is identical in a substantive manner to the invention claimed in the application published under Section 16A.

Prescription

The period of limitations under Israeli law to launch an infringement action is seven years in accordance with the general principles set out in Section 5 of the Limitations Act 1958. If the patentee was not aware of the infringement for reasons beyond their reasonable control, the seven-year limitation period would only begin on the day on which the infringement has become known – or should reasonably have become known – to the patentee (Section 8 of the Limitations Act). Further, in case of a continuing infringement, the continuing wrong doctrine would apply, and it will save all claims for recovery of damages but only to the extent of infringements committed within the seven-year limitations period. Thus, the patentee will be entitled to an injunction preventing prospective infringement as well as to damages with regard

to the part of the infringement that is not subject to limitations.

Conversely, there are no limitation periods with regard to validity challenges, either as a defence against an infringement action or as part of a motion for revocation filed with the Patent Office; as long as a patent is alive, its validity may be challenged.

Acquiescence

Even if a given cause of action for infringement has not yet prescribed (ie, become time-barred), it is possible that the defendant will raise an argument of acquiescence against it if the defendant is able to show that the plaintiff had actively provided a representation of waiving its cause of action; it is possible that the action would be rejected due to estoppel.

Effecting Service in Actions Before the Court

Under Israeli law, a court acquires jurisdiction by way of effecting service. There are several ways to effect service on a defendant: a copy of the statement of claim, which includes summons, may be served on the defendant themselves, at their home or at their place of business, either via courier or via registered mail, on an adult family member living with them, on a person authorised to manage their business, or on their counsel. Where the defendant is a company, service is usually effected by delivering a copy of the statement of claim to their registered place of business. In those cases where the defendant is not Israeli, leave for service outside the jurisdiction would need to be secured, though it would also be possible to effect service by serving the claim on the foreign entity's business manager in Israel (if such exists).

Service should be carried out immediately upon filing and no later than three days from the date of the filing. While a plaintiff may choose to wait the entire three-day period, doing so would mean that the 60-day period to file a statement of defence would be counted from the date of actual service.

Effecting Service in Nullity Proceedings Before the Patent Office

Where proceedings before the Patent Office are concerned, the Patent Office would advise the patent owner of the filing of the motion for revocation using the "address for service" recorded on the Register, and the applicant may do the same, thus effecting service.

Duration of Proceedings on the Merits

Both infringement and nullity proceedings can take anywhere between 24 and 36 months and sometimes even longer.

If the case is heard before a court, the parties would first exchange pleadings (a statement of claim, a statement of defence, and a statement in reply), conduct discovery proceedings, file their evidence, appear for trial (cross-examinations), and then file their summations, following which a decision would be handed down by the court. In addition, motion practice is likely to take place, covering subjects such as discovery disputes, the responsiveness of evidence, filing of additional evidence, production of witnesses, and extensions of time.

The exchange of pleadings will take, in most cases, between three and nine months. Discovery may take an additional six months, while the production of evidence would take a year to eighteen months. The trial will usually not take more than a week or two, with summations taking up to a year.

Revocation proceedings before the Patent Office would generally take less time than a court action would, as they do not include a discovery stage and unify the exchange of pleadings with the filing of evidence.

1.6 Requirements to Bring Infringement Action

Under Israeli law, a patent becomes assertable only once it is granted by the Patent Office, with no additional requirement, such as validation or the deposit of translations. The plaintiff bears the onus to show infringement (both the evidential burden as well as the burden of persuasion), while the defendant bears the onus to show invalidity.

Section 50(b) of the Patents Law provides for a reversal of burden of proof with respect to process patents, stating that "[F]or purpose of an invention that is a production process – in an action for infringement the defendant must prove that the process used by him for the production of an identical product differs from the patent-protected process". The Patents Law further provides that "an identical product which was produced without the consent of the patentee shall, unless otherwise proven, be deemed a product produced by a patent protected process", subject to the patentee being unable to find out by reasonable efforts which production process was actually used, and it being highly reasonable that the identical product was produced by the patent-protected process.

1.7 Pre-Action Discovery/Disclosure

As a rule, pre-action discovery is not available in Israel. The only exception is in the field of derivative actions (where shareholders or creditors seek to act on behalf a company), where a court may order a pre-action discovery of relevant documents, provided that the conditions necessary to allow a derivative action are prima facie met.

1.8 Search and Seizure Orders

Search and seizure orders are both available under Israeli law.

If filed in the framework of a motion for interlocutory remedies, that motion would be heard ex parte unless the court believes that hearing that motion inter partes would not thwart the purpose of those remedies.

A search and seizure order may not be executed by the applicant's attorneys, but rather the plaintiff-applicant should request the appointment of a temporary receiver, empowered to enter the defendant's premises in order to search, seize and assume possession over assets that are attesting to the infringing activity or are otherwise required for adjudicating the action (Anton Piller-type order).

The plaintiff-applicant will need to show – in addition to showing they have a prima facie cause of action – that there is strong prima facie evidence that, without the appointment of a receiver, the assets might be destroyed or otherwise become unavailable, thus thwarting the legal proceeding or the carrying out of the yet-unissued judgment.

1.9 Declaratory Relief

Israeli courts are generally empowered to issue declaratory relief if they deem it necessary, and the case law has established two main principles in that respect.

The first principle is that a declaratory order would not be issued if such issuance would result in a bifurcation of a given claim. In other words, the court would not grant a patent owner a declaration of infringement if it would

only serve as a precursor to a separate claim for damages.

The second principle is that negative declaratory orders would be issued only in rare cases and subject to the existence of a legitimate interest.

Section 187 of the Patents Law includes specific stipulations regarding the issuance of a declaratory order with respect to non-infringement. Under this specific arrangement, a person intending to exploit any product or process may apply to the court for a declaration that the said exploitation does not constitute an infringement of a given patent.

Section 187 further provides that the court shall not grant the declaration, unless the applicant is able to show that they gave the patent owner full particulars of the product or process they wish to use, have asked them for the declaration for which they apply to the court, and the patent holder has refused to make it or has not made it within a reasonable period. In such proceedings – to which the patent owner and the exclusive licensee must be joined as respondents – the parties' costs shall be borne by the applicant for the declaration, unless the court orders otherwise, and no argument of invalidity will be heard, nor will its result have any bearing on the issue of validity.

1.10 Doctrine of Equivalents

The Patents Law provides that infringement may be established by exploiting the invention as defined in the claims (literal infringement) or by exploiting the "essence of the invention in light of the claims" (non-literal infringements). In order to address non-literal infringements, the Supreme Court of Israel, influenced by the US Supreme Court ruling in Graver Tank & Manufacturing Co v Linde Air Products Co [339 US 605, 70 S Ct 854 (1950)] adopted the so-called Function-Way-Result test, which provides that if the accused device or process performs substantially the same function as the invention, in substantially the same way to reach the same result, it is infringing.

Later decisions employed this doctrine of equivalents with respect to pharmaceutical inventions. In one matter, the plaintiff claimed patent infringement over a formulation of a drug for the treatment of ulcers. The court found that the changes the defendant introduced into the formulation of its manufacture (the adding of an internal layer comprised of a sugar core) could not assist it in evading infringement, as it did not change the functioning of the accused formulation, which is done in the same way as the invention and also achieves the same result by applying the inventive solution of the patent.

1.11 Clearing the Way

Under Israeli law, a person may launch a product "at risk" – namely, when there is a patent claiming it – and such a person does not have to first initiate legal proceedings to revoke those patents ostensibly blocking its path, or to obtain a legal opinion of freedom to operate; failing to implement precautions against a finding of infringement could, in certain circumstances, support a contention of infringement.

1.12 Experts

The use of expert evidence in infringement and nullity proceedings in Israel is commonplace. Expert evidence in patent infringement proceedings is normally filed by each of the parties in the form of expert opinions, with those experts being later cross-examined during the evidentiary hearings (trial). The drafts of such opinions, as well as all communications between an expert

and the party by which it was retained, are privileged.

Where the questions in dispute relate to different fields, it is possible that a party will provide evidence from several expert witnesses to address each field separately.

While experts are retained by the parties, they are expected to assist the court in its fact-finding mission rather than serve as advocates for the cause of the party which had retained them.

The court may appoint its own expert in addition to the parties' experts. The parties may agree that the opinion of the court expert will replace the opinions of the parties' experts. The parties are entitled to cross-examine the court expert. The court is also empowered to appoint an assessor to advise the court on technical matters.

1.13 Use of Experiments

During both infringement and validity proceedings, it is possible to submit experimental results to show infringement or validity, eg, in support of claims of inventive step, lack of enablement, or lack of utility. Such results are filed with a supporting affidavit attesting to the conditions of the experiments and the results.

1.14 Discovery/Disclosure

Under Israeli law, parties to a claim (including an infringement claim) must disclose all relevant documents in their possession or control to the opposing party and may also be required to answer interrogatories. Copies of non-privileged documents need to be provided to the other party for inspection, in full or redacted form (eg, in case they contain trade secrets).

1.15 Defences and Exceptions to Patent Infringement

A defendant may claim in defence that its activities do not fall within the scope of the claims, and/or that the patent is invalid under any grounds on which the grant of a patent may be opposed, and/or that its activities are permitted for other reasons as explained below.

Invalidity

Any grounds, on which the grant of a patent may be opposed, shall be a good defence in an action for infringement.

Under Israeli law, a patent-eligible invention is defined as "an invention, whether a product or a process in any field of technology, which is new and useful, can be used industrially and involves an inventive step". In addition, the Patents Law provides that the patent's disclosure must enable the person skilled in the art to make and use the invention to the full scope of the claim and that the claims must be unambiguous and reasonably arise from the included disclosure.

Defendants in patent infringement proceedings are entitled to challenge the patent's compliance with any of the above requirements as part of their defence in court proceedings, and they may also file a motion for revocation of the patent at the Patent Office.

In this connection defences such as the so-called Gillette defence or Formstein defence are applicable.

Exclusions From Patentability

The Patents Law excludes from patentability a "method of therapeutic treatment of the human body". The "method of treatment" exclusion is narrowly interpreted, with only a method, as such, excluded, and products or composi-

tions used for the treatment of the human body allowed. In addition, Section 7(2) of the Patents Law excludes from patentability "new varieties of plants or animals, except microbiological organisms not derived from nature". As a result, defendants in patent infringement proceedings are entitled to argue that a claimed invention is excluded from patentability.

Fraud on the Patent Office

Under Israeli law, a patent applicant must – until the application is allowed – inform the Patent Office of all references relied upon by foreign Patent Offices examining patent applications for the same invention or those otherwise directly related to the application at hand. If the patent applicant knowingly fails to comply with this duty, the court may revoke the patent, give a licence to exploit the patent or shorten its period.

Statutory Exemptions

Section 1 of the Patents Law excludes from the definition of "exploitation of an invention":

- non-commercial acts;
- experimental acts aimed at improving the invention or developing another invention; and
- experimental acts towards obtaining regulatory licences after the lapse of the patent (a Bolar-type exception).

The exploitation of an invention would not be considered an infringement where the use of the invention was both on a non-commercial scale and of a non-commercial nature.

The second exemption – experimental use – relates to "an experimental act in connection with the invention, the objective of which is to improve the invention or to develop another invention". An act being experimental is insufficient in itself, and the defendant would have to show that the act falls within – or is necessary for – either of the two purposes provided: improving the invention or developing another.

Also exempted are experimental acts with the aim of obtaining regulatory approval. This is a Bolar-type exception.

Prior User

According to Section 53 of the Patents Law, a defendant, who would have exploited on the determining date, in good faith, in Israel, the invention for which the patent is sought, or if they in good faith made actual preparations towards exploitation, then they shall be entitled to exploit the invention themselves and in the course of their business without consideration. The "determining date" is the filing date in Israel or – if priority right was claimed– the filing date of the priority application. The right under Section 53 cannot be transferred, except together with the business in which the invention was used.

Lapse of Patent

Under Israeli law, a patent should be renewed every several years by way of paying a fee, and if a renewal fee is not paid, the patent shall lapse. Section 58 of the Patents Law provides that if a renewal fee was not timely paid, and if the owner had not cured this within a six-month grace period, then any use of the patent following that grace period will not constitute an infringement.

While the patent owner may yet reinstate the patent even after the grace period has lapsed, the Patents Law provides that any person who began to exploit the invention in Israel or made actual preparations for exploitation after the lapse of the patent was published in the Official Gazette, shall be entitled to continue to exploit the patent only for their business (Section 63).

The Patents Law limits this right only to the business owner. In other words, this right "cannot be transferred, devolved or transmitted by inheritance, except together with the business in which that invention was used" (Section 64).

Exhaustion

Exhaustion could be raised as a defence to an infringement action, however the metes and bounds of such a defence has not been resolved, especially in cases where an exclusive licensee is recorded on the register. In the latter situation, there is a likelihood that the defence will not be recognised. The matter is not adequately resolved by case law.

Licence

A defendant in a patent infringement claim may argue that they were allowed to carry out the allegedly infringing act as licensees. The success of such a defence would likely depend on whether or not the licence agreement in question was breached: if the licensee had exploited the patent in breach of the terms of the licence (eg, field of use limitations), their acts might constitute both patent infringement and breach of contract. However, breaches that are not related to the actual use of the patented invention (eg, failure to pay royalties under the agreement) will probably give rise just to contractual causes of action, as long as the licence agreement is not duly cancelled.

Compulsory Licence

While the Patents Law empowers the Patents Registrar to issue a compulsory licence subject to the satisfaction of statutory criteria, such a licence would only allow the exploitation of a given invention after it is issued and not retrospectively. It so follows that while an infringer may seek a compulsory licence immediately after the claim against them was submitted, doing so ought not serve as a defence against past infringements.

Additional Exceptions

The Patents Law also provides for a number of additional exceptions to infringement.

Under Section 180, "the exploitation of a patented product which was validly forfeited to the State shall not constitute infringement". Under Section 181(1), the use of a patented invention in the body or accessories of a vessel registered in a member state of the WTO other than Israel "exclusively for the needs of the vessel" while the vessel is "temporarily or incidentally in Israel's territorial waters" shall not constitute infringement. Similarly, the use of a patented invention in the construction or operation of an aircraft or land vehicle registered in a WTO state other than Israel, or their accessories, while they are "temporarily or incidentally in Israel" shall not constitute infringement (Section 181(2)).

1.16 Stays and Relevance of Parallel Proceedings

In general, Israeli courts follow the doctrine of lis alibi pendens, according to which the same issue would not be simultaneously heard in two different instances in Israel.

When it comes to patent infringement cases, a court hearing an infringement claim may stay the proceedings pending the Patent Office's decision in a motion for revocation if such was already pending when the action was first filed. It is also possible for the defendant to file a motion for revocation after the infringement claim was filed. In such a case, the court will decide whether validity issues will be heard by the Patent Office or by the court, and the court may also stay the infringement proceedings pending a decision by the Patent Office.

Foreign proceedings with respect to corresponding patents would not raise a claim of lis alibi pendens since patents are territorial. Nonetheless, factual findings in foreign proceedings may establish issue estoppel.

1.17 Patent Amendment

During litigation, the court, upon an application by the patentee, may amend the specification and the claims of the patent (Section 190 of the Patents Law). There is no empirical data available on how common amendments during litigation are, though it is safe to assume they are not a rarity. The court would be receptive to such an amendment application and is empowered to order the amendment of the claims even without the submission of such application.

1.18 Court Arbiter

Patent infringement cases are heard before the district courts, which are intermediary-level courts (between the magistrate courts and the Supreme Court). The Israeli courts do not use a jury system, nor do they employ specialist judges. With that being said, each court usually has one or more judges to which patent litigation cases are usually referred, and the Patents Law further allows the court to nominate an independent scientific adviser (assessor) to assist in hearing the evidence and to advise the court. Judges may reflect different tendencies, but this is not dependent on the location of the court.

2. Generic Market Entry

2.1 Infringing Acts

Under Israeli law, exploiting an invention claimed in a patent without permission is considered an infringement. "Exploitation" means either of the following:

- where the invention is a product – production, use, offer for sale, sale, or import for purposes of one of the said acts; and
- in respect of an invention that is a process – use of a product directly derived from that process.

Infringement would encompass any of the following acts: production, use, offer for sale, sale, or import for purposes of one of the aforementioned acts. There are statutory exemptions (Sections 1 and 54A of the Patents Law) where the infringement is, among other things, for non-commercial use, experimental use and experiments conducted with the aim of obtaining regulatory approval (a marketing authorisation).

It so follows that producing a patent-protected product – including a small molecule pharmaceutical product – would be infringing, as well as offering it for sale or actually selling it. While asking for – and even obtaining – a marketing authorisation would not be considered infringement, any attempt to enter the market on the basis of such authorisation during the patent term (even if the actual entry will take place once the patent lapses) would seem to amount to infringement.

2.2 Regulatory Data and Market Exclusivity

Israeli law allows for a fairly short marketing exclusivity (six to six and a half years) and only for new chemical entities (NCEs).

Section 47D of the Pharmacists Ordinance defines an NCE as a "drug which does not contain an active moiety, whether by itself or together with another active moiety, in a registered preparation or a preparation which was registered in the Register".

According to the Pharmacists Ordinance, the Israeli Ministry of Health will not issue a marketing approval in Israel to a new drug containing the active moiety of an NCE (the registration of which is based on confidential data (safety and efficacy data) filed for a previous drug containing the NCE) unless:

"(a) 6 years have lapsed from the registration date of the previous drug containing the NCE in the Israeli Pharmaceutical Register; or (b) 6.5 years from the registration date thereof in a Recognized Country (the U.S., Canada, a member of the European Union, Switzerland, Norway, Iceland, Australia, New Zealand, Israel, and Japan), whichever is earlier."

The marketing exclusivity is further dependent on the previously registered pharmaceutical preparation being the first registration of the chemical entity it contains. In addition, the marketing exclusivity period may be disregarded if the owner of the previous pharmaceutical preparation gave their consent to use the confidential information; if, in the framework of the registration of the new pharmaceutical preparation, full data to prove the safety, effectiveness, and quality of the new registration was provided; or in case of a national emergency.

It is important to note that the exclusivity provided under Israeli law relates only to the marketing of a follow-on drug, and a third party may seek registration of a follow-on drug on the basis of the data at any time. In general, a third party seeking registration of a follow-on drug product will be required to provide bioequivalence data.

No additional exclusivities exist (eg, orphan drug or paediatric exclusivity).

2.3 Acceptable Pre-Launch Preparations

The 1998 Amendment of the Patents Law introduced a Bolar-type defence as Section 54A of the Patents Act, colloquially known as a "regulatory exemption".

This "regulatory exemption" applies if a given experimental act – which might otherwise be deemed to infringe the patent – is made in order to obtain regulatory marketing approval prior to the expiration of the patent in Israel or in another country whose laws also contain a Bolar-type defence. The application of this defence is subject to the products manufactured under Section 54A not being used for any purpose other than the obtaining of a regulatory permit.

In respect of this exemption, a (non-binding) district court decision provided that any action that can be reasonably related to the experimental act will also be covered by Section 54A.

2.4 Publicly Available Drug and Patent Information

Israeli authorities do not rely on the Orange Book, nor do they have an equivalent thereof. The Israeli Ministry of Health operates the online-available Israeli Drug Registry. This website includes data about all the drugs that are registered or were previously registered in the drug register of the State of Israel. The information includes the composition of the active ingredients and their quantity, the indication approved in Israel, the form of administration of the medicine, the dose, the name of the manufacturer and the owner of the registration in Israel, the types of packaging, the registration number and the price. However, that information only becomes available to the public upon entry into effect, meaning that information regarding pending applications is not publicly available. Gener-

ally, the information in the database is updated once a week.

2.5 Reimbursement and Pricing/Linkage Markets

In Israel, granting of marketing authorisation is not linked to patent status but rather to whether a given product has already received authorisation in the United States and in the EU. As for pricing and reimbursement, those are also not linked to patent status, but are subject to certain governmental arrangements, which include pricing control and a national reimbursement programme (which is indication-specific). Israeli HMOs are generally not required to purchase non-reimbursed drugs; while legal action over such refusal could theoretically be filed, the chances of success would seem generally slim.

3. Biosimilar Market Entry

3.1 Infringing Acts

See **2.1 Infringing Acts**.

3.2 Data and Regulatory Exclusivity

As noted in **2.2 Regulatory Data and Market Exclusivity**, the limited marketing exclusivity provided under Israeli law only mentions new chemical entities. This led the Israeli Ministry of Health to adopt the view that biologics would not enjoy marketing exclusivity. The issue is yet to be resolved by way of judicial review. However, the requirements for obtaining marketing authorisation for biosimilars in Israel require former authorisation in one of several other countries – in which there is data exclusivity – leading to a de facto exclusivity.

3.3 Acceptable Pre-Launch Preparations

See **2.3 Acceptable Pre-Launch Preparations**.

3.4 Publicly Available Drug and Patent Information

See **2.4 Publicly Available Drug and Patent Information**.

3.5 Reimbursement and Pricing/Linkage Markets

See **2.5 Reimbursement and Pricing/Linkage Markets**.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Under Israeli law, the term of a pharmaceutical patent may be extended by up to five years via an order called a Patent Term Extension Order ("PTE order").

The Patents Law provides that a patent claiming any of the following may be considered a "basic patent" eligible for a term extension, subject to the satisfaction of the below-described statutory conditions:

- active pharmaceutical ingredients (APIs);
- use(s) of APIs;
- finished drugs,
- manufacturing process(es) of APIs;
- finished drugs' manufacturing processes; or
- medical devices.

This means that it would not be possible to obtain a PTE order for a combination of previously registered APIs.

Assuming the patent in question claims the eligible subject matter described above and that the application for a PTE order was filed by the applicant of a pending application, the owner

of a granted patent, or the exclusive licensee in such, the Patent Office would examine whether the following conditions – listed in Section 64D of the Patents Law – have been met.

- The PTE application was filed in good faith.
- The basic patent is in force.
- The pharmaceutical preparation of the drug containing the API is registered in the Israeli Pharmaceuticals Register.
- There are no other PTE applications for the same API or for the same basic patent.
- The registration in the Pharmaceuticals Register of a drug containing the API is the first one made.
- Marketing authorisation was issued in the United States and in any of five European countries (the UK, France, Germany, Italy and Spain), and a US PTE, UK SPC and/or EU SPC (respectively) was granted before the expiry of the basic patent (the "reference countries" and the "reference patents").

Assuming that all of these conditions have been satisfied and that the applicant had acted in accordance with the timeframes and procedures set out in the Patents Law and applying regulations, the term of the patent would be extended.

The duration of an Israeli PTE order shall equal the shortest term of extension in any of the reference countries in which PTE or SPC orders were issued and, in any case, would not exceed 14 years from the issuance of the first marketing approval in any of the reference countries. In addition, under the current PTE regime in Israel, a PTE order would expire upon the revocation of any reference PTE/SPC orders (or underlying reference patents) in any of the reference countries.

Any person may oppose the issuance of a PTE order before such is granted, as well as move for a post-grant revocation of a PTE order, on the basis that the above-listed conditions were not met or that the procedural requirements were not adhered to.

4.2 Paediatric Extensions

At present, paediatric extensions are not available in Israel.

4.3 Paediatric-Use Marketing Authorisations

At present, paediatric-use marketing authorisations are not available in Israel.

4.4 Orphan Medicines Extensions

At present, extensions for orphan medicines are not available in Israel.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

Securities

Under Israeli law, issuance of an interlocutory injunction is conditioned on the deposit of an in personam undertaking by the applicant to compensate the respondent (against which the order is directed) for whatever damages are incurred as a result of the issuance of the injunction if the injunction is revoked or if it is reduced in scope. Such an undertaking must be attached to the motion for interlocutory injunction.

In addition to the in personam guarantee, and in the absence of extraordinary circumstances requiring otherwise, the court shall order the deposit of an in rem guarantee at a sufficient amount at the discretion of the court.

As the interlocutory injunction remains in place until a final judgment is entered (if not revoked

beforehand), all securities deposited will remain in effect until such a time.

The injunction would not go into effect until all securities have been deposited, though the court is authorised to instruct otherwise. In addition, where the preliminary injunction was filed for prior to the case-in-chief being submitted, the applicant will have seven days from the decision date to file the main claim, with failure to do so resulting in the preliminary injunction's revocation.

Service

Under Israeli law, an interlocutory injunction is enforceable immediately upon lawful service on the enjoined party, assuming all relevant securities were deposited (if necessary).

The court will usually provide instruction on how the order is to be served on the respondent, but, in the absence of such, there are several ways to effect service: a copy of the decision may be served on the respondent themselves, at their home or at their place of business, either via courier or via registered mail, on an adult family member living with them, on a person authorised to manage their business, or on their counsel. Where the respondent is a company, service is usually effected by delivering a copy of the order to their registered place of business. In those cases where the respondent is not Israeli, leave for service outside the jurisdiction must be secured, though it would also be possible to effect service by serving the order on a business manager in Israel (if such exists).

As for timeframes, the court will usually instruct the applicant to effect service immediately. The applicant is incentivised to do so regardless, as the order would not be enforceable before lawful service is effected.

Enforcing Execution

If a party against which an interlocutory injunction was issued does not abide by that injunction, the prevailing party may seek to compel the losing party to do so by filing a motion under the Contempt of Court Ordinance. Under this ordinance, a non-compliant party is subject to a monetary fine and, in extreme cases, to imprisonment for as long as the breach of the order is taking place.

Staying Execution

A party against which interlocutory injunctive relief was issued may seek (alongside filing for leave to appeal) a stay of execution from either the court of first instance or from the court of appeal. If the motion for leave to appeal is yet to be filed, the court of first instance will hear the motion for a stay; if the motion for leave to appeal has been filed, then the court of appeal will hear it. In order to prevail in such a motion, the applicant must demonstrate to the court that it has a good chance of winning the appeal and that, if the injunction enters into effect, it would be either impossible (or very difficult) to go back to the previous state of affairs, or that the applicant would suffer irreparable injury.

A court allowing a stay of execution may make such stay subject to the satisfaction of whichever conditions it deems fit, such as the deposit of a security or the placing of a limitation on the price charged for the now-enjoined product/process.

5.2 Final Injunctive Relief

Enforceability of a Final Injunctive Relief

Under Israeli law, a final injunction is enforceable immediately upon its lawful service on the party which it enjoins – service which can be effected either by the court issuing the order or by the

prevailing party, the earlier of which will start the clock on the 60-day term for lodging an appeal.

A final injunctive relief will not require the prevailing party to deposit a bond, as there is no longer a chance that the claim will ultimately be rejected, and there can be no cause of action in tort over the wrongful issuance of the injunction.

Enforcing Execution

If a party against which an injunction was issued does not abide by that injunction, the prevailing party may seek to compel the losing party to do so by filing a motion under the Contempt of Court Ordinance. Under this ordinance, a party failing to comply with a duly issued court order is subject to a monetary fine and, in extreme cases, to imprisonment for as long as the breach of the order is taking place.

Staying Execution

A party against which a final injunctive relief was issued may seek – alongside the filing of an appeal – a stay of execution. If the appeal is yet to be filed, the court of first instance will hear the motion for a stay; if the appeal has been filed, then the court of appeal will hear it. In order to prevail in such a motion, the applicant must demonstrate to the court that it has a good chance of winning the appeal and that, if the injunction enters into effect, either it would be impossible (or very difficult) to go back to the previous state of affairs, or the applicant would suffer irreparable injury.

A court allowing a stay of execution may make such stay subject to the satisfaction of whichever conditions it deems fit, such as the deposit of a security or the placing of a limitation on the price charged for the now-enjoined product/process.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

The Patents Law provides that a prevailing plaintiff is entitled – as a matter of right – to both an injunction as well as to damages. The language of the law does not allow the court discretion to award damages in lieu of an injunction. Nonetheless, injunctive relief is a remedy in equity, and the court would have the discretion to refrain from issuing an injunction in rare cases.

5.4 Damages

Calculation of Damages

A prevailing plaintiff is entitled to damages, with Section 183(b) of the Patents Law providing that in awarding compensation, the court shall take into consideration:

- the direct damages caused to the plaintiff;
- the extent of the infringement;
- the profits derived by the infringer from the act of infringement; and
- the reasonable royalties which the infringer would have had to pay in consideration for a licence.

The plaintiff may opt between damages due to loss of profit and the profit made by the defendant amounting to unjust enrichment. Adjudication of reasonable royalties may be warranted where the plaintiff's business model is to issue licences at arm's length.

The Patents Law further empowers the court to order the infringer to provide accounts on the basis of which calculation of damage may be effected. If such an order is made, it is possible that a supplementary judgment would be issued, in which only the issue of the damages is addressed. Otherwise, the claim for damages would be heard as part of the main claim.

In addition, Section 183(c) of the Patents Law provides that if an infringement was committed after the patentee or its exclusive licensee warned the infringer, the court may order the infringer to pay punitive damages in an amount that will not exceed the damages adjudicated by the court, thus enabling the adjudication of double damages.

In general, damages accrue from the time when the infringement commenced. However, Section 179 of the Patents Law provides that damages may only be adjudicated from the time the patent application was published under Section 16A of the Patents Law (namely, 18 months from the priority date), with such damages being capped at reasonable royalties until the application was published for oppositions, from which the regular rate of damages provided for in Section 183 of the Patents Law shall apply. However, those reasonable royalties shall not be awarded unless the court finds that the exploitation in question constitutes an infringement of the patent as granted and that the invention claimed in the patent stage is substantively identical to the invention claimed in the application published under Section 16A.

The court may add interest and linkage to any sum it adjudicates as damages, from any date it deems fit (but not earlier than when the cause of action came to be) until the date on which the damages are to be paid (usually within 30 days of the judgment). If the damages are not timely paid, a much higher and compounding arrears interest will apply.

Damages for Revoked Injunctions

If an interlocutory injunction is either revoked or limited in scope, the enjoined party can turn to the guarantees provided by the applicant – in rem and in personam both – to obtain compensation for damages sustained. The defendant may base its claim on the doctrine of the unjust enrichment made by the plaintiff due to its exclusive position in the market, during the preliminary injunction term.

Procedurally, this can be done either by counterclaiming (if the period to do so has not yet lapsed) or by filing a new independent claim. The defendant will need to prove their damages – usually, the profits they have lost during the period they were enjoined – on the basis of factors such as anticipated market share, anticipated sale price for the defendant's product and average profit margin. The defendant may seek to disgorge the plaintiff of those profits they obtained by virtue of any exclusivity afforded to them by the interlocutory injunction since revoked.

Third parties are unable to seek damages over a revoked injunction, though they could theoretically attempt to seek disgorgement if they were charged a premium as a result of the plaintiff's de facto exclusivity mentioned above.

5.5 Legal Costs

Under Chapter 18 of the CPR (Regulations 151–157), the prevailing party is entitled to recover its actual legal costs, with consideration being given to the results of the proceedings, the resources required, and the conduct of the parties. As a result, Israeli courts are instructed to adjudicate fair and reasonable legal costs at the conclusion of the proceedings unless they have found that there are extraordinary reasons not to do so.

Where attorney's fees are concerned, the courts are instructed not to go below the minimum rates set by the Israeli Bar Association (unless

there are extraordinary reasons to do so), and to take into account:

- the proportion between the remedy actually adjudicated and the remedy originally requested;
- the manner in which the parties conducted themselves;
- the complexity of the case, the resources spent to conduct it; and
- the sum of the fees requested by the prevailing party.

Where other costs are concerned, the courts are instructed to adjudicate all costs actually made and required for the proceedings, subject to the prevailing party detailing those costs in their summations and providing documentation in support.

In addition, if the court finds that a party has caused the unnecessary elongation of a proceeding (including an interlocutory proceeding), it may order that party – regardless of the result of the action – to pay the costs of that proceeding to either the opposing party or the State of Israel.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

In Israel, all legal actions – including the launch of litigation proceedings and the conduct of such – are subject to good faith. Failure to act in good faith may result in the non-granting of equitable relief (such as an interlocutory injunction) or in a limitation on the enforceability of a substantive right (in forms such as reduced damages or an injunction with a delayed entry into force).

6. Other IP Rights

6.1 Trade Marks

Trade mark law in Israel is governed by the Trade Mark Ordinance of 1972, and, to a lesser extent, by the Commercial Torts Law of 1999 (which deals with the law of passing off).

There have been several cases of trade mark disputes relating to the life sciences and pharma sector, centred mostly around naming and get-up – either names or get-ups which were too close for comfort to the name or get-up of an existing, established drug, or names that were too similar to the relevant International Non-proprietary Names (INN), which should remain open to the trade and therefore excluded from trade mark protection.

In respect of the first kind of disputes, the case law provides that where a consumer's mistake, however unlikely, could bring about severe health hazards – as is the case with pharmaceuticals and medical devices – even a lesser degree of similarity is sufficient to establish the misleading similarity needed for a finding of trade mark infringement. The same is true for passing off, where – subject to a showing of goodwill inured to the benefit of the plaintiff or its product – using misleadingly similar get-up is prohibited.

In respect of the second kind of disputes, the case law provides that INNs or the dominant parts thereof cannot be registered as trade marks, either because those should remain open to the trade (if the preparation is based on the same API) or because they could lead to confusion between different preparations using the same API (albeit differently).

6.2 Copyright

The issue of copyright in Israeli law is governed by the Copyright Law of 2007. The Copyright Law provides, among other things, protection for textual works. Copying of any text which is original and fixed – such as use instructions of a given preparation – could amount to copyright infringement.

A plaintiff in a copyright infringement may pass the burden of proof on to the defendant if it is able to show that the defendant had access to and produced a work similar to the original.

6.3 Trade Secrets

The issue of trade secrets in Israeli law is governed by the Commercial Torts Law of 1999, which forbids the misappropriation of trade secrets, defined therein as "Commercial information of any kind, which is not public knowledge, or which cannot readily and legally be discovered by the public, the secrecy of which grants its owner an advantage over his competitors, provided that its owner takes reasonable steps to protect its secrecy".

While trade secrets disputes in the life sciences and pharma sector are not common in Israel, there are many types of trade secrets associated therewith – such as lists of clients, lists of providers, and marketing strategy documents – and so such disputes can theoretically arise.

7. Appeal

7.1 Timeframe to Appeal Decision

District court decisions may be appealed to the Supreme Court by right. Leave to appeal interlocutory decisions, including decisions in motions for a preliminary injunction, must be obtained. The term for filing an appeal is 60 days from the date the judgment was issued to the appealing party. The same applies to motions for leave to appeal.

7.2 Appeal Court(s) Arbiter

There is no specific arrangement in place regarding patent litigation appeals. Assuming the first instance was the district court, an appeal thereon will be heard before three Supreme Court judges, whereas an appeal over an interlocutory decision (for which leave must first be secured) will be heard by one Supreme Court judge.

7.3 Special Provisions

Once an intellectual property case is filed with a regular civil court – be it a court of first instance or that of appeal – it is governed by the CPR.

Where nullity proceedings are concerned, they are governed by a separate set of regulations; namely, the Patent Regulations, which closely resemble the CPR and rely thereon.

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

While the Israeli Customs Authorities are not authorised to seize patent-infringing goods, they are able – and will – seize counterfeit pharmaceuticals, as well as products that infringe the trade marks and/or copyrights of another.

The seizure procedure under Israeli law closely resembles the arrangement provided in Part III, Section 4 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In addition, the Israeli Customs Authorities may seize and destroy shipments containing trade mark/copyright infringing goods and have set up a simplified procedure whereby they confiscate

shipments of infringing goods without requiring the trade mark or copyright owner to take legal action or file a bank guarantee.

9. Alternative Dispute Resolution

9.1 ADR Options

Israeli law allows for both mediation and arbitration, though both require the consent of the parties.

Mediation is not binding and could be stopped at any moment, with all information exchanged remaining confidential. Mediation usually takes place before litigation – especially if there is an agreement between the parties so necessitating – or during litigation, at the suggestion of the court. Turning to mediation enables parties to reach a confidential settlement, whereas a court judgment would usually be made public.

Arbitration is different from mediation: once the parties have agreed to arbitration, they are bound by that agreement, with arbitration agreements being vigorously enforced and rarely set aside. In addition, unless a right to appeal is specifically provided for, it is very difficult to set aside an arbitral award, as the criteria to interfere as such are very narrow. Arbitration in Israel – be it local or international, with Israel as either the seat or the governing law – is usually faster than court proceedings and – subject to the agreement of the parties – can be confidential. The parties are free to appoint their arbitrators, as well as to determine every other attribute of the proceedings, such as the procedural law and the degree to which the tribunal would be bound by evidence law or have to reason its decision.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The Economic Competition Law of 1988 prohibits the making of arrangements involving restrictions that are likely to prevent or reduce competition, unless such are cleared in advance by the Israel Competition Authority.

Under Section 3(2) of the Economic Competition Law, arrangements whose restrictions all relate to patent use rights (and other listed intellectual property rights), entered into directly by the patent owner and the party receiving the rights, will not be deemed "restrictive arrangements".

However, a patent owner or its exclusive licensee may still be accused of abusing their monopolistic power, for example, by charging too high a price. To that end, the relevant market would have to be determined, and, if indeed a finding of a monopoly is reached, it is possible for a patent owner to be found liable for such abuse, as was recently the case with a pharmaceutical company ordered to pay ILS8 million for charging exorbitant prices.

11. Collective Redress

11.1 Group Claims

Israeli law allows for the filing of class actions, including in the life sciences/pharma sector. Under the Class Actions Law of 5776-2006, a plaintiff's claim may be certified as a class action if the claimant manages to establish:

- the existence of an issue common to all members of the putative class;
- that there is a reasonable chance of success;
- that a class action is the appropriate and efficient method to litigate the matter; and

- the adequacy and good faith of the proposed representatives.

Over the years, there have been many class action proceedings in the life sciences/pharma sector, litigating claims such as misrepresentation of side effects, failure to disclose expiration dates, misrepresentation of ingredients, and misclassification of preparations.

ITALY

Law and Practice

Contributed by:
Daniela Ampollini, Luca Pellicciari, Elena Mannini and Andrea Beltrame
Trevisan & Cuonzo

Contents

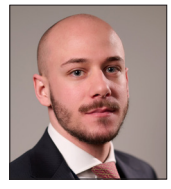
Trevisan & Cuonzo has top-quality expertise in the complex issues raised by contentious pharmaceutical and biotech litigation. Appearing regularly before the Italian IP courts and with solid experience working with other European law firms in defending the Italian arm of pan-European pharma litigation, the firm is in a formidable position to serve both Italian and international clients in this sector. On the transactional front, clients range from biotech start-ups to medium and well-established pharma businesses with blockbuster products on the Italian market. Advice and strategy are sought on capital formation guidance for start-ups, licensing agreements for technology transfer, distribution, manufacture and supply agreements, joint venture research and development collaboration agreements, clinical trial and clinical research agreements, as well as high-profile partnering deals. The firm regularly advises on Italian and European anti-competitive issues in the pharmaceutical sector and handles regulatory matters such as data exclusivity, Italian market authorisation, and patent extensions.

Authors

Daniela Ampollini is a partner at Trevisan & Cuonzo. With more than 20 years of experience in IP, Daniela has advised and assisted both Italian and international clients in many types of contentious and non-contentious intellectual property matters. She has an outstanding track record of advising clients in a variety of industries, from pharmaceutical and chemical to mechanical and electronic, from cosmetics and fashion to food and beverages, the seed industry and FMCGs.

Luca Pellicciari is a partner at Trevisan & Cuonzo who specialises in contentious work. He assists and represents domestic and foreign clients in complex, contentious commercial and intellectual property matters in a wide range of industries, including pharmaceuticals and biotechnology, mechanics and consumer goods. He runs a strong life sciences practice.

Elena Mannini is an associate at Trevisan & Cuonzo. Her main focus is patent litigation, as well as non-contentious IP work (including trade marks, designs, copyright and trade secrets) and unfair competition, especially in the life sciences industry.



Andrea Beltrame is a junior associate at Trevisan & Cuonzo. He mainly collaborates on national and international litigation in the field of patents and unfair competition, especially in the life sciences industry.

Trevisan & Cuonzo

Palazzo Beccaria
Via Brera, 6
20121 Milan
Italy

Tel: +39 02 8646 3313
Fax: +39 02 8646 3892
Email: info@trevisancuonzo.com
Web: www.trevisancuonzo.com

Trevisan & Cuonzo

1. Life Sciences and Pharma/Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

The standing to bring patent infringement actions lies with the registered patent holder. Established case law confirms that exclusive licensees have the autonomous right to initiate patent infringement proceedings, provided they can demonstrate their status as exclusive licensees when filing the case in court. This can be achieved by either submitting a copy of the exclusive license agreement along with the initial statement of claim or, preferably, by registering a confirmatory license with the Italian Patent Office. The latter option is often preferred due to the sensitive data and information that may be included in the license agreement.

No statutory provision clarifies whether co-owners have autonomous legal standing to sue for infringement, ie, to bring a patent infringement action without other co-owners as co-plaintiffs, and the point is debated. In practice, this debate is often less significant because the ability of a patent co-owner to take independent action is typically governed by the contractual agreements that either led to the invention (such as R&D agreements) or were specifically created to establish and regulate co-ownership of the patents related to that invention.

Revocation actions and declaratory actions for non-infringement can be initiated by anyone with an interest in the matter, and the threshold for doing so is typically low. A statement that the party filing for revocation or declaratory relief is interested in doing business in the technical field relevant to the patent will normally suffice. A higher threshold normally applies to declaratory actions of non-infringement when filed in the form of preliminary proceedings in that an additional layer is required in relation to the urgency of the action, ie, the petitioner needs to establish it would suffer irreparable harm absent the requested preliminary declaratory relief.

1.2 Defendants/Other Parties to an Action

Patent infringement actions in the life sciences industry would normally target the infringing MA holder and the related Italian affiliate distributor, along with any further party involved in the manufacturing and supply chain of the infringing generic or biosimilar product, as long as they are active on the Italian territory. It is quite uncom-

mon for healthcare providers and hospitals that sell or prescribe infringing generic or biosimilar products to be involved in patent infringement proceedings, even though they are technically infringers. Healthcare regulatory authorities (such as the Italian Medicines Agency) may be involved at a very early stage of the case as the target of pretrial proceedings aimed at collecting evidence, for instance, in cases where demonstrating infringement requires accessing the related MA dossier or Drug Master File. The Italian Patent and Trademark Office is not a party to patent infringement proceedings; however, it must be formally notified of court actions regarding national patents or nationally validated EPs.

1.3 Preliminary Injunction Proceedings

Preliminary injunctions are available subject to the requirements of prima facie case and urgency. The former requires a reasonable case that the patent is both valid and infringed and is normally dealt with by Italian courts via the appointment of a Court Technical Adviser (CTA). Whilst experienced in patent matters, judges of the IP courts have a purely legal background. A CTA is, therefore, normally appointed to tackle the technicalities that need to be untangled to assess validity and infringement. CTAs are selected amongst senior patent attorneys registered with the court. The urgency requirement is met whenever a reasonable case can be made that the market launch of the infringing GX, biosimilar or medical device is imminent. Delay in seeking relief might be a factor that works against urgency. Balance of convenience can also be a factor, especially in relation to the interest of patients or other third parties who may be at risk of losing treatments or diagnostic tools if the infringing product or device is removed from the market.

Preliminary injunctions (PIs) can be granted ex parte, although only in very exceptional cases. Standard practice is for PIs to be issued inter partes. The timeline for an inter partes preliminary injunction is at least six months, depending on the court involved. Generally speaking, the trigger for a PI is any activity beyond market approval that can qualify as preparatory for the market launch of the infringing product or device. Courts are normally strict when applying this threshold, although ways to work around/mitigate this threshold are available, such as sending notice/warning letters. A response that is either ambiguous or explicitly declines an undertaking not to launch the infringing product or device on the market might be used as leverage to argue urgency at the PI hearing.

Once lodged with the competent court, the PI motion will be assigned to a single, designated instructing Judge of the IP Chamber who will handle the proceedings and eventually adjudicate the PI. Upon receiving the motion, the instructing judge will either:

- issue the PI ex parte (if a request has been made to this sense and if the conditions for an ex parte PI are met) and set up an inter partes PI hearing while assigning the defendant a deadline to submit their defence prior to the PI hearing; or
- issue a decree setting up a PI hearing and assign the defendant a deadline to submit its defence.

The defence would normally need to consider validity as well as infringement and urgency/procedural defences, although only the latter will likely trigger an immediate rejection, ie, a rejection for lack of urgency/other procedural requirements. Defences on the substance of the case, namely on validity and infringement, will normally need the benefit of a technical background in order to be adjudicated. Thus, if at the

PI hearing, the instructing judge were to agree that urgency and procedural requirements are all met/in place, the judge will normally appoint a CTA and charge said CTA with the task of providing a reasoned, non-binding opinion on whether the patent is valid and infringed. Appointment of a CTA normally happens at a formal case conference one to two weeks after the first PI hearing.

Upon being formally appointed, the CTA will also receive indications as regards the timeline for delivery of the CTA opinion. The CTA will call for the parties to submit detailed, comprehensive technical submissions presenting their arguments (no less than two rounds) before issuing a preliminary opinion, which the parties will be asked to comment upon in writing. The CTA will then issue a final opinion that takes those comments into account and, subsequently, upload it onto the court e-registry. Save for the delivery of the CTA final opinion (which is court-mandated), the calendar of these activities is defined by the CTA in agreement with the parties and on a case-by-case basis.

A final hearing for oral pleadings will take place within one to two weeks after delivery of the CTA opinion. The PI is adjudicated with an out-of-court order that the instructing judge issues after the final hearing (ie, no decision is announced at the hearing). The order that either grants or denies the PI can be appealed before a panel of three different judges from the same IP chamber within 15 days. The appeal will normally consist of a single hearing, preceded by the filing of a thorough, detailed defensive brief by the party bringing the appeal. PI appeals normally last for two to three months.

Further, and importantly, Italian PIs are "stable", ie, there is generally no need to file subsequent main proceedings to stabilise the PI if the latter has been requested or granted without ancillary measures (such as saisie-type measures or seizures). The court might request that the petitioner post a bond as a condition for granting the PI, although this provision is rarely applied.

Italian national courts do not allow protective letters.

1.4 Structure of Main Proceedings on Infringement/Validity

Infringement and validity proceedings are not bifurcated, resulting in infringement being counterclaimed in the course of pending invalidity proceedings. Consequently, invalidity can be challenged/counterclaimed in pending infringement proceedings.

The above does not prevent parties from filing two different proceedings, one claiming invalidity and one claiming infringement of the same patent. A landmark judgment issued by the Italian Supreme Court in 2016 stated that infringement proceedings have to be stayed until a decision on the parallel, separate, validity proceedings is issued, thereby opening the door to bifurcation strategies, especially by defendants of an infringement action.

Invalidity and infringement proceedings can be filed while opposition proceedings are pending, and there is no provision in Italian patent law requiring that said proceedings be stayed due to the existence of opposition proceedings pending before a patent office. Italian courts may decide that an infringement or invalidity case needs to be either stayed or postponed pending the outcome of parallel opposition proceedings. However, this occurs on a case-by-case basis and only when a party can demonstrate that a decision in the opposition proceedings is imminent and will significantly affect the scope

of patent protection or the parties' respective arguments. Italian courts are normally hesitant/resistant to staying or postponing the case on account of pending EPO oppositions.

1.5 Timing for Main Proceedings on Infringement/Validity

Patent infringement and invalidity actions are instituted under and governed by the Italian Civil Procedural Code, with the addition of some special procedural provisions contained in the IP Code. The Italian Civil Procedural Code underwent a major reform with the entry into force of Legislative Decree No 149 of 10 October 2022 (the so-called Cartabia Reform), which led to a substantial revision of the structure of the main proceedings.

Main proceedings are instituted via the service of a writ of summons on the defendant. The writ must carry a fairly detailed summary of the plaintiff's arguments and a precise indication of the plaintiff's requests to the court, including an indication of the specific remedies the plaintiff intends to pursue. The plaintiff must subsequently lodge the writ of summons with the court within ten days of applying for service, along with any exhibits/documents mentioned in support. The case is then assigned to an instructing judge.

In the writ of summons, the plaintiff must also indicate a first hearing date, allowing a "space" between the service of the writ and the date of the hearing of either 120 days (if service has to take place in Italy) or 150 days (if service has to take place abroad). If the defendant wishes to file a counterclaim, call third parties or raise any procedural or substantive defence that the court could not raise ex officio, they must file a statement of defence at least 70 days before the above-mentioned hearing. The judge carries out preliminary checks and confirms (or postpones up to a maximum of 45 days) the date of the first hearing with a decree that the judge must issue within 15 days of filing the defendant's statement of defence.

Proceedings are subsequently fragmented into three sets of briefing notes exchanged between the parties, each due in, respectively, 40, 20 and 10 days prior to the first hearing. These rounds of briefing notes are intended for the submission and presentation of evidence/evidentiary requests, such as witness testimonies. The second of these rounds (due 20 days before the first hearing) also marks the cut-off deadline to present purely factual evidence, ie, non-technical and unrelated to technical aspects of validity and infringement (see below).

Further to the Cartabia Reform, the first hearing is now more substantive, whereby the judge not only sets out the calendar of the case but also gives specific directions as to how the judge intends to manage the case from the perspective of evidence. Importantly, having had the benefit of seeing the evidence before the judge and the parties' evidentiary requests before the first hearing, the judge is now in a position to either recommend or direct the parties to a settlement at the first hearing.

Unless the parties initiate or reach settlement discussions, the first hearing typically results in the judge appointing a CTA. The CTA's role is to provide a non-binding opinion on the technical aspects of both the validity and infringement of the patents in question. The panel will then use this opinion as guidance to adjudicate the case. The procedural aspects are similar to those described for PI proceedings; however, the timeline for obtaining a CTA opinion is generally longer than in urgent preliminary proceedings.

Additional evidence (such as witness testimonies deemed relevant by the judge) is typically addressed alongside, or more commonly after, the CTA opinion has been delivered.

After addressing the above issues, a final hearing will be scheduled, which will be preceded by:

- (i) the parties confirming their final requests to the court (60 days before the hearing);
- (ii) the parties submitting final written pleadings (30 days before the hearing); and
- (iii) the parties submitting a final brief in reply (15 days before the hearing).

Upon confirming their final requests to the court under (i), parties may request that submission of the final briefs in reply under (iii) be substituted by oral pleadings that shall take place before the panel of three judges, who will eventually adjudicate the case. The average timeframe for first instance main proceedings is between two and two and a half years, depending on the seized court and its workload.

Validity and/or infringement actions can always be filed, provided the claimant retains an interest. A statute of limitations of five years applies to claims for damages resulting from patent infringement; however, case law has clarified that claims for the return of profits are subject to a longer "general" statute of limitations of ten years.

Claims for damages and the return of profits typically occur after a discovery of infringement. This can happen either as part of sub-proceedings that follow the main case — if damages or the return of profits were requested at the outset — or as separate, independent proceedings.

1.6 Requirements to Bring Infringement Action

Italy is one of the few jurisdictions where patents can be enforced at the application stage, both in preliminary as well as in main proceedings. While preliminary measures, including preliminary injunctive relief, can be granted based on patent applications, Italian courts have to wait until the patent is granted before issuing a judgment in the main proceedings.

As far as patent applications are concerned, a condition for their enforcement is that they must either be published or, if not yet published, officially served on the defendant before the action is actually filed. Further, and importantly, in the case of EPO or international patent applications, a translation of the claim set must be filed with the Italian PTO before enforcement. A translation requirement also exists with respect to granted patents stemming from EPO or international applications: ie, an Italian translation of the patent specification (description and claims) as granted needs to be filed with the Italian PTO for the patent to be validated and enforceable in Italy.

There must be evidence of infringing activity taking place in the national territory for the filing of an infringement action. In cases seeking preliminary relief, there should be a reasonable indication that such infringing activity may begin in the national territory and that this potential activity poses a risk of causing irreparable harm to the patent holder if a preliminary injunction is not granted. The general view shared by Italian courts is that obtaining a marketing authorisation and/or applying for price and reimbursement is not sufficient to justify an infringement claim (ie, commercial exploitation of the patented invention) and/or a threat of infringement and the consequent irreparable harm and further elements

(such as, for instance, refusals to enter into an undertaking not to launch) are required.

Patent infringement proceedings follow the general principle according to which each party bears the burden of proof with respect to their own claims. Accordingly, patentees must bring forward evidence that the targeted product, device or process infringes the patents. Italian courts are normally careful in not allowing "fishing expeditions", with a single exception applied to process patents. A product identical to that obtained through the patented process is presumed to have been directly obtained by the use of the patented process if either of the following alternatives apply:

- (i) the product obtained through the patented process is new; or
- (ii) there is a reasonable likelihood that the same process was used and the patentee was incapable of determining the process used by the infringer by using reasonable efforts.

1.7 Pre-Action Discovery/Disclosure

Italy has no pretrial discovery, at least not in a US manner of speaking (see **1.8 Search and Seizure Orders**).

1.8 Search and Seizure Orders

Search and seizure orders are available in Italy. Search orders are saisie-type measures by means of which the competent court issues – on an ex parte basis – an order authorising the patentee to forcefully (ie, with the aid of a court bailiff) access the premises of the infringer and collect evidence of the infringing conduct in cases where such evidence cannot reasonably be obtained other than by accessing the infringer's premises. This criterion – which is typically met in cases where the infringing product is not (yet) on the market or is not easily retrievable from the market, as well as in cases where infringement consists of the implementation of a patented process – is the one threshold that the patentee must meet when presenting its case for a search order before the court. Italian courts perceive search orders as evidentiary means only, ie, they will generally not look into the validity or the merit of the infringement case before granting one.

One upside of Italian search orders is that their actual execution and any connected activity that might need to be performed at the infringer's premises is court-mandated. While parties are authorised to attend the operations via their attorneys and patent counsels, the actual collection of evidence (including any appropriate investigation) is handled by the court bailiff and a court-appointed technical adviser (normally, a patent attorney). This reduces to a great extent the risk of objections being raised by infringers who might want to leverage potential procedural abuses when opposing the validation of the search order.

In granting the search order, the judge also schedules a hearing for its validation, during which the defendant has the right to present arguments and potentially object to the validation. The hearing takes place after the search operations, within 15 days from the issue of the search order.

Once the search order is validated, the collected evidence can be used to institute main infringement proceedings, which must be commenced within 31 calendar days or 20 working days (whichever accounts for the longest period) from validation. Failure to comply with these deadlines will extinguish the search and invalidate all the collected evidence. The collected evidence

can also be used to file parallel infringement proceedings in foreign jurisdictions.

The motion for a search may also include a request for the court to issue a seizure of infringing goods or a preliminary injunction. The patentee can make these requests contingent on the outcome of the search proceedings. If the search yields positive results, the case can then progress to an evaluation of validity and infringement on an inter partes basis. In this scenario, the deadline to file main infringement proceedings begins from the date a final order is issued regarding these additional remedies.

1.9 Declaratory Relief

Declaratory actions can be pursued both in the form of merits proceedings aimed at ascertaining non-infringement with a judgment susceptible to become res judicata, as well as in the form of urgent proceedings aimed at the grant of preliminary declaratory relief, ie, an order declaring on a preliminary and urgent basis that the allegedly infringing product or process does not infringe. In both cases, declaratory relief can be applied based on pure non-infringement arguments as well as on pure invalidity arguments (ie, the product or process at issue does not infringe in that the patent is invalid).

The threshold to access declaratory relief in the form of main proceedings is low as it will generally be sufficient for the alleged infringer to demonstrate that it holds and/or plans to develop an allegedly infringing product or process and to bring arguments supporting non-infringement and/or invalidity. The threshold to access declaratory relief in the form of preliminary proceedings (de facto reverse PIs) is higher because the petitioner also needs to establish a risk of suffering irreparable harm in the absence of the requested declaratory relief. This threshold is typically met by making the case that the allegedly infringing product is either being developed or inching closer and closer to launch and that the patentee has either implicitly or explicitly threatened infringement proceedings, including the filing of PI motion(s) from which the alleged infringer needs to be shielded.

Arrow declarations (declarations aimed at obtaining an assessment that an allegedly infringing product or process would implement prior art and, therefore, cannot infringe upon anything) do not exist in Italy. Arrow declarations have been devised (in the UK) for those situations where the feared infringement was in respect of a patent that was still at the application stage/awaiting formal grant, which made it impossible to file for declaratory relief as the latter would only become available upon patent grant. In Italy, declaratory preliminary relief can, however, be sought with respect to patent applications (just as much as PI relief can be obtained based on patent applications), which makes arrow declarations moot in Italian jurisdictions.

1.10 Doctrine of Equivalents

The doctrine of equivalence is available in Italy and the subject matter of a specific statutory provision, according to which “when determining the scope of protection conferred by a patent [based on the patent claims interpreted in light of both description and drawings] due account must be taken of any element that is equivalent to the elements identified in the claims” (see Article 52(3bis) Italian IP Code).

Italian case law has developed and applied several tests over the years. The test most widely used in the past relied on identifying the same “inventive idea” or same “core” of the patented invention in the accused product. Nowadays,

the two main criteria to assess equivalence followed by Italian courts are as follows:

- the obviousness test, according to which infringement by equivalence is found if the solution used to circumvent the literal wording of the claim when facing the need to solve the same technical problem would be obvious to the skilled person in light of the prior art and the common general knowledge; and
- the Function-Way-Result (FWR) test (or triple test), according to which the element of the accused product that makes it different from the claimed product is equivalent, and therefore does not avoid infringement, if it performs the same function, in substantially the same way, and so as to obtain the same result, compared to the element recited by the claim.

Italy does not have a prosecution history of estoppel, although discussions over statements rendered to the EPO examiner during prosecution often arise in patent litigation to determine the scope of protection. Italian courts often view the patentee's statements made during prosecution as not necessarily relevant for defining the scope of protection. Recent case law of the Supreme Court confirmed this approach and stated that interpreting a patent strictly on the basis of the prosecution history would introduce an inadmissible purely voluntarist hermeneutical element. In addition, some courts have stated that any relevance of the file history may (at most) be limited to claim amendments necessary to differentiate the claims from the prior art and overcome objections of novelty or inventive step. In contrast, amendments intended to overcome formal objections, such as added matter, by concerning solely the literal formulation of the text of the claims (and, hence, the literal scope of protection) cannot become relevant in order to exclude a potential equivalence assessment.

1.11 Clearing the Way

There is no obligation to "clear the way" ahead of a new product launch, although taking appropriate steps towards obtaining an assessment of invalidity or non-infringement can mitigate the risk of being reached by a PI. Institution of main revocation or non-infringement proceedings ahead of a new product launch is indeed standard practice for generics or biosimilars, at least in cases of patents at high risk of being enforced.

1.12 Experts

In Italian patent litigation, either in preliminary or merits proceedings, the evaluation of the relevant technical issues relating to validity and infringement is always subject to consideration by a court-appointed independent expert (Court Appointed Expert, CAE). The CAE is generally chosen amongst relatively senior Italian patent attorneys with specific experience in the given technical field and asked to produce a written opinion untangling the technicalities of the case. Acting as a court adviser, the CAE must be impartial.

Delivery of the CAE opinion is a stepwise process. First, the court will appoint the CAE by decree, who will be requested to appear at a specific hearing to give the formal oath and to hear the technical question under dispute that the CAE is called upon to solve. Then, a technical discussion will take place before the CAE through the submission of written briefs and replies to be prepared by the parties through their own counsel and technical consultants. The parties thus feed their arguments (mostly in writing) and technical evidence to the CAE. All relevant documents can be submitted to the

CAE even after the expiry of the deadline for the submission of evidence to the judge. The CAE may also conduct experiments or inspections, which the parties have a right to attend. After the technical discussion is completed, the CAE produces a preliminary opinion and asks the parties to comment on it. The parties review said opinion and provide their own observations (once again, mostly in writing). Further to this, the CAE produces a final opinion for the court, and another hearing takes place to discuss it.

The findings of the CAE are significant as they serve as a "primer" or guidance for the judge to adjudicate the case. Therefore, the technical phase before the CAE is crucial and must be conducted with the necessary care and deployment of effort by the parties. However, the CAE opinion is not binding, and the court retains the right to overrule it and/or appoint another CTA to discuss the same technical issue.

Parties are allowed to appoint their own experts and avail of their support when submitting their arguments and evidence to the CAE. However, these experts do not act as "expert witnesses". They are professionals (mostly patent attorneys skilled in the relevant technical field) who work alongside and cooperate with lawyers when preparing arguments for the CAE.

1.13 Use of Experiments

Experiments can be conducted (i) during the technical phase by the CAE or (ii) "out-of-court" by the parties. In (i), the CAE and the parties agree on the specific mechanisms to perform the experiments and the results thereof are included in the CAE report. The process is normally long and complicated as it entails agreeing on potentially complex experimental protocols, including the selection of an independent facility suitable to run and record the experiments. Costs can also become significant.

While (i) can be the one and only way in some cases, a party can submit its own experiments and related experimental report, which more often than not can become the basis for the discussion with the CTA, provided that the other party is given a chance to review the experimental protocol and raise potential objections/criticism. In this connection, Italian courts favour cooperation between the parties and are normally not impressed by defences that merely leverage the non-independent nature of a party's own experiments whilst not clarifying the specific technical reasons as to why these should not be held as reliable. Defences of this kind have sometimes been stigmatised as "reverse-fishing expeditions", ie, tantamount to asking the court to disprove the adversarial evidence.

1.14 Discovery/Disclosure

Usually, the disclosure of documents relevant for assessing validity and/or infringement issues occurs voluntarily by the parties or upon the issue of a specific court order. In the latter case, the interested party must have established that its claims are reasonably well-founded. Also, the documents or particular piece(s) of information for which disclosure is requested must be specifically identified, ie, the disclosure order cannot become a fishing expedition.

Disclosure orders are also commonly issued (at the request of the interested party) with respect to the infringer's books and accounting records when the time comes to calculate damages or infringer's profits.

Disclosure may occur through the acquisition of witness depositions or formal interrogation of the party or its legal representative; however,

only with reference to certain, specific pieces of information relating to the origin and the distribution network of the infringing goods or services.

1.15 Defences and Exceptions to Patent Infringement

Typical defences against infringement are non-infringement, invalidity, and exemptions set forth in Article 68 of the Italian IP Code, the most important being the experimental use exemption and the Bolar exemption. The experimental use exemption shields "activities carried out in a private, non-commercial environment and for non-commercial purposes, or of an experimental nature". The prevailing interpretation is that this exemption typically shields only those research and development activities aimed at achieving innovations, overcoming or winning over the patented product or process, ie, achieving new inventions.

The Bolar exemption instead covers studies and experiments directed at obtaining a marketing authorisation (MA) for a medicinal product (generics as well as originators) and the consequent practical requirements, including the preparation and use of the patented active substance in the amounts that are strictly necessary for the MA registration procedure. While Bolar litigation is hardly frequent in Italy, a seminal judgment issued in 2018 by the Milan Court clarified the boundaries of the Bolar exemption and, in particular, the conditions that must exist for the latter to be invoked by mere API manufacturers, thus bringing clarity over the issues that had been left open in the unresolved Astellas v Polpharma litigation. The 2018 judgment was confirmed by the Milan Court of Appeal in 2021.

Other available defences are the prior-user right defence, patent exhaustion, and violation of competition law and/or the contractual promise to offer FRAND licences. In contrast, a compulsory licence is generally not a defence, as Italian law expressly indicates that there is no obligation of a compulsory licence in favour of an infringer. As regards the prior-user right, the impact of this defence is rather limited as the law establishes that the prior user may continue to use the patented invention as long as such use remains within the limits of the prior use. According to the case law, this means that the prior user will not have the possibility to expand the invention's use beyond the specific use previously made, both from a quantitative and a qualitative perspective. Patent exhaustion may be used when the product claimed by the patent was put into the market by the patent holder or with its consent in the EEA territory. Finally, as stated above, violation of competition law and/or the contractual promise to offer licences on fair, reasonable and non-discriminatory (FRAND) terms may be a defence in the case of standard essential patents, depending on the specific remedy sought. In particular, an Italian court would follow the CJEU case law in determining the circumstances in which an injunction may be granted based on a standard essential patent.

1.16 Stays and Relevance of Parallel Proceedings

Italian patent law does not contain any provision requiring the stay of infringement or invalidity proceedings due to pending opposition proceedings before a patent office or related foreign proceedings unless both parties request it. Italian courts remain fairly independent in the face of foreign judgments but may, in any event, be inclined to consider and potentially draw guidance from decisions issued in parallel litigation abroad. Greater relevance is usually given to decisions rendered by European courts whose

procedural rules are more similar to the Italian ones.

1.17 Patent Amendment

A patent in the midst of litigation can be amended either by means of an application filed directly with the Italian Patent and Trademarks Office (ITPTO) or, if the litigation includes a claim of invalidity, directly in court by means of a declaration submitted to the judge. There are no time limits to do so. The Italian system does not contemplate the filing of auxiliary requests. No matter whether it is filed before the ITPTO or in court, an application to amend is a dispositive withdrawal of the broader scope of protection defined by the previous claim set.

1.18 Court Arbiter

Commercial chambers instituted in the 23 main court districts have exclusive jurisdiction over intellectual property cases, including pharma/life sciences cases. If the proceedings involve a foreign party, only the following 11 district courts have jurisdiction: Bari, Bolzano, Cagliari, Catania, Genoa, Milan, Naples, Rome, Trento, Turin and Venice. Italian commercial judges are usually selected among senior members of the judiciary system, and despite having a legal, non-technical background, most of them are specifically skilled in intellectual property matters (although their level of experience in the field may vary depending on the court seized).

The court having territorial jurisdiction to hear a patent infringement action is:

- the court of the domicile of the defendant; or
- the court of the place where the alleged infringement took/is taking place (ie, locus commissi delicti).

In case of invalidity/revocation actions, territorial jurisdiction is determined by reference to the right holder's elected domicile. These criteria allow the parties to forum shop to their courts of choice. The main and more experienced commercial chambers are those of Milan, Rome and Turin courts.

2. Generic Market Entry

2.1 Infringing Acts

Every act that involves putting the patented invention into effect and earning a profit or commercial advantage out of it can qualify as direct patent infringement. Direct infringement typically involves manufacturing, using, offering for sale, marketing, importing and exporting the allegedly infringing goods.

Infringement proceedings can also consist of indirect or "contributory" infringement acts. A finding of contributory infringement is subject to two conditions:

- the supply of means that are essential to put the patented invention into effect in a country where the invention enjoys patent protection; and
- the fact that the contributory infringer is aware, or should be aware using normal diligence, that those means are intended to be used for putting the invention into effect.

Contributory infringement applies regardless of whether the direct infringement occurs or is intended to occur in Italy or any other country where the invention is protected by patent law. This holds true even if the infringement targets individuals or entities covered by patent exemptions, such as the experimental exemption or the Bolar exemption. However, contributory

infringement cannot be established if the supplied means are considered staple commercial products unless the supplying party has actively encouraged the receiving individual or entity to engage in infringing activities.

Specifically regarding small molecule products, activities such as marketing and pre-marketing — like informative campaigns, distributing promotional materials, pre-order sales to wholesalers, distributors, or pharmacies, and storage — can constitute acts of infringement. This also includes listing the product as available in commercial databases (eg, Farmadati), submitting public or private tender offers, and awarding a tender. Conversely, merely submitting or obtaining marketing authorisation applications, initiating price negotiations for reimbursement, or approving a reimbursement price does not in itself warrant infringement proceedings unless there is evidence of an imminent market launch.

With regards to second medical uses, carving out (ie, skinny labelling) is not considered sufficient to rule out infringement of a second medical use patent. In the recent case of Novartis v Medac, 10 January 2022, the Court of Milan issued an injunction specifically ordering the generic to not only carry out and maintain a carve-out of the protected indication from the SmPC and PIL but also to take further steps to inform the various stakeholders in the market that the product could not be used in the protected indication.

2.2 Regulatory Data and Market Exclusivity

With regards to data and market exclusivity, Directive (EC) 2001/83 and Regulation (EC) No 726/2004 apply. Accordingly, medicinal products intended for human use benefit from an eight-year period of data protection and a ten-year period of marketing protection (the latter being extendable up to 11 years if the MA holder obtains authorisation for a new therapeutic indication which brings a significant clinical benefit compared to other therapies).

Orphan medicinal products are regulated by Regulation (EC) No 141/2000 and the Commission Regulation (EC) No 847/2000, which provides for a market exclusivity lasting ten years, to which two additional years may be added if the product is compliant with paediatric investigation plan (PIP).

Challenges to data and market exclusivity are not common. Two different fora could be relevant: if the challenge is brought against the regulatory authority that granted the MA in breach of regulatory exclusivity, the forum would be the Administrative Court. In the case of a challenge against a generic company violating the regulatory exclusivity regime, the ordinary courts would be competent.

2.3 Acceptable Pre-Launch Preparations

Italian law contemplates two different exempted uses of the patented product. First, Article 68(1) (a-bis) of the IP Code establishes that the exclusive right of the patentee shall not extend to acts that are performed for purely experimental purposes relating to the subject matter of the patented invention and to the use of biological material for the purpose of breeding or discovering and developing other plant varieties. An experimental purpose is deemed to exist whenever the activity aims at achieving technical progress that wins over the patented invention and its shortcomings, ie, at obtaining new inventions. Although rarely discussed before Italian courts, it is generally accepted that the experimental use exception also applies when the experimental activity is carried out in the framework of a busi-

ness activity and not just for the purpose of pure research.

Second, Italian law has also implemented Article 10(6) of Directive 2001/83/EC by introducing the Bolar exemption under Article 68(1)(b) of the IP Code. The Bolar exemption covers studies and experiments directed at obtaining a marketing authorisation for a medicinal product (generics as well as originators) and the consequent practical requirements, including the preparation and use of the patented active substance in the amounts strictly necessary for the MA registration procedure. While Bolar litigation is hardly frequent in Italy, a seminal judgment issued in 2018 by the Milan Court clarified the boundaries of the Bolar exemption and, in particular, the conditions that must exist for the latter to be invoked by mere API manufacturers, thus bringing clarity over the issues that had been left open in the unresolved Astellas v Polpharma litigation. The 2018 judgment was confirmed by the Milan Court of Appeal in 2021.

2.4 Publicly Available Drug and Patent Information

MAs are published in the Official Gazette of the Italian Republic, whereas information regarding pending MA applications is usually published on the official website of the Italian Medicinal Agency (AIFA). This information often includes the MA applicant, the active ingredient and the name of the medicinal product. Both these platforms are public and are, therefore, freely available.

Italy has no patent linkage, ie, market approval by the competent regulatory agencies (the EMA or AIFA, the Italian medicines agency) is not subject to the relevant product being clear of third parties' patent rights. Further, no communication is due to the patent holder regarding the details of pending MA applications. The patent holder can nevertheless submit Freedom of Information letters with the competent regulatory agency in order to obtain said information.

2.5 Reimbursement and Pricing/Linkage Markets

While Italian law does not have patent linkage mechanisms (see **2.4 Publicly Available Drug and Patent Information**), it does contemplate a provision according to which generic drugs can enter into price and reimbursement negotiations with AIFA but will not become NHS-reimbursable until the expiry of the related compound patent or supplementary protection certificate. In spite of being rather controversial and often referred to as establishing some sort of otherwise prohibited patent linkage, this provision – which was first introduced in 2012 – survived a significant legislative reform in 2022 and is still in place.

3. Biosimilar Market Entry

3.1 Infringing Acts

See the response set out in **2.1 Infringing Acts**.

3.2 Data and Regulatory Exclusivity

See the response set out in **2.2 Regulatory Data and Market Exclusivity**.

3.3 Acceptable Pre-Launch Preparations

See the response set out in **2.3 Acceptable Pre-launch Preparations**.

3.4 Publicly Available Drug and Patent Information

See the response set out in **2.4 Publicly Available Drug and Patent Information**.

3.5 Reimbursement and Pricing/Linkage Markets

The provision discussed in **2.5 Reimbursement and Pricing/Linkage Markets** is worded to explicitly apply to "equivalent products", ie, generics only. It is unclear whether it should also apply to biosimilars, as these are not "equivalents" by definition.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Supplementary Protection Certificates (SPCs) are available in Italy for medicinal products under the conditions set forth in EC Regulation No 469/2009. A thick body of national case law revolving around the grant or validity requirements of SPCs for medicinal products has formed over the years, fostered by the continuous stream of referrals decided by the Court of Justice of the European Union (CJEU) ever since the 1990s. As of today, the most controversial requirement is arguably Article 3(a) of the SPC Regulation and, in particular, the interpretation of the actual meaning of the wording "protected by the basic patent" following the Medeva (C-322/10), Actavis (443/12) and Eli Lilly (493/12) CJEU judgments. Recent case law from the Milan Court has also engaged with the interpretation of the meaning of the expression "active ingredient" as used in the SPC Regulation and eventually applied the principles set forth on the subject in the Forsgren referral (C-631/13).

Some controversy has also arisen as to whether the SPC Regulation allows the grant of a certificate to a patent holder who is not, at the same time, the holder of the relevant marketing authorisation. While it is known that this ground is being used in court proceedings (as part of broader invalidity claims encompassing other reasons for invalidity), Italian courts have yet to pronounce on the issue. With regards to Article 3(c) of the SPC Regulation No 469/2009, Italian case law has followed the ECJ's reasoning set out in the Actavis case (C-443/2012), stating that said article must be interpreted as precluding the patent holder from obtaining two separate SPCs: one in relation to the active ingredient of a medicinal product and another for the active ingredient in combination with a different active ingredient and marketed as a different medicinal product (see Court of Milan, 8 August 2014, in Darts-IP).

The implementation of the European legislation regarding SPCs also extends to the so-called SPC waiver introduced with EU Regulation No 2019/933. In particular, Article 5(2) lists a number of acts which do not require the SPC holder's consent, such as:

- the manufacturing of a product or medicinal product when aimed at export to third countries (so-called manufacturing waiver); and
- the manufacture of a medicinal product for storage in the Member State until the exclusive rights expire (so-called stockpiling waiver).

For the above-mentioned activities not to infringe on the SPC, the interested party must fulfil certain requirements, such as notifying the SPC holder and the Italian Patent and Trademark Office (IPTO) at least three months prior to the commencement of the manufacturing process.

4.2 Paediatric Extensions

Paediatric extensions are available in Italy, in line with Regulation (EC) No 1901/2006. Said Regulation established that the duration of the SPC

for a medicinal product may be further extended for six months if the medicinal product has to undergo a series of clinical trials under the Paediatric Investigation Plan (PIP), ie, a research and development programme aimed at providing clinical data to verify the usability of the medicinal product in the paediatric field.

4.3 Paediatric-Use Marketing Authorisations

Paediatric use marketing authorisations (PUMAs) are available in Italy, in line with Regulation (EC) No 1901/2006, which lays down rules on medicinal products for paediatric use.

PUMAs have been designed to promote the paediatric development of already authorised medicinal products, which are no longer covered by an SPC or a patent qualifying for an SPC and are dedicated marketing authorisations covering indication/s and formulation/s for medicines developed exclusively for use in the paediatric population.

According to Articles 30 to 38 of Regulation (EC) No 1901/2006, (i) PUMA applications have automatic access to the centralised procedure if the applicant chooses this route, (ii) the development of a PUMA must follow a paediatric investigation plan (PIP), and (iii) PUMAs benefit from the period of 8 plus 2 years of data and market protection. In addition, a medicinal product for which a PUMA has been granted may retain the name of another medicinal product containing the same active substance for which the same holder has been granted an MA for use in adults.

4.4 Orphan Medicines Extensions

Extensions for orphan medicines are available in Italy, in line with Regulation (EC) No 141/2000 of the EU Parliament and of the Council, and Commission Regulation (EC) No 847/2000, which set out the criteria and the procedure for the designation of a medicinal product as an orphan drug and attributes the granting of said designation to the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA). According to said provisions, for a medicinal product to be designated as an orphan drug, the following requirements shall be met:

- the medicinal product shall be intended for the diagnosis, prevention or treatment of a life-threatening or chronically/seriously debilitating condition affecting:
  - (a) no more than five in ten thousand persons (calculated at the EU level); or
  - (b) in any event, a relatively small population, so it is unlikely that, without incentives, the marketing of the medicinal product in the EU would generate sufficient returns to justify the necessary investment;
- there are no satisfactory methods of diagnosis, prevention or treatment of the condition in question that have been authorised in the EU, or if such method exists, the medicinal product is of significant benefit to those affected by that condition.

In order to speed up the availability of orphan drugs in Italy, Article 12(3) of the Balduzzi Decree (Law Decree No 158/2012, as amended by Law No 189/2012) provides that applications for classification and price reimbursement relating to orphan drugs and/or drugs of exceptional therapeutic importance may be submitted as soon as a positive CHMP opinion is issued, ie, also prior to the granting of the marketing authorisation itself. In addition, such applications for classification and price reimbursement relating to orphan drugs or drugs of exceptional therapeutic importance are examined by the Italian Medicines Agency (AIFA) as a matter of priority

within 100 days (see Article 12(5-bis) of the Balduzzi Decree).

Lastly, in the absence or pending centralised authorisation by the EMA, access to an orphan drug may be granted in Italy also on the basis of Law No 648/1996, Law No 94/1998 relating to the prescription of drugs on a nominal basis and Law No 326/2003 concerning the so-called "Compassionate Use".

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

Italian law does not require the patentee to give any undertaking as to damages in exchange for a preliminary injunction. However, the judge might order the petitioner to post a bond to cover potential liabilities in case the PI is lifted, but this provision is almost never applied in practice. This is because, unlike in other European jurisdictions, there is no automatic liability for the petitioner where the PI is granted and subsequently lifted following a finding of invalidity/non-infringement. Findings of liability on the part of the petitioner are only reached in exceptional cases of negligence and bad faith, ie, when it can be demonstrated that the latter has taken legal action out of due diligence.

Regardless of the type of proceedings (either ex parte or inter partes), PIs are immediately enforceable, and the possible subsequent appeal does not suspend the execution of the preliminary decision. However, the appeal judge may suspend the measure or order the petitioner to provide a bond where the PI would cause serious harm to the defendant due to supervening circumstances. The bond amount may vary depending on the case's value.

Italian PIs are "stable"; there is generally no need to file subsequent main proceedings to stabilise the PI if the latter has been requested or granted without ancillary measures (such as saisie-type measures or seizures). When merits proceedings are necessary because the PI is coupled with those other measures, then the deadline for commencing them may be set by the judge granting the PI. If the judge does not set such a deadline, merits proceedings must be commenced within 20 working days, or 31 calendar days if longer, from the grant of the order or its subsequent communication to the parties.

PIs are self-executing orders, and there is no need for the patentee to attend to any additional formality (such as making a payment) to enforce a PI. PIs often also include penalties.

5.2 Final Injunctive Relief

Enforcement of final injunctions follows the same rules as those outlined in **5.1 Preliminary Injunctive Relief** and applies to enforcing preliminary injunctions. Final injunctions are also immediately effective, although the defendant may file, together with the appeal, a motion requesting the Court of Appeal to order that the appealed judgment be stayed. The Court of Appeal decides whether or not to grant the request by assessing if there are serious and well-founded reasons (eg, the risk of insolvency of one of the parties). The decision on the suspension usually takes place during the first oral hearing. Upon showing an actual urgency, the defendant may file an ex parte motion before the President of the Panel, asking for an early decision on the matter. In this case, the President can suspend enforcement of the decision even prior to the first hearing. Regardless of the moment at which the court decides on the stay of the order (ie, prior to or during the first oral hearing), the decision is not appealable. The court may provide for the pay-

ment of a bond, the amount of which may vary depending on the value of the case.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

Although Italian law does not specifically contemplate the possibility of limiting/eliminating the scope of injunctive reliefs, Italian case law is quite responsive in applying a balance of convenience between the rights of the patentee and the interests of the parties affected by the injunction, including the interest of third parties such as healthcare providers or patients. These concerns are normally dealt with by the court, allowing phase-out periods, ie, a given timeframe during which the enjoined party can continue selling the infringing product or device, however, in such a way as to exit the market gradually. Phase-out sales, of which the injuncted party must notify the patentee, are normally considered when establishing damages/return of profits. Cases where injunctive relief was denied as a whole on account of proportionality/public interest concerns are unheard of.

5.4 Damages

Damages are calculated mainly in the form of the patentee's lost profits, namely the profits that the patentee would have earned on the infringer's sales had the infringement not occurred. To seek lost profits, the patentee must provide evidence of its cost structure. The "lost profit" is normally calculated based on the profit margin obtained by deducting variable costs from the revenues earned on the infringing sales, also referred to as the "contribution margin". Whatever the patentee's contribution margin, the patentee's lost profits are never lower than the reasonable royalty the infringer would have had to pay had it taken a licence on the patent. The reasonable royalty awarded in patent infringement proceedings is normally "punitive", ie, it is increased as opposed to market standard royalty rates to take a deterrent effect on board.

As an alternative to damages or, in any event, to the extent that they exceed lost profits, the patentee can always request the court to order the infringer to return all the profits it scored on the infringing sales/activities. The determination of the patentee's lost profits and/or reasonable royalty and the infringer's profits is normally assigned to a Court Accounting Expert in the framework of damage proceedings that are often separate/taken up after the issue of a first instance judgment on the merits of the case. The Italian system does not contemplate the award of exemplary/punitive damages.

5.5 Legal Costs

The successful party generally has a right to obtain reimbursement of the legal costs incurred in the course of the proceedings, namely:

- court fees;
- party expert fees; and
- part of the attorney fees.

These legal costs are assessed directly by the judge and reported in the order/judgment. Immediately after the publication of the decision, the party can forward the losing party a corresponding request for payment. With reference to attorney fees, Italian courts have a history of awarding them based on rates set forth by the Ministry of Justice. Recent legislative amendments have increased the discretionary power of Italian judges in awarding attorney's fees, leading to a marked improvement of the legal cost awards, although these are still a fraction of the costs that a party is likely to bear for its attorneys.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

Courts often consider the claimant's conduct prior to the commencement of the proceedings, especially when dealing with PI proceedings. In such cases, claiming alleged irreparable harm (ie, one of the requirements to obtain a PI) after having, for example, delayed in seeking relief or shown tolerance with respect to the infringer's conduct could undermine the possibility of obtaining the requested measures. Refusal to attempt amicable solutions is also a conduct that may be assessed negatively by the court, especially when it comes to merits proceedings.

6. Other IP Rights

6.1 Trade Marks

In Italy, disputes over trade marks in the pharmaceutical and life sciences sectors are quite common. When it comes to pharmaceutical trade marks, it's important to consider not only the provisions of the IP Code but also Legislative Decree 219/2006, which implemented Directive 2001/83/EC in Italy. Additionally, there are relevant non-binding regulations to keep in mind, such as Article 25 of the Italian Code of Self-Regulation for Marketing Communication and the Guidelines issued by the Ministry of Health.

For public health protection purposes, the name of the medicinal product must be submitted to AIFA (Italian Medicines Agency) for approval before its product is marketed. It may be either a creative name or a common or scientific name, but the creative name shall not lead to confusion with the common name (International Non-proprietary Name (INN) or, in the absence of the INN, the usual common name).

6.2 Copyright

Copyright matters are governed by Law No 633/1941. Copyright disputes are very rare in the life sciences and pharma sector and may concern images used on the packaging, leaflets and advertising material of medicinal products.

6.3 Trade Secrets

The rules governing trade secrets are Articles 98 and 99 of the IP Code, which identifies what can be regarded as a trade secret and the scope of protection thereof. Disputes on this matter in the life sciences and pharma sector are rare.

7. Appeal

7.1 Timeframe to Appeal Decision

Appeals against PI orders must be filed within 15 days from the communication of said order by submitting a motion for appeal and the relevant evidence in court. Appeal proceedings are held before a panel of three judges, with no leave to appeal. Once an appeal against a PI order is filed, the President of the Panel schedules by decree the hearing to discuss the appeal (which is usually held one month after the filing of the appeal) and grants the other party a deadline to file its brief in reply and relevant evidence. Appeal proceedings are generally shorter than first-instance preliminary proceedings, and the order is usually issued two or three weeks after the hearing. Appeal proceedings involve a full review of the case on the points raised by the parties in their briefs, and it is also possible that the panel deems it necessary to reopen the technical discussion of the case and appoint a new court expert. The panel may also take into account possible circumstances and grounds that have arisen after the PI order, and the parties may file new (ie, supervened) evidence, provided that the other party is given the possibility

to counter-argue. The decision issued by the panel is final and cannot be further appealed.

On the other hand, the term for appealing a first-instance judgment is twofold:

- where the winning party serves the judgment on the losing party, the appeal must be filed within 30 days from said service (the so-called short appeal time limit); or
- in the absence of any service of the judgment within six months from the issue of the first-instance judgment (the so-called long appeal time limit).

Unlike appeals against preliminary orders, main appeal proceedings are instituted by the service of the writ of summons and the statement of appeal on the other parties. Within ten days of such a service, the writ of summons and the relevant evidence must be filed in court. The other parties may file an interlocutory appeal or a statement of defence, along with the relevant evidence, within 20 days before the first case conference.

The filing of the appeal does not stay the execution of the first instance decision, which is always immediately enforceable. However, when serious and grounded reasons exist, also relating to the possibility of insolvency of one of the parties, the Court of Appeal may stay the execution of the appealed first instance decision, with or without ordering the posting of a bond. In addition, appeals are subject to preliminary scrutiny by the competent Court of Appeal on the point of compliance with the relevant procedural requirements, inadmissibility or manifest unfoundedness. Legislative Decree No 149 of 10 October 2022 amended said preliminary scrutiny, and Article 350bis of the Italian Civil Procedural Code now provides for a simplified procedure to be followed when the appeal is considered inadmissible, manifestly unfounded or, on the contrary, manifestly founded, or when the appeal is deemed of minor complexity or urgent.

The panel carries out a revision on the points of facts and law of the parts and points of the appealed decision that the parties have challenged in their briefs. The parties are not allowed to bring evidence or documents additional to those already filed in the first instance proceedings, except in the case of new (ie, supervened) documents or documents that were not filed within the specific deadlines for reasons that are not imputable to the parties. In these two latter cases, the court may authorise the filing of new documents.

Appeal proceedings are generally shorter than first-instance preliminary proceedings, usually lasting one to two years, and Courts of Appeal do not usually reopen the technical discussion unless absolutely necessary.

The relevant injunction is automatically lifted if a preliminary or final injunction decision is overturned on appeal or the patent is revoked. Unlike in other European jurisdictions, there is no automatic liability for the petitioner where the PI is granted and subsequently lifted following a finding of invalidity/non-infringement. Liability for the petitioner is only found if it can be demonstrated that the latter has taken legal action out of due diligence. As far as the writers are aware, liabilities were only found in exceptional cases of negligence and bad faith.

7.2 Appeal Court(s) Arbiter

Patent litigation appeals are heard and decided by a panel of three judges (comprising a rapporteur judge and a chairman). In case of appeals

against PI orders, the panel includes judges of the same Commercial Chamber to which the judge who issued the appealed preliminary order belongs, excluding the latter. In the case of appeals against first-instance decisions, the panel comprises three judges of the Court of Appeal that is territorially competent.

7.3 Special Provisions

Intellectual property proceedings are subject to the general provisions on appeal proceedings laid down by the Civil Procedural Code. There are no special provisions for Intellectual Property Proceedings.

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

In Italy, no particular forums/procedures are relevant to life sciences and pharma IP litigation, which are subject to the provisions regulating IP proceedings in general. Following the ratification of the UPC agreement, from 1 June 2023, European patents are also subject to the jurisdiction of the Unified Patent Court unless the patentee has opted out of their patent.

9. Alternative Dispute Resolution

9.1 ADR Options

Alternative dispute resolutions (such as arbitration proceedings and mediations) are possible in life sciences and pharma disputes. However, ADR is not a common way of starting or settling a life science case, and there is little or no practice in this respect. Concerning arbitration proceedings, there are two main issues to consider: the high costs involved and the ongoing debate over whether arbitrators can decide on the validity of patents. It is important to note that Legislative Decree No 149/2022 has expanded arbitrators' powers to include the issuance of preliminary measures during arbitration. However, it is also crucial to understand that before arbitration begins, the court retains exclusive jurisdiction to issue these preliminary measures.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

There is no specific consideration or particular scrutiny that is worth mentioning relating to the Italian jurisdiction.

11. Collective Redress

11.1 Group Claims

Group claims, also known as class actions, are possible in Italy. They are, however, very rare in life sciences and pharma disputes, and there is little or no practice in this respect.

As of May 2021, class actions are governed by Articles 840-bis to 840-sexiedecies of the Italian Code of Civil Procedure (CPC), whereas the provisions on class actions were previously contained in the Italian Consumer Code. These new provisions have strengthened this tool and broadened its scope to cover both contractual and non-contractual liability.

More in detail, according to Article 840-bis CPC, a non-profit organisation or association (registered in a specific list, established at the Italian Ministry of Justice), or each member of a relevant class, may bring an action against an undertaking or a public service or utility company to obtain a declaration of liability and an order for damages and restitution. The action must be

brought before the Commercial Chamber of the territory where the undertaking/company has its registered office.

The proceedings are quite streamlined. Once it has been established that the class action is admissible, the court issues an order and sets a deadline of 60 to 150 days to join the class action; the court proceeds in the most appropriate manner and without any particular formality to gather the relevant evidence and, at the end of the evidentiary stage, upholds or dismisses the claims by judgement.

When upholding the claims on which the class action has been based, the Court *inter alia*:

- ascertains the rights that have been breached and rules on the claims for damages and/or restitution;
- appoints a common representative of the claimants and a delegated judge; and
- sets a new deadline of 60 to 150 days from the date of the judgement's publication to join the class action.

Joining the class action can thus be done either before or after the judgment upholding the class action and is admissible even without the assistance of a lawyer.

The common representative of the claimants then prepares a schedule of the rights of each adherent, on the basis of which the delegated judge then orders the defendant undertaking/company to pay the sums due to each of the claimants.

JAPAN

Law and Practice

Contributed by:
Hirofumi Tada
Ohno & Partners

Contents

Ohno & Partners is one of the leading intellectual property law firms located in Tokyo, Japan. Currently, the firm has 29 attorneys highly specialised in IP litigation and prosecution. Despite its relatively small size, the firm has represented many difficult litigations and has established numerous case laws before the Supreme Court and the Intellectual Property High Court. Attorneys-at-law Mr Seiji Ohno and Mr Hirofumi Tada have handled many pharmaceutical litigations of both small molecules and biologics. For example, the current Japanese antibody patent practice is largely based on the case law established by the team. The firm promises to offer its clients the highest quality total solution service in all areas of intellectual property rights.

Author

Hirofumi Tada is an exceptionally experienced patent litigator at Ohno & Partners, who is admitted to practice both in Japan and in California. His experience covers more than a hundred patent litigations and encompasses the fields of pharmaceuticals, biotechnology, chemicals, AI, IoT, information technology, and software, among other fields. He is also familiar with US patent practices as he practised in the United States at Finnegan.

Ohno & Partners

Marunouchi Kitaguchi Bldg 21F
1-6-5, Marunouchi
Chiyoda-ku
Tokyo 100-0005
Japan

Tel: +81 3 5218 2331
Fax: +81 3 5218 2332
Email: info@oslaw.org
Web: www.oslaw.org/en/

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Patentee

A patentee may file an infringement action. Even when a patentee has granted an exclusive licence to a third party, they may file an action without consent or involvement of the licensee. A co-owner of a patent may file an infringement action without consent or involvement of the other co-owners.

Exclusive Licensee

An exclusive licensee may file an infringement action and seek both injunction and damages without consent or involvement of a patentee. Registration is required for a valid exclusive licence.

Non-Exclusive Licensee

Japan distinguishes a sole non-exclusive licensee (a licensor may not grant a licence to other third parties) from a usual non-exclusive licensee (a licensor may grant a licence to other third parties). A sole non-exclusive licensee may file an infringement action without consent or involvement of a patentee but can seek only damages, not an injunction. A usual non-exclusive licensee may not file an infringement action.

Standing for Invalidity Trial

A defendant may raise an invalidity defence in infringement litigation. Another option is an invalidity trial before the Japan Patent Office (JPO). A petitioner at an invalidity trial before the JPO must have some legal interests. This standing requirement is liberally construed by the court and is met if a petitioner's future business conflicts with the patent.

1.2 Defendants/Other Parties to an Action

Usually, suppliers, manufacturers, and local distributors/wholesalers are sued as defendants in infringement actions. It is highly unlikely that a patentee sues pharmacists, doctors, hospitals, or HRAs in Japan. Infringement and nullity proceedings do not require notification to, or involvement of, HRAs/IPOs.

1.3 Preliminary Injunction Proceedings

Preliminary Injunctions Are Available in Japan

Preliminary injunctions are generally available in Japan, but they are almost always inter partes and not quick.

Procedures

The procedures are very similar to those of permanent injunctions. Inter partes hearings will be held every one to two months, both parties are given opportunities to file allegations and evidence several times, and it takes about six to ten months in total to determine the case as Japanese judges carefully review both infringement and validity. Typically, a patent owner can initiate a preliminary injunction procedure soon after patent registration as far as the patent owner themselves is implementing the patent. Only one who has legal interest in the case can access the documents, and even such access may be prohibited upon request by a party showing that the part contains a trade secret.

Notification of Preliminary Injunction

A written demand for preliminary injunction is served on an opponent. It can be served by Express Mail Service on a foreign opponent together with an English translation, which takes only several weeks. However, some countries, including Germany and China, do not accept this type of service, and the service process takes a long time, sometimes more than a year. The

following proceedings may be delayed if the service is delayed. The opponent will be given opportunities to file counter-arguments and evidence. The court carefully reviews allegations and evidence submitted by both parties.

Requirements

The requirements for preliminary injunction are not so strict for patent infringement cases, and it will be granted if an accused infringer causes substantial harm to a patent owner by infringing a valid patent. The court usually finds substantial harm as long as a patent owner is implementing the patent by themselves.

Life Sciences Cases

Drug sales/manufacturing application itself does not constitute infringement in Japan. Thus, a patent owner typically must wait for a drug sales/manufacturing approval grant of infringing products for a preliminary injunctions grant.

1.4 Structure of Main Proceedings on Infringement/Validity

Infringement and Validity Are Bifurcated

Usually, both infringement and validity issues are disputed and reviewed in an infringement action before the courts.

Invalidity Trial Before Japan Patent Office

An accused infringer may separately file an invalidity trial proceeding before the Japan Patent Office (JPO).

Relationship Between Litigation and Invalidity Trial

In Japan, invalidity trial proceedings before the JPO are not restricted by parallel infringement litigation. Therefore, often the same invalidity issues are disputed in these two tracks. Some court judges tend to wait for the JPO decision if it will be granted in a few months, but others do not. Both first instance infringement litigation and the JPO invalidity trial outcomes may be appealed before the Intellectual Property High Court (the "IP High Court"). Inconsistencies between these two tracks are expected to be solved by the IP High Court.

1.5 Timing for Main Proceedings on Infringement/Validity

Statute of Limitations

Litigation

An injunction claim may be filed as long as the infringement of an unexpired patent continues. On the other hand, a damages claim should be filed within the earlier of:

- three years from when a patentee recognises infringement and an infringer; or
- twenty years from infringement.

Even after this period, an unjust enrichment claim can be filed if it is within the earlier of:

- five years from when a patentee recognises that the claim can be filed; and
- ten years from infringement.

Patent Office proceedings

Invalidity trial proceedings before the JPO can be filed even after patent expiration to inhibit a damages claim, which can be filed even after patent expiration within the statute of limitations explained above.

Service of Complaint/Written Demand

Litigation

A complaint should be served on the defendant in an infringement action. Usually, it is served via specifically certified mail. The service usually takes a few weeks if the defendant is a domestic entity. If the defendant is a foreign entity, the plaintiff must prepare a translation of the com-

plaint, and the service itself takes around three months to one year depending on the country where the defendant sits. The whole timeline of litigation will be delayed if service is delayed.

Patent Office proceedings

A written demand for invalidity proceedings before the JPO also should be served on the patent owner under similar requirements. However, a foreign patent owner is supposed to designate a Japanese patent administrator under the Japanese Patent Act, and a written demand against the foreign patent owner will be served on the patent administrator.

Timeline

Litigation

Oral hearings will be held every one to two months. Each party files briefs and evidence every few months. Judgment will be granted in about 12 months (injunction only) and about 18 months (injunction and damages). When a plaintiff seeks both an injunction and damages, a court discloses its preliminary conclusion at the end of the infringement and invalidity stage, and decides whether to proceed to the damages stage.

Patent Office proceedings

Typically, both parties have one or two opportunities to file assertions and evidence before an oral hearing. After the oral hearing, typically, a preliminary conclusion will be disclosed to give the opportunity to amend claims when the JPO considers that the patent claims should be invalidated. A decision will be granted about three to four months after the oral hearing. The total procedure takes about ten months.

1.6 Requirements to Bring Infringement Action

A patent must be granted and registered before filing an infringement lawsuit. There are no additional requirements such as validation or translation. The types of patents do not matter to the requirements for bringing an action.

1.7 Pre-Action Discovery/Disclosure

Japan does not have discovery at all. There are pre-action evidence preservation procedures, but availability is significantly limited due to the strict standard. Japanese courts generally accept materials legally obtained in other jurisdictions without limitation. In fact, US discovery under 28 USC Section 1782 is sometimes used to collect evidence for Japanese infringement actions.

1.8 Search and Seizure Orders

Search and seizure orders are not available for patent cases. A court grants a document production order under certain circumstances, but the availability and scope are substantially limited.

Recently, Japan newly established an inspection procedure which allows a court-appointed expert to inspect the manufacturing plant of an accused infringer. However, a patent owner first must show a certain level of probability of infringement to use this procedure, and the availability is limited.

Japanese courts generally accept materials legally obtained in other jurisdictions such as US discovery without limitation.

1.9 Declaratory Relief

Declaratory Judgment of Patent Dispute

Currently, Japanese courts are very reluctant to grant declaratory judgments for patent disputes.

Typically, a patent owner's intent to assert a patent with knowledge of details of accused products is required to support the necessity of a declaratory judgment. Once standing is found, the plaintiff of the declaratory judgment proceeding may typically seek judgment declaring non-infringement and/or invalidity.

Declaratory Judgment in the Life Sciences Field

In the life sciences field, the IP High Court recently denied the standing of a declaratory judgment filed by a generic drug company that filed a generic drug marketing application, holding that the application alone does not support the standing of a declaratory judgment, even though a new drug applicant expressed the possibility of patent assertion once the generic drug is approved. Under this decision, it is difficult to judicially resolve the patent issues between a new drug company and a generic drug company before a marketing approval grant.

However, the case law in this area is now under development, and the current practice might change.

Once a generic drug is approved (and price listed), a generic drug company likely may file a declaratory judgment action to seek declarations of non-infringement and invalidity. However, often a generic drug application cannot get approval due to the substance/dosage/usage patent of a new drug applicant, and the only option for a generic drug company will be invalidity trials before the JPO under such circumstances.

1.10 Doctrine of Equivalents

The Doctrine of Equivalents (DoE) in Japan has five requirements:

(1) the difference between a claim and an accused product is not an essential part of a patented invention;

(2) the invention can achieve the same purpose and function even with the replacement of the difference;

(3) a person ordinarily skilled in the art could easily conceive the replacement at the time of manufacture of the accused product;

(4) configuration of the product was neither publicly known nor easily conceived at the time of the patent application; and

(5) there are no special circumstances such as prosecution estoppel.

Requirement (3) is a significant difference from other jurisdictions such as the US. If a patent is granted to the replacement, it might be difficult to assert infringement under the DoE.

Requirement (4) corresponds to the Doctrine of Ensnarement or the Formstein Defence.

As to requirement (5), Japanese courts traditionally have adopted a "complete bar", meaning that, if a patentee excluded part of a claim during a prosecution history, the DoE does not apply to the excluded part whatever the reason for the exclusion was. However, a recent lower court decision adopts a more flexible approach, so future case law will need to be watched closely.

1.11 Clearing the Way

Japan basically does not have patent linkage as to a new drug, and there is no obligation to "clear the way" ahead of a new product launch. As a result, an approved new drug might be sued

for patent infringement after launch and can be excluded from the market later on.

1.12 Experts

Expert declarations often help parties persuade judges on technical issues both on infringement and validity. There are no specific requirements or procedures for evidence from experts, but the parties file written declarations instead of oral testimonies as Japanese procedures are highly focused on written evidence.

Sometimes, a party retains multiple experts, but too much focus on technical issues is usually not effective nor persuasive to the judges as most of them do not have technical backgrounds. However, it is highly important to choose a good expert trustworthy to Japanese judges.

The Japanese court separately appoints an expert who supports the judge's understanding of technical aspects of the case from a very early stage in the proceedings.

1.13 Use of Experiments

Japan does not have specific mechanisms or procedures to submit experimental results. Any forms of experimental result report are admissible as long as the person who prepared the report signs and/or seals it. As most Japanese judges do not have technical backgrounds, too complicated or lengthy a report is not preferable, and it is helpful to attach an expert declaration explaining the meaning of the results.

1.14 Discovery/Disclosure

Japan does not have discovery even in the post-action stages. There are document production order and inspection procedures, but their availability is limited, as explained in **1.7 Pre-Action Discovery/Disclosure**.

1.15 Defences and Exceptions to Patent Infringement

In Japan, invalidity is the most frequently asserted defence in infringement actions. Also, the consent/licence, prior use, exhaustion, and experimental use defences are available.

In the life science field, it is often asserted that an injunction is vastly against the public good, but it is highly unlikely that the court will refrain from granting an injunction based on this ground. Japan has a compulsory licence system, but it has never been granted.

1.16 Stays and Relevance of Parallel Proceedings

Japan does not have any official framework to stay litigation due to parallel proceedings. Some court judges tend to wait for the outcome of an invalidity proceeding before the JPO if it will be granted in a few months, but others do not. It is important to know your judge. Japanese courts generally do not wait for foreign proceedings.

1.17 Patent Amendment

Even during infringement litigation, a patent owner may file an amendment demand before the JPO. A patent owner is required to file an amendment demand to raise an amendment re-defence against an invalidity defence in the infringement litigation, so it is highly important to timely file an amendment demand before the JPO. (In some circumstances, such as when a patent owner cannot file an amendment demand due to the timing limitation imposed by the Patent Act, an amendment demand is not required to raise the re-defence.) The amendment re-defence is often used and effective in infringement actions.

1.18 Court Arbiter

All patent litigation cases in Japan are decided by a panel of three judges from IP-specialised

divisions. Japanese courts have divisions highly specialised in IP, but they are not specific to pharma/life sciences patent litigation.

There is little room for forum selection in Japan. Tokyo and Osaka District Courts have exclusive jurisdiction over first-instance patent-related cases. In some circumstances, patent owners may have options between these two courts, but there is no significant difference between these two courts. Tokyo District Court has more cases.

2. Generic Market Entry

2.1 Infringing Acts

Infringement Acts

Japan does not have infringing activities specific to pharmaceutical products. Thus, just like general patent infringement, selling, making, using, exporting, importing, and offering to sell generic drugs constitutes infringement. Other acts such as a marketing approval application or grant; an application for reimbursement, pricing or listing; a submission or award of tender; or offer to supply after patent term expiry usually does not constitute infringement.

Skinny Labelling

In Japan, an invention for a new use of a known substance is allowed as a product patent. This means that a product patent can be granted for a second medical use. But the scope of such a patent is not clear. The government agency (Ministry of Health, Labour and Welfare of Japan (MHLW)) grants approval for skinny labelling generics. However, it is not clear whether and to what extent skinny labelling avoids infringement.

Parallel Importation

Generally speaking, parallel importation usually does not constitute patent infringement unless (i) there is an agreement between a patent owner (or an entity substantially identical to the patent owner) and an original buyer which excludes Japan from the sales area, and (ii) the agreement is displayed on products. Depending on the facts, this exception may apply to drugs and the parallel importation may constitute patent infringement, although there is no case law and it is not clear.

2.2 Regulatory Data and Market Exclusivity

The typical data exclusivity periods in Japan are as follows:

- new substance drug – eight years;
- orphan drug – ten years;
- paediatric drug – ten years;
- new administration route – six years; and
- new indications, combinations, reclassifications – four years.

Challenges to data exclusivity is not common in Japan.

(To be more accurate, Japan does not have official data exclusivity periods. There are periods for post-grant re-evaluation of effect/efficacy and safety. The government agency, MHLW, substantially utilises these re-evaluation periods as data exclusivity periods.)

2.3 Acceptable Pre-Launch Preparations

Experimental use exception applies to generics, and activities necessary for clinical trial do not constitute infringement.

2.4 Publicly Available Drug and Patent Information

Japan does not have a publicly available list of new drug patents such as the Orange Book. New drug applicants voluntarily report sub-

stance and use patents covering their new drugs to the government agency, MHLW, so MHLW has a non-public list of patents. MHLW does not grant marketing approval if a generic drug is covered by substance or use patents of new drug applicants.

2.5 Reimbursement and Pricing/Linkage Markets

Japan does not have an official patent linkage scheme but has an informal process based on rules set by notifications by the government agency, the MHLW. The process has two stages.

In the first stage, the MHLW decides if a generic drug infringes (i) substance patent, (ii) effect/efficacy patent, or (iii) use/dosage patent of new drug applicants. In determining this, the MHLW relies on the non-public list of patents voluntarily submitted by new drug applicants. If there is no patent infringement found, it proceeds to the second stage.

In the second stage, the MHLW requests the generic drug applicant to negotiate and solve problems with other patents (such as dosage form or manufacturing method patents), if any, before the drug pricing. Even if the generic drug company fails to solve the problem, it usually does not matter to the price listing.

Typically, even if there is a second medical use patent, a generic drug application can be approved but the patented use should be excluded from the indication. Sometimes it is difficult to exclude the patented use from the label, and the generic drug application will not be granted.

Unlike ANDA in the US, Japan does not have specific litigation procedure for generic drugs. Thus, typically, a new drug applicant files litigation against generics after launch.

3. Biosimilar Market Entry

3.1 Infringing Acts

There are no differences between small molecules and biologics in terms of infringement acts, skinny label, and parallel importation.

3.2 Data and Regulatory Exclusivity

The data exclusivity periods of biologics are basically the same as small molecules.

3.3 Acceptable Pre-Launch Preparations

There are no differences between small molecules and biologics in terms of acceptable pre-launch preparations. Experimental use defence applies to biologics, and activities necessary for clinical trial do not constitute infringement.

3.4 Publicly Available Drug and Patent Information

There are no differences between small molecules and biologics in terms of publicly available drug and patent information. New drug applicants of biologics voluntarily report substance and use patents covering their new drugs to the government agency, MHLW, so MHLW has a non-public list of patents. MHLW does not grant marketing approval if a biosimilar drug is covered by substance or use patents of new drug applicants.

3.5 Reimbursement and Pricing/Linkage Markets

Japan does not have an official patent linkage scheme. The approval process for biosimilars is unclear, just internally being handled by the government agency, MHLW. But MHLW reveals that the process is similar to the two-stage process of generic drugs.

Unlike the Biologics Price Competition and Innovation Act (BPCIA) in the US, Japan does not have specific litigation procedures (ie, patent dance) for biosimilars. Thus, typically, a new drug applicant of biologics files litigation against biosimilars after launch.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Japan has a patent term extension for a shorter period (i) from the start of clinical trials to the marketing approval grant, and (ii) from the patent registration to the marketing approval grant. The maximum extension period for a patent is five years even if it takes longer than that.

Japan adopts a flexible policy in terms of patent term extension. Not only substance patents but also other patents such as use/dosage patents can be extended. Unlike the US and many European countries, each plurality of patents that covers the same product can be extended. If a plurality of marketing approvals were granted to product(s) covered by one patent, the extension of the patent can be possible for each approval as long as the subsequent approval is not encompassed by the preceding approval.

To obtain an extension, a patentee or its licensee must be the one who was granted marketing approval.

4.2 Paediatric Extensions

Patent term extensions specific to paediatric drugs are not available in Japan. But Japan gives a ten-year data exclusivity period for paediatric drugs.

4.3 Paediatric-Use Marketing Authorisations

Additional MAs are available for new doses for children, and a ten-year data exclusivity period is available for such new doses. The statute amendment for medicines specifically for children is currently under discussion in Japan.

4.4 Orphan Medicines Extensions

General patent term extensions are available for orphan medicines. A ten-year data exclusivity period is available for orphan medicines.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

In order to enforce a preliminary injunction, usually, a bond to secure potential damages to be incurred by an accused infringer is required. The bond should be deposited within the term determined by the court, which is usually three to seven days from notification of the amount. In determining the amount, the court considers various factors including the monetary size of the case and the degree of proof of infringement. The amount can be huge, especially in pharmaceutical disputes. Thus, preparing for bond well before the order is necessary. A patent owner may require a return of the deposit after it wins the patent infringement litigation.

Usually, the order is enforceable upon proving the deposit of the bond. It is necessary to initiate an ex-parte enforcement procedure before the court to enforce the preliminary injunction order against patent infringement. Typically, it will be enforced by imposing a duty to pay a certain amount of money during continuing infringement. It is also possible to have the drugs retained by a bailiff.

There is no term limitation for the effect of the preliminary injunction, but the accused infringer may require a patent owner to file litigation seeking a permanent injunction; and, if the patent owner fails to do so, the preliminary injunction will be revoked.

To stay the enforcement, the accused infringer must clearly show a change of situation denying the fulfilment of preliminary injunction requirements, irreparable harm, etc, in opposition or revocation procedure. A bond is required for the stay.

Also, if the preliminary injunction order allows payment of a certain amount of deposit to lift the order, such a deposit will be a basis for revocation of the order.

5.2 Final Injunctive Relief

Final injunctions are enforceable when they become final. Usually, it is when the final appeal before the Supreme Court is dismissed.

Final injunctions are enforced through separate enforcement procedures before the courts, but it is not so common to enforce permanent injunctions because many infringers obey the court decisions and voluntarily stop infringement. It will be enforced by imposing a duty to pay a certain amount of money during continuing infringement. Also, the disposition of product stock can be sought and enforced.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

The court does not have the discretion to award damages in lieu of an injunction. An accused infringer often makes public interest arguments to avoid an injunction, but the Japanese court does not accept such an argument and grants an injunction.

5.4 Damages

Damages are presumed based on:

- marginal profit of plaintiff's product multiplied by quantity of infringing products sold by defendant;
- marginal profit of defendant's product multiplied by quantity sold by defendant; or
- reasonable royalty.

The first two listed are available when a plaintiff could have obtained profits but for infringement. Typically, it means that the plaintiff has competing products, but it is not strictly limited to such a situation. A plaintiff may assert more than one of these three options, and the court adopts the highest amount among these.

A defendant may rebut the presumption by proving factors such as market difference, existence of other competing products, its marketing effort, or product features other than invention.

Special Damages for Pharma

Basically, there are no special damages for pharma cases. Japan does not allow treble damages for intentional infringement. However, if the drug price dropped because of infringing generic/biosimilar products, the dropped price can be included in damages.

Interest on Damages

Interest of 3% per year from each infringing activity is payable.

Damages Examination

The court first examines infringement and validity. Then, if the court thinks the accused infringer infringes a valid patent, the court discloses a preliminary conclusion, and then proceeds to the damages examination stage.

Timing of Damages Payment

Often, the damages are preliminarily enforceable soon after the first instance court judgment. Theoretically, it must be paid soon after the rendition of the judgment, but usually the accused infringer appeals before the IP High Court and seeks pending enforcement by depositing around 80% of the damages awarded by the first instance court.

Wrongful Injunction Damages

Usually, damages for a wrongful injunction are not available because an injunction is not enforceable until the judgment becomes final.

Third Party

Theoretically, a third party may seek damages (as long as they suffer damage caused by patent infringement) through the usual civil litigation, but it is not common in Japan.

5.5 Legal Costs

Court costs including court fees paid by a winning party are recoverable from a losing party, but they are often neglected because the amount is small.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

In patent infringement lawsuits, the court may not withhold or reduce relief as a penalisation for negative conduct from the plaintiff.

6. Other IP Rights

6.1 Trade Marks

Trade mark disputes in the life sciences and pharma sector are somewhat common in Japan. Just like the usual trade mark disputes, the cases are governed by the Trade Mark Act. Often, the main issue of the case is whether the trade mark causes consumer confusion about the product's source, just like usual trade mark cases.

The government agency notified rules for generic drug naming, so trade mark disputes between brand-name and generic products are not common.

6.2 Copyright

Copyright disputes are not common in the life sciences and pharma sectors in Japan. Potentially, the copyright of software (such as health tech software or drug research software) can be disputed.

6.3 Trade Secrets

Unlike the tech sector, trade secrets disputes are not so common in the life sciences and pharma sectors in Japan. However, such disputes could happen in the future because many pharma companies now develop and use AI or high-tech software for drug discovery. The Unfair Competition Prevention Act governs trade secrets disputes.

7. Appeal

7.1 Timeframe to Appeal Decision

An accused infringer may file an appeal within two weeks from the service of a preliminary injunction order. The appellate court reviews the case without deference. Also, opposition and revocation procedures are available, and the preliminary injunction will be vacated if the injunctive right no longer exists due to significant situation change after the preliminary injunction order grant.

Appeal Against Permanent Injunction

A defendant may appeal within two weeks from the service of a judgment ordering a permanent

injunction. A foreign defendant has an additional 30 days to appeal. The first hearing will be held within a few months from the appeal, and the judgment will be granted about six months after the appeal. The appellate court reviews the case without deference. A party who lost in the appellate court may file a final appeal before the Supreme Court although the success rate of the final appeal is as low as 1%.

7.2 Appeal Court(s) Arbiter

A panel of three judges from the IP High Court, which has exclusive jurisdiction over patent appeal cases, hears and decides a patent litigation appeal. The court often retains a court expert who supports judges' understanding of technical aspects of the case.

7.3 Special Provisions

Patent litigation is governed by the Civil Procedure Code, just like normal civil litigation. However, the court usually expects more professional litigation activities from both parties, and delayed submission of arguments and evidence might be more strictly evaluated than usual civil cases and can be dismissed.

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

A custom suspension to prevent the import of infringing products is available. A panel appointed by Japan Customs reviews the case, but they often wait for a court decision, especially in a complex case. Thus, the effectiveness of the custom suspension is often limited for a pharma patent owner. However, it is often effective for suspension based on a trade mark.

The JPO provides a procedure called "*hantei*" in which a panel of three examiners decides whether a product falls within the technical scope of a patent claim. However, this is not binding on the court, so its impact is very limited.

9. Alternative Dispute Resolution

9.1 ADR Options

ADR in the life sciences and pharma sectors is not common at all in Japan so far. Many patent owners choose litigation over mediation or arbitration, trusting formal court procedures. Recently, Tokyo and Osaka District Courts started providing arbitration services for IP-related disputes, but they are directed to simple cases and are not suitable for complex patent infringement disputes.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

Japan has not experienced antitrust cases regarding "pay-for-delay" or "reverse payment". However, depending on the facts of each case, "pay-for-delay" or "reverse payment" might violate Japan's Anti-Monopoly Act.

11. Collective Redress

11.1 Group Claims

There is no special system for group claims such as class action in Japan. However, patients may file a lawsuit as joint plaintiffs.

Trends and Developments

Contributed by:
Kenji Tosaki and Takahiro Hatori
Nagashima Ohno & Tsunematsu

Nagashima Ohno & Tsunematsu is widely recognised as a leading law firm and one of the foremost providers of international and commercial legal services. Based in Tokyo, Japan, the firm's overseas network includes locations in New York, Singapore, Bangkok, Ho Chi Minh City, Hanoi, Jakarta (associate office) and Shanghai. Nagashima Ohno & Tsunematsu also maintains collaborative relationships with prominent local law firms. In representing its leading domestic and international clients, it has successfully structured and negotiated many of the largest and most significant corporate, finance and real estate transactions related to Japan. In addition to its capabilities spanning key commercial areas, the firm is known for path-breaking domestic and cross-border risk management/corporate governance cases and large-scale corporate reorganisations. The over 500 lawyers of the firm work together in customised teams to provide clients with the expertise and experience specifically required for each matter.

Authors

Kenji Tosaki is a partner at Nagashima Ohno & Tsunematsu. He specialises in intellectual property (IP) litigation. He handles both IP infringement litigation and IP invalidation litigation before the IP High Court, the Supreme Court, District Courts and the Japan Patent Office. His IP expertise includes a wide variety of IP matters in many areas, such as telecommunications, electronics, social games and pharmaceuticals. He also provides pre-litigation counselling, including infringement/invalidity analysis.

Takahiro Hatori is an associate at Nagashima Ohno & Tsunematsu. His practice focuses on intellectual property (IP) and dispute resolution. He has experienced a variety of IP matters, especially dispute resolutions, and provided legal advice in relation to patent infringement, patent invalidation, trade marks, the Unfair Competition Prevention Act, copyright, and IP-related agreements.

Nagashima Ohno & Tsunematsu

JP Tower
2-7-2 Marunouchi
Chiyoda-ku
Tokyo 100-7036
Japan

Tel: +81 3 6889 7000
Fax: +81 3 6889 8000
Email: kenji_tosaki@noandt.com
Web: www.noandt.com/en/

Recent IP Litigation Cases, Judgments and Decisions in Japan

Overview

Japan has frequently (almost every year) amended its intellectual property (IP) laws in recent years. However, since 2023 there have been no amendments that are likely to have an impact on IP litigation in the life sciences and pharma field in Japan, and, therefore, it can be said that there have been no acts or amendments regarding IP laws in this field that are noteworthy and expected to influence the practice thereof in the last couple of years.

There were several notable IP litigation cases, judgments and decisions in the life sciences and pharma field in Japan from late 2023 to 2024. Among them, the following cases should be noted in particular.

- Vision Care and VC Cell Therapy v RIKEN et al (Petition for Compulsory Licence 2021–1).
- Tokai Ika v an individual, IP High Court, Case Number: 2023 (Ne) 10040 – Procedure for Calling for Opinions from Third Parties.
- Samsung Bioepis v Bayer HealthCare LLC. (Tokyo District Court Decision regarding Preliminary Injunction, 28 October 2024, Case Number: 2024 (Yo) 30029).

Overviews of the cases and some of the key points in each of the cases are provided below.

Vision Care and VC Cell Therapy v RIKEN et al (Petition for Compulsory Licence 2021–1)

Introduction

Under the Patent Act of Japan, a compulsory licence may be awarded (ie, an involuntary non-exclusive licence granted by the government) in three situations. The first situation is when a patented invention has not been worked properly in Japan for three years or more (Article 83(1) of the Patent Act). The second situation is when a person's patented invention cannot be worked without using another person's patented invention (Articles 92(1) and (2) of the Patent Act). In these cases, one party may request discussions with the other party regarding the granting of a non-exclusive licence, and if no agreement is reached or discussions cannot be held, the party may file a petition for a compulsory licence with the Commissioner of the Japan Patent Office (JPO) (Articles 83(2) and 92(3) and (4) of the Patent Act). The third situation is when the working of a patented invention is particularly necessary for the public interest (Article 93(1) of the Patent Act). In this case, a person intending to work the patented invention may request discussions with the patentee regarding the granting of a

non-exclusive licence, and if no agreement is reached or discussions cannot be held, the person may file a petition for a compulsory licence with the Minister of Economy, Trade and Industry. Before making a decision in response to a petition for a compulsory licence, the opinions of the Industrial Property Council, an administrative committee established under the Ministry of Economy, Trade and Industry, must be sought.

On 13 July 2021, Vision Care Inc. and VC Cell Therapy Inc. (collectively, the "Petitioners") filed a petition for compulsory licence to work Japanese Patent No 6518878 (Title of Invention: "Method for producing retinal pigment epithelial cells") (the "Patent Right"), which is jointly owned by RIKEN, Osaka University and HEALIOS K.K. (collectively, "Counterparties"), under Article 93(2) of the Patent Act (Petition for Compulsory Licence 2021–1; the "Petition"). The Petition was handled by the Invention Practice Subcommittee (the "Subcommittee"), established under the Industrial Property Council. After nearly three years, the Petition was withdrawn following a settlement agreement reached by the parties on 30 May 2024 (the "Settlement Agreement"). This article introduces the course of events related to the Petition. Since the discussions before the Subcommittee are not publicly available, this article relies on the Settlement Agreement, including the attachments thereto, which the parties posted on their website.

According to the "Operational Guidelines for Compulsory License System", the following two situations, among others, are considered as situations where the working of a patented invention is particularly necessary for the public interest (Article 93(1) of the Patent Act). The first is when it is particularly necessary in fields directly related to people's living, such as the preservation of life and property of the people, and the construction of public facilities. The second is when not granting a non-exclusive licence for the patented invention hinders the sound development of the relevant industry, and as a result, substantially harms people's living.

Facts

As mentioned above, the Petition was filed by the Petitioners on 13 July 2021. In response to the Petition, RIKEN stated on 4 October 2021, that it was willing to discuss this matter with the Petitioners, Osaka University and HEALIOS. Osaka University responded on 5 October 2021, that it had no opinion at that time. HEALIOS requested on 6 October 2021, that the Petition be dismissed.

On 2 December 2021, the first meeting of the Subcommittee was held to deliberate on the Petition. A total of 22 meetings of the Subcommittee were held before the settlement was reached. During that time, the Petitioners and HEALIOS each submitted written opinions and evidence in response to requests from the Subcommittee.

While the Subcommittee deliberated on the Petition and made its preliminary assessment, the Subcommittee reached the preliminary view that it would be desirable for the parties to settle the case through self-initiated discussions between the parties. Based on this view, one member of the Subcommittee, a former Chief Judge of the IP High Court, took the lead and informed the Petitioners, the representative director of Vision Care, HEALIOS, and Sumitomo Pharma Co., Ltd. (Sumitomo Pharma and HEALIOS were jointly developing a treatment using retinal pigment epithelial (RPE) cells derived from allogeneic iPS cells.) (within the bounds of confidentiality) that, based on the preliminary view of the Subcommittee, there was a possibility that granting a

non-exclusive licence would be awarded in part. The relevant parties were then encouraged to engage in discussions to seek a settlement.

As a result of further discussions, the relevant parties (including the Petitioners and the Counterparties) reached the Settlement Agreement on 30 May 2024. Under the Settlement Agreement, the Counterparties covenant not to exercise the Patent Right against a certain range of acts in which the Respondents are involved, on the condition that the term of the no-assertion of the Patent Right will remain in effect from the conclusion of the Settlement Agreement until the expiration of the Patent Right, and the number of cases shall be limited to 30 cases in principle.

Comments

This case is significant because it was the first reported case where a compulsory licence was sought based on the particular necessity for the public interest. It is also significant because the key member of the Subcommittee suggested that a compulsory licence might be awarded in part after considering the arguments and evidence submitted by the parties.

Tokai Ika v an individual, IP High Court, Case Number: 2023 (Ne) 10040 – Procedure for Calling for Opinions from Third Parties

Background

The Patent Act of Japan provides that, in a lawsuit regarding infringement of patent rights or utility model rights (only in the first instance and the appellate instance), if the court finds it necessary upon the petition of a party, and after hearing the opinions of the other party, the court may call for the submission of written opinions from the general public regarding the application of the Patent Act to the case and other matters, setting a reasonable and specified period for submission (Article 105-2-11 of the Patent Act). This procedure ("Procedure for Calling for Opinions from Third Parties") was established by the amendment to the Patent Act in 2021. Among the written opinions submitted by third parties, the court can only use those submitted as evidence by a party as a basis for its judgment, and the general public may have access only to those submitted as evidence.

The Procedure for Calling for Opinions from Third Parties was carried out for the first time in 2022 in the appellate instance of Dwango v FC2 et al (IP High Court, Case Number: 2022 (Ne) 10046). The second Procedure for Calling for Opinions from Third Parties was carried out by the IP High Court in 2024. This article briefly introduces this second one.

Facts

The Plaintiff (Tokai Ika K.K.) owns the patent right entitled "Composition for Promoting Increase in Subcutaneous Tissue and Subcutaneous Adipose Tissue" (Japanese Patent No 5186050) (the "Patent Right"). The patented invention at issue is the invention claimed in Claim 4, which is a dependent claim to Claim 1. Claims 1 and 4 read as follows.

Claim 1: A composition for promoting an increase in subcutaneous tissue, characterised in that it comprises autologous plasma, basic fibroblast growth factor (b-FGF), and fat emulsion.

Claim 4: A composition for breast augmentation, comprising a composition for promoting increase in subcutaneous tissue according to any of Claims 1 to 3 used for breast augmentation.

The Defendant is a physician who operates a plastic surgery clinic (the "Clinic"). At the Clinic, the Defendant provided breast augmenta-

tion surgery. In the course of the surgery (the "Surgery"), the Defendant (a) produced medicine by mixing (i) plasma from which the cellular component of blood taken from the recipient was removed, (ii) "Fiblast® Spray", which is a genetically modified trafermin product, (iii) "Intralipos®", which is a fat emulsion, and other medicines, and (b) administered the medicine into the recipient's chest by injection. Whether a single drug made by mixing all of (i) through (iii) was used, or whether two separates were used sequentially, is disputed between the parties.

Judgment in the First Instance (Tokyo District Court, Judgment 24 March 2023, Case Number: 2022 (Wa) 30029)

The Plaintiff sued the Defendant seeking compensation for damages, arguing that the act of manufacturing the above-mentioned medicine for use in the Surgery constitutes working of the patented invention (production of the patented product).

The Tokyo District Court did not find that the Defendant prepared medicine containing cell-free plasma gel, trafermin, and Intralipos® at the same time and administered it to the recipient. Therefore, the Tokyo District Court dismissed the Plaintiff's claim. The Plaintiff filed an appeal to the IP High Court.

Procedure for calling for opinions from the third parties

The IP High Court decided to call for opinions from third parties. The matters for which opinions are requested are as follows.

- Should the Patent be invalidated through a patent invalidation trial on the ground that it was granted for "an invention lacking industrial applicability" (Article 29(1) of the Patent Act)?
- Does the Patented Invention fall under "a medicinal invention that is to be manufactured by mixing two or more medicines (medicine meaning a product used for diagnosis, therapy, treatment or prevention of human diseases) being mixed together" (Article 69(3) of the Patent Act)?
- Assuming that the ingredients (i) through (iii) above fall under "autologous plasma", "basic fibroblast growth factor (b-FGF)", and "fat emulsion" of the patented invention respectively:
  - (a) does the act of the Defendant, a physician, instructing nurses or assistant nurses without issuing of a prescription to prepare the medicine (the "Mixed Medicine") by mixing all of the ingredients (i) through (iii) together for use in the Surgery at the Clinic fall under "the act of preparation of a medicine as per a physician's or dentist's prescription" (Article 69(3) of the Patent Act)?
  - (b) can it be said that the effect of the patent right does not extend to the act of preparing the Mixed Medicine by the Defendant, a physician, for some reason, while the act is closely related to medical treatment?
  - (c) when the Defendant, a physician, uses in the Surgery a medicine containing the ingredients (i) and (ii) above, and another medicine containing the ingredient (iii) above separately in the Clinic and these ingredients (i) through (iii) are mixed in the body of the recipient, does the Surgery performed by the Defendant fall under a "production" of the "composition" pertaining to the patented invention?

Comments

This case is noteworthy because there have been only two cases where the Procedure for Calling

for Opinions from Third Parties was implemented. In addition, there have not been many cases involving disputes over the interpretation and/or application of "an invention lacking industrial applicability" (Article 29(1) of the Patent Act) or Article 69(3) of the Patent Act.

This case is pending before the Grand Panel of the IP High Court. Note that at the IP High Court, cases are heard by a panel of three judges but in cases that address a particularly important issue, a Grand Panel of five judges oversee the proceedings and render the judgment. According to the website of the IP High Court, the Grand Panel of the IP High Court will render a judgment on 19 March 2025.

Samsung Bioepis v Bayer HealthCare LLC. (Tokyo District Court Decision regarding Preliminary Injunction, 28 October 2024, Case Number: 2024 (Yo) 30029)

Background

Japan does not have a statutory patent linkage system. In other words, there is no statute requiring the health authority to consider whether there is any patent that may cover a generic or a biosimilar when determining whether to issue marketing authorisation of that generic or biosimilar. Even so, the health ministry of Japan, the Ministry of Health, Labor and Welfare (the MHLW), does consider at its own discretion in practice. The MHLW relies on a letter (the "MHLW Letter") which it issued to the prefectures stating that when reviewing a marketing authorisation application for a generic or a biosimilar:

- if the manufacture of the active ingredient of the brand-name drug is not possible due to the patent covering the active ingredient, marketing authorisation for a generic shall not be issued; and
- if a patent covers certain indications, or dosage and administration ("Indications, etc") of the brand-name drug but it is possible to manufacture a drug with other Indications, etc, marketing authorisation for a generic or a biosimilar may be issued without the Indications, etc covered by the patent.

It should be noted that the MHLW Letter is an internal administrative document and does not have any legally binding effect.

Based on the MHLW Letter, when a marketing authorisation application for a generic or a biosimilar is filed, the MHLW takes into account the relevant patents that cover the brand-name drug, and if the MHLW believes that the generic or the biosimilar would infringe the patents, the MHLW does not issue marketing authorisation.

Facts

Bayer HealthCare LLC. (the "Respondent") owns the Japanese Patent No 7320919 titled "Treatment of age-related macular degeneration with a small active choroidal neovascularization lesion" (the "Patent"). The Patent was registered on 27 July 2023. Claim 1 of the Patent covers a pharmaceutical composition comprising aflibercept, as a VEGF inhibitor, for use in the treatment of a certain group of wet age-related macular degeneration (wAMD) patients. Bayer Yakuhin, Ltd, an affiliate of Bayer HealthCare, started selling EYLEA solution for IVT inj. 40mg/mL (the "Respondent's Product") in November 2012.

Global Regulatory Partners GK (GRP) filed a marketing authorisation application for Aflibercept intravitreal injection solution 40 mg/mL GRP (SB15) (the "Claimant's Product") as a biosimilar correspondent to the Respondent's Product on 31 May 2023. The Claimant's Product was to be produced by Samsung Bioepis (the "Claim-

ant"). According to the draft package insert of the Claimant's Product which was submitted by GRP, "age-related macular degeneration with choroidal neovascularization in the subfoveal area" is included in the indications and usage of the Claimant's Product. According to the parties, "age-related macular degeneration with choroidal neovascularization in the subfoveal area" falls under wAMD according to the Patent.

The Claimant, GRP and the MHLW had a meeting on the aforementioned marketing authorisation application by GRP on 21 September 2023, and, in the meeting, the MHLW referred to an opinion by the Respondent. The Claimant asked the MHLW about the opinion. In response, the MHLW responded by email on 27 December 2023 that the MHLW received Respondent's opinion in response to the MHLW's inquiry stating to the effect that, if marketing authorisation for a biosimilar correspondent to Eylea is issued and the biosimilar is marketed, it would constitute an infringement of the Patent (the series of information-providing activities by the Respondent to the MHLW and the Pharmaceuticals and Medical Devices Agency (the PMDA) are referred to as the "Notification").

The Claimant filed with the Tokyo District Court an application for preliminary injunction enjoining the Respondent from notifying the MHLW or the PMDA that the Claimant's Product infringes the Patent, arguing that the Notification falls under an Unfair Competition set forth in Article 2(1)(xxi) of the Unfair Competition Prevention Act (the UCPA) and the business interests of the Claimant have been harmed by the Unfair Competition.

Article 2(1)(xxi) of the UCPA sets forth that "acts of making or disseminating a false statement that is to harm the business credibility of another person in a competitive relationship" are considered as an "Unfair Competition."

Decision of the Tokyo District Court

The Tokyo District Court rendered a decision dismissing the application for preliminary injunction on 28 October 2024. Regarding the key issue in the case, ie, whether an act of making a false response under the patent linkage system to the effect that a generic would infringe a patent pertaining to the brand-name drug falls under an unfair competition" stipulated in Article 2(1)(xxi) of the UCPA, the Tokyo District Court held as follows.

"The act of a patentee pertaining to the brand-name drug falsely responding that a generic would infringe the patent pertaining to the brand-name drug under the patent linkage system would be deemed to interfere with fair competition among businesses and would fall under an "Unfair Competition" set forth in the UCPA if the patentee aims to put the applicant of the marketing authorisation application for the generic in an unfavourable position and to seek to place the patentee in a competitive advantage. In light of this, "if there are special circumstances where an act of the patentee pertaining to the brand-name drug providing a false response under the patent linkage system to the effect that a generic infringes the patent pertaining to the brand-name drug is considered as seriously lacking reasonableness in light of the purpose and objective of the patent linkage system, it would be reasonable to consider the act to fall under an "Unfair Competition" set forth in Article 2(1)(xxi) of the UCPA as an act of making a false statement that is to harm the business credibility of the applicant of the marketing authorisation application for the generic, who is in competition with the patentee."

The court then moved forward to determine whether the notification that a biosimilar correspondent to Eylea would constitute an infringement of the Patent is a false statement, and concluded that it was a false statement because while the Patent covers a pharmaceutical composition comprising aflibercept for use in the treatment of a certain group of wAMD patients, the Claimant's Product does not specifically target that specific group of wAMD patients and would not infringe the Patent.

The court then proceeded to the determination of whether there are special circumstances where the act is considered as seriously lacking reasonableness in light of the purpose and objective of the patent linkage system. The court pointed out the following.

- It cannot be understood that the Respondent's allegation that the Claimant's Product infringes the Patent is totally unreasonable because the Claimant's Product would be partly used for the treatment of the specific group of wAMD patients and there had been no Supreme Court precedent that makes the Respondent's argument totally groundless.
- There had been no court precedent which addressed whether the provision of information by a patentee, etc, under the patent linkage system in Japan falls under an "Unfair Competition" set forth in the UCPA.
- Similar patent infringement actions had been filed worldwide in which the issue of whether a biosimilar infringes the Patent is disputed and this case is a part of the global dispute, so it was inevitable that the Respondent made the argument that the Claimant's Product infringes the Patent to the MHLW and the PMDA.

Based on the above-mentioned analysis, the court concluded that "unless the Notification is repeatedly made in the future, it cannot be said that the Notification is considered as seriously lacking reasonableness in light of the purpose and objective of the patent linkage system, and the aforementioned special circumstances cannot be found."

Comments

This decision is noteworthy because there had been no court decision addressing the issue handled by the court, ie, whether an act of a patentee pertaining to the brand-name drug providing a false response to the effect that a generic infringes the patent pertaining to the brand-name drug under the patent linkage system falls under an "Unfair Competition" set forth in Article 2(1)(xxi) of the UCPA. The Tokyo District Court set the criteria to handle the issue for the first time. However, it should be noted that this decision is that of the court of first instance and the upper court may make a different decision. As this issue is not widely discussed, it would be better to keep checking further discussions by scholars and practitioners.

MEXICO

Trends and Developments

Contributed by:
Carlos Perez de la Sierra and Ciara Cleary
Calderón & De La Sierra

Calderón & De La Sierra was established in Mexico City in 1982 as a trade mark firm and has grown to incorporate a full range of intellectual property services. The firm now has a multidisciplinary practice consisting of expert professionals and lawyers focusing on a broad array of cutting-edge matters for clients in different technical areas such as mechanics, electrical engineering, computational science, communications, biochemistry, pharmaceuticals and chemistry. The patent department at Calderón includes a team of lawyers and technology specialists with scientific and technical degrees, who together provide creative, strategic and robust counselling for the protection of patent rights. The firm acts for a client roster featuring companies from the consumer products manufacturing, food and beverage, and life sciences sectors.

Authors

Carlos Perez de la Sierra is the founding and managing partner of Calderón & De La Sierra and has devoted his professional life to intellectual property matters. While his principal activities have traditionally encompassed litigation and enforcement of IP rights, he has also been active in counselling, prosecution, searches and strategy for both patents and trade marks. He frequently lectures in Mexico and abroad on a wide range of IP issues and has actively collaborated with the Mexican Patent and Trademark Office and in professional associations concerned with intellectual property, in legislative efforts, and in educational events pertaining to IP issues.

Ciara Cleary is a senior associate in the patent department at Calderón & De La Sierra. Her principal activities at the firm involve analysing complex patent issues pertaining to the biotechnology and pharmaceutical areas. Her daily work also includes matters relating to patent prosecution, freedom to operate, invalidity opinions, and patent litigation. Ciara brings her specialist education in biochemistry and genetics to the table, as well as her legal experience in biotech and pharmaceutical intellectual rights, giving the prosecution and litigation team at the firm wide-ranging confidence in numerous technical fields.

Contributed by: Carlos Perez de la Sierra and Ciara Cleary, **Calderón & De La Sierra**

Calderón & De La Sierra

Avenida Santa Fe 481 – PH
Lomas de Santa Fe
05349
Mexico City
Mexico

Tel: +52 55 5047 7500
Email: cps@cyslaw.mx
Web: www.cyslaw.mx

The Latest in Mexican Life Sciences and Pharmaceutical Intellectual Property Litigation

Biologics research and manufacturing has increased rapidly in the last few decades and shows no sign of slowing down. This recent increase in the development of biologics for therapeutic use has driven substantial growth in the global litigation sector. Naturally, the expanding area of biologics has also led to increased interest in the development of biosimilars. While litigation continues for small molecules, cases concerning the complex technologies behind biologics have also begun to creep into the Mexican courts, mainly due to the increased use of biologics and biosimilars in the Mexican market. This is not surprising, given that Mexico represents a large market opportunity for many international companies due to its proximity to the US, particularly for the manufacture and sale of biosimilars. In this article, we explore the latest trends and emerging issues shaping life science litigation in Mexico today.

Legal standing to file invalidation actions: third-party invalidation filings have now become more difficult

Post-grant invalidation actions are available in Mexico. These are usually filed with the Mexican Patent Office, also known as the Mexican Institute of Industrial Property (*Instituto Mexicano de la Propiedad Industrial*, or IMPI), to counter a claim for patent infringement initiated by the patentee. A defendant in such a claim has automatic legal standing to start invalidation proceedings against the corresponding patent. However, a third party can also file an invalidation action without the presence of an infringement action, provided that they can demonstrate sufficient legal standing. When there is no claim for infringement, the plaintiff will be considered to comply with this legal standing requirement if they can show that they have suffered direct harm as a result of the granting of the patent.

In previous years, the simple act of being a company involved in the pharmaceutical field was sufficient to prove legal standing in a pharmaceutical case. However, this is no longer the case. After considerable debate in the courts, new decisions have made this requirement much stricter, making it much more difficult for a third party to prove legal standing without an infringement action.

The Supreme Court of Mexico recently confirmed legal standing as a valid requirement in a decision resulting from a challenge asserting that the requirement should have been considered to misrepresent constitutional provisions.

Generally, to prove legal standing in civil law proceedings, the plaintiff must show that a fact or set of facts is capable of harming or affecting the exercise of their rights. Being a defendant in a patent infringement action is sufficient to show legal standing to counterclaim and seek to invalidate the patent. However, in the absence of an infringement action, the simple fact of being a pharmaceutical company is no longer sufficient to prove legal standing.

During previous years, for pharmaceutical patents, a third party could establish standing by showing that it conducted industrial or commercial activities in the pharmaceutical industry. Unfortunately, this is no longer sufficient and more detailed evidence is now required. According to a decision by the IP Branch of the Federal Tribunal, in the absence of an infringement action, third parties had only the following two options to prove legal standing to institute invalidation proceedings against a pharmaceutical patent:

- As a first option, a third party can assert that it has legal standing if it has filed a request for market approval of a product covered by the relevant patent with the regulatory authority, the Federal Commission for Protection Against Sanitary Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios*, or COFEPRIS), which entails a tacit admission that the product for which approval is being sought would infringe on the patent.
- A second option occurs if a third party has applied for market approval for a pharmaceutical product and the regulatory authority has objected on the grounds of potential infringement of a patent under the Linkage System. This entails that the Mexican Patent Office has provided relevant information drawing attention to the potential infringement. This option does not therefore entail an admission of infringement on the part of the third party.

The decision by the IP Branch of the Federal Tribunal was recently confirmed, albeit with a minor yet relevant difference on how to demonstrate sufficient legal standing. In the wording of the decision, Justice Farjat failed to list specific circumstances which could be used to demonstrate legal standing, leaving third parties free to come up with appropriate arguments and evidence to demonstrate how the relevant patent prevents them from exercising earlier rights. This method, which diverges from the two options originally provided by the IP Branch of the Tribunal, consists of the third party demonstrating the development or sale of an asset which may be in conflict with the claimed subject matter of the patent. This has proved successful and can be considered a third option for an interested third party wishing to pursue an invalidation action.

In any case, because of the considerations offered in the decision by the Supreme Court of Justice, legal standing is to be analysed on a case-by-case basis, albeit it is no longer valid to assert legal standing based on the condition of being a pharmaceutical company.

The challenges surrounding the inclusion of process patents in the Mexican Linkage System

As is well known, the manufacturing process plays an essential role in the development of biologics. The manufacturing processes for such biologics involve many steps, such as cell line development, cell culturing conditions, bio-reactor conditions, purification, and quality control testing. These processes are sensitive to change and any modification in one or more of these complex steps runs the risk of changing the quality and/or quantity of the final biologic product. Thus, it is no

surprise that process patents now play a central role in the litigation of biologic patents.

Despite the important role that processes play in biologics and their IP protection, the Mexican Patent Office does not consider these types of patents as listable in the Mexican Linkage System. The Mexican Linkage System's purpose is to establish a direct line of communication between the Mexican Patent Office and the Mexican regulatory authority to prevent the marketing authorisation of generic versions of patented products. Under the Linkage System, the Mexican Patent Office publishes a special gazette (similar to the Orange Book) every six months.

To be listed in this special gazette, the patents should refer to inventions "susceptible to be used in allopathic medicines". Product, combination and formulation patents are eligible for listing. However, medical use and process patents, among others, remain an issue, despite their clear use in allopathic medicines. This outright rejection of medical use and process patents contradicts the objective of sanitary registrations (ie, pharmaceutical products with defined therapeutic indications) and there are numerous court cases where the Mexican Patent Office has been compelled to list medical-use patents. Litigation is thus currently required to list use patents and process patents in the Linkage Gazette. In light of the recent increase in patents relating to biologics and their processes, increased efforts are being made to include such processes in the gazette, particularly since processes play an essential role in the development of "allopathic" medicines, such as biologics, and are becoming a common target for infringement cases. This issue is currently being debated and represents an area of evolvement. A close eye should be kept on developments in this area over the next few years.

Burden of proof in infringement cases: how do we prove the technical facts of cases involving process patents?

Regarding the litigation of process patents, the technical facts of these cases may be difficult to prove in a case of infringement. For instance, it is commonplace that many different processes may exist for manufacturing the same biologic product. However, certain processes offer certain advantages for a biologic product, which is why these processes are often patentable. Unfortunately, when it comes to the enforcement of such process patents, reverse engineering to determine the process used to manufacture the infringing product is often not possible. Thus, it may not be obvious or easy to determine if the biologic at the centre of the litigation case infringes on a process patent. This is where the reverse of burden of proof comes into play.

Under normal circumstances, the burden of proof lies with the plaintiff. Yet, as mentioned above, in the case of manufacturing/process patents for biologics, this can pose a challenge. For instance, a particular process may increase the amount of product produced, but the final product produced is the same as that produced by any other process used to manufacture the same biologic. Or perhaps a specific process increases the quality of the product being manufactured, reducing the need for purification processes. For this reason, and through many binding precedents, the constitutional courts in Mexico have introduced the idea of a "dynamic" burden of proof, which permits that the burden of proof be reversed in certain situations. The circumstances for such a situation are as follows:

- the plaintiff has difficulty accessing the documents required to demonstrate the facts of the case; and

- the defendant has easier access to the evidence or can easily prove the evidence in the trial.

Article 335 of Mexican Patent Law states the following:

"When the subject matter of the patent is a process for obtaining a product, in the administrative infringement declaration procedure, the alleged infringer must prove that said product was manufactured using a process other than the patented one when:

I.- The product obtained by the patented process is new, or

II.- There is a significant probability that the product was manufactured using the patented process and the patent holder has not succeeded, despite having tried, in establishing the process actually used."

Thus, Mexican Patent Law does contemplate the problem associated with product patents when debated during infringement actions. However, despite this provision in the law and the availability of a reversal of the burden of proof, process patents relating to biologics remain one of the more difficult types of infringement cases to litigate.

Patent term extensions of pharmaceutical patents: complementary certificates

Pharmaceutical patents can often take a while to move through prosecution, particularly due to their complexity. Thus, patent term extensions have become an attractive option for clients in recent years, particularly for biologic patents which may move slowly through the prosecution system at the Mexican Patent Office. However, patent term extensions filed before 5 November 2020 remain a difficult issue. Such patents are barred from term extension under the former governing law, yet litigation has made them possible (in a few cases). Specifically, when prosecution of the relevant application took more than five years, it was possible to seek a conventional interpretation of the Paris Convention together with the so-called "pro-homine" principle, under which a patent term could be adjusted to 17 years from the date of granting (in Mexico), as opposed to the current 20 years from date of filing (priority date). The path to seek the extended term must initiate before the patent expires, and in a best-case scenario, at least two or three years before the original expiration date, to ensure sufficient time to reach the courts and obtain the injunctive remedy preventing the term from expiring before a final decision in the case can be rendered. The injunction then results in a relative win in the case, as it provides the patent holder with an additional term for at least as long as it takes for a final decision in the case to be rendered.

On the other hand, the new law clearly outlines how patent term extensions can be obtained for any patent application filed on or after 5 November 2020. These are obtained via "complementary certificates", which can be requested if the time between the filing date and the granting date is more than five years, and the Mexican Patent Office is directly responsible for this delay.

NORWAY

Law and Practice

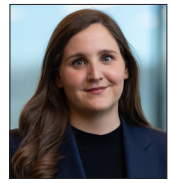
Contributed by:
Lars Erik Steinkjer, Nora Bratheim and Guro S K Nybø
Wikborg Rein Advokatfirma AS

Contents

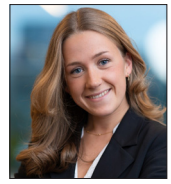
Wikborg Rein Advokatfirma AS is one of Norway's leading law firms, with headquarters in Oslo and offices in Bergen, Stavanger, London, Singapore and Shanghai. The firm's long-standing presence overseas distinguishes Wikborg Rein as the Norwegian law firm with the most international experience and expertise. Wikborg Rein's practice group for IP and technology offers its clients a breadth of knowledge and significant expertise in the field. The team consists of highly qualified and dedicated lawyers with a varied skill-set in the legal and technology areas relating to IP. The firm assists its clients in enforcing and defending all types of IP rights, as well as providing advice on patent issues from a range of technology areas, including pharmaceuticals, biotechnology, oil and gas, electronics and fish farming.

Authors

Lars Erik Steinkjer is a partner at Wikborg Rein Advokatfirma AS's Oslo office, and part of the firm's technology and digitalisation group. Lars Erik has a degree in law from the University of Bergen (2004) and obtained his PhD within patent law at the same institution in 2010. He has extensive experience of assisting clients in IP rights matters, including providing advice on securing, licensing and enforcing IP rights. Among other things, Lars Erik has been involved in a number of major patent and trade secrets disputes within the life sciences field. He regularly assists both international and domestic life sciences companies in IP-related matters and before the Norwegian courts.



Nora Bratheim is a senior lawyer at Wikborg Rein Advokatfirma AS's Oslo office, where she specialises in IP law, including life sciences and pharma patent litigation. Nora has experience with conducting cases before the courts, the Norwegian Industrial Property Office and the Norwegian Board of Appeal for Industrial Property Rights. She is an editor of the European Patent Lawyers Association's (EPLAW) patent blog and a co-author of a law commentary on the Norwegian Patent Act.



Guro S K Nybø is an associate at Wikborg Rein Advokatfirma AS's Oslo office. She is part of the firm's technology and digitalisation team, working mainly with IP, IT and data protection law. Guro holds an LLM in IP and information law from King's College London.

Contributed by: Lars Erik Steinkjer, Nora Bratheim and Guro S K Nybø, **Wikborg Rein Advokatfirma AS**

Wikborg Rein Advokatfirma AS

Dronning Mauds Gate 11
0250 Oslo
Norway

Tel: +47 22 82 75 00
Email: oslo@wr.no
Web: www.wr.no/en/

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Revocation Actions

As long as a patent is in force, any party may initiate an action to have the patent revoked, including individual co-owners and third parties such as licensees.

Infringement Actions

The patentee and an exclusive licensee – ie, a licensee that has the exclusive right to make, sell and/or put the invention on the market – has standing to commence an action for patent infringement. Registration or recording of an exclusive licensee is not required in order for it to bring an action.

The patentee does not need to be joined as a party to the infringement action. However, if infringement proceedings are commenced by a licensee, the patentee must be notified. The same applies if the patentee brings an action – licensees registered in the official patent register must be notified.

1.2 Defendants/Other Parties to an Action

The parties in life sciences/pharma actions in Norway are, almost without exception, manufacturers of pharmaceuticals. The Norwegian Industrial Property Office (NIPO) is required to be notified if a revocation action is initiated, but they have no role in revocation or infringement actions between pharmaceutical manufacturers.

1.3 Preliminary Injunction Proceedings

Preliminary injunctions (PIs) are available in Norway, including ex parte PIs. A PI is available on the condition that the claimant establishes as probable that there is either:

- an infringement of a patent; or
- the defendant has made significant preparatory acts with the aim of carrying out an infringing act.

Moreover, the claimant must establish that an injunction is necessary, as pursuing the claim would otherwise be substantially more difficult or cause substantial harm or inconvenience. Additionally, the court must find that an injunction is justified when taking into account the interests of both parties. Upon granting a PI, the court may order the claimant to provide a guarantee for compensation to the defendant in the event that it is later established that the injunction was unjustified.

A patentee should not delay in commencing the PI action once they become aware of potential

imminent infringement or actual infringement. A warning letter with a short deadline (normally two weeks, or shorter if there is urgency) should be issued first, followed by filing a request for a PI fairly soon thereafter – normally within two to four weeks. Note that protective letters are not available in Norway.

Inter Partes PIs

The timeline in inter partes PI proceedings is typically as follows.

- The patentee will file a PI request, together with evidence to support that the defendant's product constitutes infringement and that infringement is imminent.
- The defendant will be notified of the request by the court and then normally allowed a short limited period of time in which to file a defence.
- Where matters concerning validity and/or infringement involve complex scientific issues, the court will usually allow time for experts to submit reports – for example, within a limited time period of one or two months.
- A hearing takes place in court, which could last between three and seven days. The hearing and the proceedings correspond in many respects to an ordinary case on the merits.
- A verdict is normally delivered two to four weeks after the hearing took place.

The verdict may be appealed within a month to the Court of Appeal, which normally will assess the matter based on the written pleadings and evidence.

Ex Parte PIs

The criteria for obtaining an ex parte PI are based on extreme urgency and the threat of substantial harm to the patentee's interest if inter partes proceedings are allowed. The threshold for the grant of an ex parte injunction in Norway is high in pharma patent cases. In complex patent cases, they are rarely granted.

1.4 Structure of Main Proceedings on Infringement/Validity

In Norway, revocation claims and infringement claims are dealt with in the same proceedings.

1.5 Timing for Main Proceedings on Infringement/Validity

A typical timeline for a revocation and/or infringement action in Norway is as follows.

- A writ is filed with the Oslo District Court, which is the mandatory venue for patent cases.
- The defendant is normally granted a time limit of three weeks in which to file a defence to the writ. The time limit may be extended by another three to four weeks in complex cases.
- A case management conference with the judge and counsel is held a few weeks after the defendant has submitted the defence. Hearing dates, appointment of expert lay judges, etc, will be decided at this conference.
- A main hearing, typically lasting four to nine consecutive court days, would normally take place between six and ten months from commencement of proceedings.
- A judgment from the Oslo District Court can be expected within six to ten weeks, depending on complexity.

1.6 Requirements to Bring Infringement Action

Infringement actions are normally brought on the basis of a granted patent. In theory, an infringement action can be filed before the grant or vali-

dation of a patent, but there are very few examples of this in practice.

1.7 Pre-Action Discovery/Disclosure

There is no pre-action discovery/disclosure as such in Norway.

One may, however, initiate measures for securing of evidence prior to proceedings. This is relevant if the evidence is at risk of being lost otherwise. Additionally, securing of evidence prior to proceedings is possible if done in order to provide an opportunity to assess a claim and possibly reach an amicable settlement.

The securing of evidence – specifically, information related to patent infringement – can under certain conditions be obtained prior to an action for infringement. The securing of evidence does not necessarily imply that the claimant may obtain access to the evidence, especially if the evidence is confidential. As mentioned earlier, the claimant must show that:

- there is a clear risk that the evidence will be lost or considerably impaired otherwise; or
- there are other reasons that make it particularly important to obtain access to the evidence before the lawsuit is instigated.

A request for such evidence may also be made ex parte if there is reason to fear that notice to the opposite party could lead to obstruction of the securing of evidence. If granted, the opposite party will be allowed an oral hearing. The petitioner shall, in that case, not be allowed access to the evidence until the ruling is final.

The issue of confidentiality may be resolved by the court appointing an expert to look into the material and give the court advice concerning the relevance of the material and its suitability as evidence in the case at hand. The petitioner pays all costs – including those of the defendant – in this kind of procedure, which is very rarely used in patent matters. The authors are not aware of examples where it has been used in pharma patent litigation.

Note that materials obtained by discovery or disclosure requests in other jurisdictions can be used in Norwegian proceedings.

1.8 Search and Seizure Orders

Norway has implemented quite a similar customs regime to Customs Regulation (EC) No 1383/2003, under which the court can issue a PI ordering the custom authorities to seize products if importation of the products will constitute infringement of IP rights. An injunction can be issued even where the recipient of the products is unknown. If necessary, a PI can be issued without an oral hearing of the evidence.

The customs authorities can also, ex officio, decide to withhold goods for up to ten days if they have reasonable grounds to suspect that the goods will constitute infringement of IP rights. If the goods are withheld, notice shall be given to the recipient of the goods and the patent owner. To prevent further release of the goods, the patent owner must obtain a preliminary injunction.

1.9 Declaratory Relief

Declaratory relief is, in principle, available in Norway, both in the form of declarations of non-infringement as well as in the form of “arrow declarations”.

1.10 Doctrine of Equivalents

Norwegian courts recognise a Doctrine of Equivalents (DoE). The legal test follows from the Nor-

wegian Supreme Court decision in the "*Donepezil*" matter (Rt-2009-1055).

The three questions to be answered in the DoE are:

- Does the variant achieve the same solution/solve the same technical problem as the patented invention?
- Would a person skilled in the art find the modifications from the patented invention obvious?
- Does the variant belong to the available prior art?

If these three questions are answered affirmatively, infringement of the original patent can be established. The Norwegian DoE is, however, rather narrow in scope. According to the Supreme Court in the above-mentioned decision, protection by equivalence is a matter of claim construction and can only encompass modifications that are "fairly identical" to the features set out in the patent claim.

1.11 Clearing the Way

Filing a claim for revocation and/or a non-infringement declaration is often used as a strategy to "clear the way" before the launch of a new product. However, there is no legal obligation for a potential competitor to clear the way ahead of product launches.

1.12 Experts

In matters where complex scientific issues are involved in terms of validity and/or infringement, the party-appointed experts will normally submit reports and provide testimony during the proceedings.

In a PI action, the court will normally appoint independent expert witnesses with particular expertise in the relevant field. Typically, two court-appointed experts will attend the hearing including the evidence; at the end of evidence, they will deliver a report and also expand their view by oral testimony to the judge. Thereafter, it will be for the counsel to put further questions to the court-appointed experts – following which, the experts will leave the courtroom and not take further part in the proceedings.

In an action on the merits, with infringement and/or validity issues at hand, there will be no court-appointed experts as per PI proceedings; instead, expert lay judges will be appointed by the court. They will typically have technical expertise in the relevant field. In some pharma patent litigation cases, the expert lay judges have comprised one technical expert (eg, a professor in biochemistry) and a patent attorney working within life sciences.

The expert lay judges participate during the hearing as members of a panel of three, including the patent judge. In the court of appeal, this will be a panel of five (including three legal judges).

1.13 Use of Experiments

Results from experiments may be filed as evidence in order to prove/disprove infringement/validity of patents and Norwegian courts allow experiments in patent cases. There are no specific procedures that must be followed in order for the experimental results to be admissible; however, the courts will assess the relevance of the experiments based on the protocols of the experiment(s).

1.14 Discovery/Disclosure

In response to an infringement claim, the defendant will normally provide evidence in the form of a product or process description. Confi-

dential information in such descriptions may be redacted.

1.15 Defences and Exceptions to Patent Infringement

The most relied-upon defence against an infringement claim is a counterclaim for invalidity. A separate claim for revocation must be filed, leading to the validity and infringement being assessed in the same case before the Oslo District Court.

Another ground for defence is that the defendant is entitled to a compulsory licence. Other available defences include the defendant being entitled to a prior use right on the basis that they were already using the invention before the priority date, experimental use and exhaustion. For life sciences cases, the Norwegian "Bolar" exemption is particularly relevant (see **2.4 Publicly Available Drug and Patent Information**).

1.16 Stays and Relevance of Parallel Proceedings

As the Oslo District Court is the mandatory venue both for infringement cases and revocation actions, infringement and revocation actions will be joined and heard together in most cases. Thus, the infringement proceeding will normally not be stayed.

When Norway acceded to the European Patent Convention (EPC) on 1 January 2008, the Patents Act was amended with a provision stating that a court may decide to stay a trial until a final decision concerning the same patent is delivered by the European Patent Office (EPO). In practice, this also applies to Norwegian patents granted nationally, but the court will normally only stay the proceedings if a decision from the EPO can be expected within a few months. The fact that the validity of a corresponding patent is disputed in another country is normally not considered directly relevant for proceedings in Norway.

If invalidity or revocation proceedings are pending before both the NIPO and a court at the same time, one of the actions will be stayed. In most cases, this will be the proceedings before the NIPO.

1.17 Patent Amendment

A patent can be amended in administrative proceedings before the NIPO or in a trial before the court. After the opposition period, a patent may also be amended upon request by the patent owner. Amendments can be made to the claims or the description.

Furthermore, the patent holder may file auxiliary requests to the court in revocation/cancellation proceedings. The amendments made in the auxiliary requests must not extend the scope of the patent as granted.

1.18 Court Arbiter

The Oslo District Court has a panel of judges with particular experience in patent matters, who will hear all cases brought before the court. However, requests for PIs must be initiated in accordance with the general law on civil procedure – meaning that the venue will normally be either the district court where the alleged infringer has its headquarters or, alternatively, the court at the place of infringement. If an infringement action or revocation action is already pending, the venue for the request for a PI must be filed to the Oslo District Court.

As mentioned, in proceedings on the merits there will be two appointed expert lay judges in both the first and second instances. These expert lay judges will be accompanied by one legal judge in the first instance and three legal judges in the

second instance. The expert lay judges are normally appointed upon (often joint) proposal from the parties and have their background within the technical field to which the case relates.

Expert lay judges cannot be appointed in PI proceedings, but it is common to use court-appointed experts in such proceedings. These experts are not associated with any of the parties and will be appointed to assist the legal judge in their assessment of the case. They are not part of the panel of judges, but will hear the trial and deliver an opinion on the matter in open court. Often, they also deliver a written opinion.

2. Generic Market Entry

2.1 Infringing Acts

An application for a marketing authorisation (MA) is not an infringing act, and will not in itself be considered sufficient for the grant of a PI. However, the court will consider if there are additional circumstances that – together with the grant of an MA – constitute sufficient evidence that infringement is either imminent or likely in the near future.

A communication to customers of the intended launch date after patent term expiry will normally be viewed as an offer to deliver after expiry; this is generally considered an infringing act in Norway. Responding to a request for tender, where supply would take place after expiry of the relevant rights, may equally be classed as an act of patent infringement. In theory, a PI application could be made on such basis, but the authors are not aware of any such PI being granted in Norway.

2.2 Regulatory Data and Market Exclusivity

EU legislation on data and market exclusivity is included in the EEA Agreement and implemented in Norwegian law under the Norwegian Medicine Regulation of 18 December 2009 No 1839 (NMR).

Chapter 3 of the NMR, as a main rule, distinguishes between an eight-year period of data protection (Section 3-10(c) and 3-10a(b)) and a ten-year period of market protection (Section 3-11(b) and 3-11a (b)) (the "8+2 system"). During the two-year period after expiration of the data protection, the market protection prohibits the placing on the market of a generic medicinal product but does not prohibit preparatory actions prior to putting the product on the market.

In addition, under Chapter 3, Sections 3-11b and 3-11d, the MA holder of the reference product may qualify for another year of market exclusivity if the MA holder is granted further marketing authorisation for a significant new indication for the relevant medicinal product (the "8+2+1 system").

However, Chapter 3 of the NMR does not distinguish between the data and market protection where the reference product application was filed prior to:

- 12 January 2010, if made by way of the national procedure (NP); or
- 1 November 2005 (or later), if made by way of the central procedure (CP).

NP applications filed in the period between 1 November 2005 and 12 January 2010, and CP applications filed prior to 1 November 2005, enjoy a ten-year period of data protection with

no additional market protection period (Sections 3-10(b), 3-10a(a), 3-11(a) and 3-11a(a)). NP applications filed prior to 1 November 2005 enjoy a six-year data protection period with no additional market protection period (Sections 3-10(a) and 3-11(a)).

2.3 Acceptable Pre-Launch Preparations

The Bolar exemption introduced in Directive 2001/83/EC Article 10(6) has been implemented in the Norwegian Patent Act Section 3(3) No 5. The Bolar exemption applies to patents and Supplementary Protection Certificates (SPCs) covering pharmaceuticals, and allows the undertaking of "tests, trials and similar" of pharmaceuticals that are necessary for obtaining market authorisation. Furthermore, the Bolar exemption is applicable for obtaining marketing approvals in all WTO-signatory countries – ie, the Bolar exemption is not limited to EU/EEA countries.

As mentioned previously, applying for an MA or a pricing and reimbursement (P&R) decision is not an infringing act and will not in itself be considered sufficient for the grant of a PI. See **2.1 Infringing Acts** for exceptions.

2.4 Publicly Available Drug and Patent Information

Publicly Available Information

The Norwegian Medicines Agency (NOMA), which is the authority responsible for granting MAs and P&R decisions, publishes updates to the following different lists on their website.

- A list, which is updated from time to time, of first-time generic and hybrid mutual recognition procedure (MRP), decentralised procedure (DCP) and NP applications. The list includes information about the active ingredient, marketing status, Anatomical Therapeutic Chemical (ATC) classification, procedure, grounds for the application (eg, hybrid or generic application), and date of the application. The product name, the applicant and other countries involved (including the reference country) are not published.
- A list containing all new granted MAs in CP, MRP, DCP and NP applications is updated on a monthly basis and thus becomes publicly available. The list includes information about product name, MA status, MA date, MA holder, MA number, application procedure, the active ingredient, medical indication, prescription status and product type and dosage.
- A list of P&R decisions that includes the above-mentioned information (as per the MA granted listed), as well as information about pricing and reimbursement.
- When approved, generic drugs for which generic substitution applies, will also appear on the so-called "substitution list". This list is updated on the first and the 15th day of each month.

In addition, information about granted MAs, P&R decisions, and substitution status is made available in NOMA's public database (*Legemiddelsøk*). The database is updated shortly after NOMA has granted the MA. Hence, information may be published in NOMA's database before the aforementioned lists and databases are updated.

Moreover, the product must be listed in the database of the Association of Pharmacies (*Farmalogg*). In practice, a product is available on the market when it is included in *Farmalogg*. This register is also updated on the first and 15th day of each month.

Freedom of Information Requests

Freedom of information requests to NOMA are available under the Freedom of Information Act. Usually, when requests under the Norwegian Freedom of Information Act are made to NOMA, a reference will be made to the published lists and databases without giving any additional information. Additional information about pending applications is generally classed as trade secrets, and therefore excluded from the right to information (see Section 13 of the Norwegian Freedom of Information Act and Section 30 of the Norwegian Medicine Act). NOMA will not notify the generic MA applicant/holder if someone (eg, the MA holder of the reference product) requests information under the Norwegian Freedom of Information Act.

2.5 Reimbursement and Pricing/Linkage Markets

Generally, NOMA will neither consider the patent situation on its own, nor act upon notifications from the patent holder covering an innovative product, when it comes to marketing authorisation, pricing and reimbursement, and generic substitution.

There is one exception. According to Section 2.3 of NOMA's guidelines regarding the substitution list, generic drugs covered by a second indication patent are still added to the substitution list – albeit with the instruction that the drug is not to be substituted if the pharmacy is aware that the drug is prescribed for the patented use. Hence, the holder of a second indication patent will regularly notify NOMA following the grant of an MA to a generic product for which the originator holds a second indication patent.

The holder of the MA for the reference product is not notified of any MA, P&R or listing applications made by a generic or biosimilar, nor of the grant of such applications. Information may be obtained through freedom of information requests or, alternatively, by monitoring publicly available lists and databases (see **2.4 Publicly Available Drug and Patent Information**).

3. Biosimilar Market Entry

3.1 Infringing Acts

See **2.1 Infringing Acts**.

3.2 Data and Regulatory Exclusivity

See **2.2 Regulatory Data and Market Exclusivity**.

3.3 Acceptable Pre-Launch Preparations

See **2.3 Acceptable Pre-Launch Preparations**.

3.4 Publicly Available Drug and Patent Information

See **2.4 Publicly Available Drug and Patent Information**.

3.5 Reimbursement and Pricing/Linkage Markets

See **2.5 Reimbursement and Pricing/Linkage Markets**.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

SPC protection is available in Norway. This is regulated by the relevant EU regulations and these have been implemented into Norwegian law by application of the EEA agreement. SPCs are therefore available for patents that cover an authorised medicinal or plant pharmaceutical product.

The relevant law is Regulation 469/2009 concerning the supplementary protection certificate for medicinal products; however, this has been amended at EU level through Regulation 2019/933 implementing the SPC manufacturing waiver. The waiver enables manufacturers of generics and biosimilars to manufacture such medicines for the purpose of exporting them outside the EU during the SPC protection term. After a lengthy process, the waiver entered into force in Norway on 1 February 2023 by amendment of the Norwegian Patents Act Section 62a.

4.2 Paediatric Extensions

Paediatric extensions are available in Norway and regulated by EU law. The Paediatric Regulation was introduced into Norwegian law and entered into force on 1 September 2017, bringing some statutory amendments that make it possible to apply for a six-month extension to the period of validity of SPCs.

4.3 Paediatric-Use Marketing Authorisations

There are no special MAs available for medicines specifically developed for children.

4.4 Orphan Medicines Extensions

A supplementary protection certificate may, upon request, be extended by a further period of six months if it is granted for a medicinal product which is encompassed by Article 36 of EU Regulation No 1901/2006.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

The court may provide for when the PI should be enforced and how long it should last. Enforcement of a PI shall take place as soon as requested by the claimant, and must follow the rules of the Enforcement Act of 1992.

If the court has required a bond in relation to a PI, the PI will not take effect before a bond is in place. The value of the bond is normally calculated on the basis of the potential damage the defendant could suffer in the period before delivery of judgment in the first instance (after which the PI will be lifted, if the defendant is successful).

For a PI to be enforced, the patentee is not required to have commenced a main action; however, the claim in question must normally be established as probable. If a PI is granted, the courts will normally set a deadline for the patentee to initiate main proceedings.

5.2 Final Injunctive Relief

Final injunctions are granted if the claimant is successful at proving at trial that infringement or significant preparatory acts with the aim of carrying out an infringing act took place. Such injunction will normally not be enforceable pending an appeal.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

Preliminary Injunctions

The court will assess the proportionality of a PI in PI proceedings. In such assessment, the court may also take public interest arguments into account.

Final Injunctions

If requested by the defendant, a court may – in lieu of a final injunction – award a licence against reasonable compensation to the patentee. However, the defendant must establish that there are some special circumstances in order for such a licence to be awarded. To date, this narrow

exception has not been used by a Norwegian court.

5.4 Damages

Damages are calculated on the basis of lost profits. In order to estimate the potential damages exposure, one would need to provide proof of the suffered damages (eg, loss of sales of a generic or biosimilar). The time period for claiming damages based on a patent infringement is three years from when the cause of action accrued. This period will commence at the time of infringement; however, if the infringement has been concealed during this three-year period, the damage claim is not time-barred until the expiration of a one-year period from the time when the claimant should – with reasonable diligence – have discovered the infringement.

Damages are normally assessed as part of the infringement action – ie, there is no separate procedure for establishing the quantum of damages. The infringer is liable for damages in the form of remuneration for the exploitation of the invention and, if applicable, compensation for any further economic loss to the claimant caused by the infringement. The patentee can also choose to claim the infringer's profits. Thus, the patent owner can either claim their own lost profits, reasonable royalties on sales by the defendant, or the defendant's profits.

If the infringement has been committed intentionally or through gross negligence, the patentee can claim compensation corresponding to 200% of a reasonable royalty.

With the exception of the option of claiming 200% of a reasonable royalty when the patent infringement was wilful or grossly negligent, punitive damages are not an option under Norwegian law.

5.5 Legal Costs

Legal costs are normally recoverable from the losing party unless the court decides to reduce the amount, owing to it being unreasonably high. Hence the losing party will typically be required to pay all costs to the party that prevails in a litigation.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

The court may decide that the winning party should bear its own costs partially or in full – for example, if the winning party is to blame for the matter coming before a court or has declined a reasonable settlement offer. The Norwegian Dispute Act further provides that a party may recover costs that arise from the counterparty's conduct, such as censurable actions or omissions that make the procedure more complex than it already is. The parties' conduct prior to the proceedings is also relevant – for example, if the claimant fails to notify or inform about the existence of relevant evidence.

6. Other IP Rights

6.1 Trade Marks

Trade mark disputes within the life sciences and pharma sector are not very common in Norway. The few cases that have been tried before the courts concern medical devices and repacking issues related to parallel import of pharmaceuticals.

6.2 Copyright

Copyright issues may also arise in the life sciences and pharma sector, but are very seldom litigated before the courts.

6.3 Trade Secrets

Trade secrets disputes have been seen within the life sciences and pharma sector, particularly in relation to a company's former consultants or employees. The relevant sources of law are the Norwegian Trade Secrets Act of 2021 and the Norwegian Marketing Act of 2009.

7. Appeal

7.1 Timeframe to Appeal Decision

Preliminary Injunctions

A PI decision may be handled in the second instance if appealed. An appeal may be filed within a limited one-month time period. The appellate court will normally only review the case based on the written submissions and evidence.

Main Actions

A judgment in infringement (and/or revocation) proceedings from the Oslo District Court may be appealed to the "Borgarting" Court of Appeal. A court of appeal hearing in Norway implies hearing the case all over again with evidence, expert witnesses and legal arguments; also, new evidence and arguments are allowed. The appeal hearing in the appellate court will normally take place about a year after an appeal was made. A judgment is normally expected within four to ten weeks of the hearing, depending on the complexity of the case.

A further appeal is possible to the Supreme Court; however, leave for appeal is only granted if the appeal raises principal points of law for which guidance from the Supreme Court would be deemed useful. The appeal hearing in the Supreme Court will normally take place within three to five months of an appeal being made to the Supreme Court. A judgment is normally expected two to four weeks after the Supreme Court hearing.

7.2 Appeal Court(s) Arbiter

The "Borgarting" Court of Appeal decides patent litigation appeals from the Oslo District Court in the first instance. The appeal is heard by three legal judges and there is no specialisation in patent matters; however, the appellate court will be assisted by two appointed expert lay judges.

An appeal to the Supreme Court is heard by five legal judges and, as in the Court of Appeal, there is no specialisation in patent matters.

7.3 Special Provisions

The Oslo District Court is the mandatory venue for design, trade mark and patent cases. IP proceedings are, however, dealt with in accordance with the general procedural rules set out in the Norwegian Dispute Act.

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

The holder of the relevant right may request that the Customs Authority retains goods that are in the authority's control if there is reasonable suspicion that the importation of said goods will constitute:

- a violation of the individual's rights under the Norwegian Marketing Act; or
- an infringement of their IP rights such as a patent or copyright.

This may be done if the infringement consists of an imitation of someone else's product, characteristic, advertising material or other similar material.

The holder of the right must send an application to the Customs Authority containing, among other things:

- the applicant's name and address;
- potential agent's name and address;
- a list of the IP rights in question; and
- information making it possible to identify authentic goods.

9. Alternative Dispute Resolution

9.1 ADR Options

The parties are not required to undertake mediation before commencing court proceedings. Nevertheless, according to Section 5-4 of the Norwegian Dispute Act, the parties shall consider whether it is possible to reach an amicable settlement of the dispute before action is brought and shall make an attempt at settlement.

According to Section 8-1 of the same Act, the court shall also – at each stage of the case – consider the possibility of a full or partial amicable settlement of the legal dispute through mediation or judicial mediation, unless the nature of the case or other circumstances suggest otherwise. Mediation or arbitration is, however, not commonly used in patent disputes.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The parties cannot agree upon terms prohibited by Norwegian competition law or EEA/EU competition law. Terms that restrict competition in the relevant market and extend the monopoly conferred by the patent – for example, by restricting the licensee's use of its own technology – might be unlawful under competition law.

11. Collective Redress

11.1 Group Claims

Group claims are generally available in Norway according to Chapter 35 of the Norwegian Dispute Act. To date, group claims have been mostly seen in consumer-related cases. Group claims may also be for products/services within the life sciences/pharma sector.

Trends and Developments

Contributed by:
Camilla Vislie, Magnus Hauge Greaker, Martin Guldbrandt Hansen and Nora Solberg Bjørnnes
Advokatfirmaet Thommessen AS

Advokatfirmaet Thommessen AS is considered to be one of Norway's leading commercial law firms, with offices in Oslo, Bergen, Stavanger and London. It provides advice to Norwegian and international companies and organisations in both the public and private sectors. With approximately 300 lawyers, Thommessen covers all business-related fields of law, including M&A and corporate law (private and public transactions), banking and finance, IP, life sciences regulatory law, compliance and investigation, insolvency and restructuring, insurance, litigation and other dispute resolution, tax, competition, employment, real estate, technology data protection and cybersecurity, sustainability and climate risk, and energy (hereunder oil and gas, oil service and renewable energy and infrastructure).

Authors

Camilla Vislie is a partner of Thommessen, where she heads the firm's intellectual property practice group. Her fields of expertise are intellectual property law and commercial litigation. Camilla mainly works in dispute resolution and advice in relation to life sciences, technology, and media. She leads the team of lawyers in complex multi-territorial disputes in patent and technology-related matters, and has a large international network. She has published a number of papers and frequently lectures on topics within patent, trade mark and copyright law. She is admitted to the Supreme Court and is continuously involved in patent litigation matters.

Magnus Hauge Greaker is a partner of Thommessen in the firm's intellectual property practice group. He works with patent, trade mark and trade secrets litigation, for clients within life sciences, oil and oil-service, aquaculture and other technology. His practice also covers regulatory law relating to pharmaceuticals, medical devices, nutrition, etc. He has published a number of articles and regularly lectures on intellectual property topics. He is admitted to the Supreme Court.

Martin Guldbrandt Hansen is a senior associate in Thommessen's intellectual property practice group, where he assists Norwegian and international clients within IP law, including life sciences and patent litigation related to the life science industry.

Contributed by: Camilla Vislie, Magnus Hauge Greaker, Martin Guldbrandt Hansen and Nora Solberg Bjørnnes,
Advokatfirmaet Thommessen AS

Nora Solberg Bjørnnes is a senior associate in Thommessen's intellectual property practice group. Nora assists Norwegian and international clients with advice and dispute resolution within patent law, copyright, trade secrets, trade mark law, and marketing law, with a particular focus on matters related to the life science industry.

Advokatfirmaet Thommessen AS

Ruseløkkveien 38
0251 Oslo
Norway

Tel: +47 23 11 11 11
Email: cav@thommessen.no
Web: www.thommessen.no

THOMMESSEN

Contributed by: Camilla Vislie, Magnus Hauge Greaker, Martin Guldbrandt Hansen and Nora Solberg Bjørnnes, **Advokatfirmaet Thommessen AS**

The Latest Trends and Developments Within Norwegian Life Sciences and Pharmaceutical IP Litigation

Introduction

In 2024, the Norwegian pharmaceutical patent landscape continued to evolve, marked by legal developments that addressed issues of patent validity and inventive step. Notable cases, such as those involving Bristol-Myers Squibb's patent covering apixaban and Bayer's patent covering rivaroxaban, have provided insights into how Norwegian courts interpret patent law, particularly in relation to an alleged technical effect substantiating inventive step. Additionally, a ruling concerning Merck Sharp & Dohme LLC provides clarification regarding the requirements for administrative patent limitations.

As for public administrative matters, the Norwegian Ministry of Health and Care Services (the HOD) upheld Novo Nordisk's appeal against a decision by the Norwegian Medical Products Agency (the NoMA) regarding alleged illegal advertising of its medicinal products Wegovy, Saxenda and Ozempic. This decision underscores the importance of procedural fairness in administrative regulatory actions and highlights ongoing discussions regarding medicinal product advertising standards in Norway.

Ongoing discussions regarding the EU's pharmaceutical reform may also have implications for Norway's regulatory framework and the pharmaceutical industry. This article will explore these developments and their potential impact on stakeholders within the sector.

Market development – increased focus on developing the life science industry in Norway

The Norwegian life sciences industry continues to show development and innovation, but is still behind Norway's neighbouring countries, Denmark and Sweden.

In their "Life Science Trend Analysis" for 2024, BiotechGate, Nordic Life Sciences Database and Venture Valuation (in collaboration with The Life Science Cluster and Oslo Cancer Cluster) reported that in 2023, biotechnology companies comprised 48% of companies in the life science sector, and that nearly half of these companies fall under the category "Biotech – Other". This category describes companies in areas such as AgBio, environmental, veterinary, and industrial biotechnology. In the field of therapeutics and diagnostics, oncology remains the frontrunner in terms of therapeutic development in Norway. Biotech companies in the therapeutics and diagnostics field appear to be mainly focusing on developing small molecules (16%), immunotherapies (15%), and anti-infectives (10%).

A notable point from the above-mentioned analysis is that in 2023, digital health had emerged as a key sector, now representing a fourth of all life science companies in Norway. Another notable point from the analysis is that fully integrated pharma companies only constitute 3% of the life science companies in Norway.

The emerging focus on the life science industry in Norway has also been cemented by The Association of the Pharmaceutical Industry in Norway, a sector organisation for the pharmaceutical industry, and Norway Bio forming a new group for CEOs of biotech companies – the Norwegian Biotech CEO Group. The purpose of the group is to address the common challenges these companies face, enhance the political influence, and bolster sustainable development in the sector.

A spokesperson for Norway Bio has pointed to a number of challenges facing the life science

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industry in Norway, one point being that a high proportion of companies are established within life sciences sector, but only a few are scaled up in Norway. This means that the value already invested in Norway is not necessarily realised here. The same can be said about Norwegian research results within life sciences. Norwegian research results are to a high degree an export good, meaning that the large scale return on investment is not necessarily realised in Norway.

Consequently, there is room for development, and the Norwegian Parliament decided in 2021 to facilitate Norwegian pharmaceutical production, which was described as "a moon step for the Norwegian health industry".

EU pharmaceutical reform: potential implications for Norway

The EU's comprehensive pharmaceutical reform, proposed by the European Commission in April 2023, could have significant consequences for the Norwegian pharmaceutical market through the EEA Agreement.

The overarching goals of the reform are to make medicines more accessible and affordable while enhancing the competitiveness of the EU's pharmaceutical industry. Specifically, it aims to ensure access to safe, effective, and affordable medicinal products across all member states, improve medicinal product supply chains, and create an attractive environment for pharmaceutical research and development (R&D) in Europe. By balancing these objectives, the reform seeks to address both public health needs and economic interests in the European pharmaceutical sector.

Key points of the reform include:

1. Adjustment of regulatory data production (RDP), with proposals for a 7.5-year data protection period and potential extension.

Regulatory Data Protection (RDP) Reform: The EU pharmaceutical reform proposes significant changes to the current data protection mechanism for medicinal products. Currently, pharmaceutical companies enjoy eight years of data protection under the 8+2 system, which prevents generic manufacturers from using their original research data. This is followed by an additional two years of market protection, during which generics cannot be marketed but can prepare for market entry. The European Parliament suggests reducing this to 7.5 years, with potential extensions up to 8.5 years based on specific criteria such as addressing unmet medical needs, conducting comparative clinical studies, or performing research and development within the EU. The proposed reforms aim to balance innovation incentives for original drug developers with the need for generic market competition. Pharmaceutical Industries have expressed concerns that shorter protection periods might diminish Europe's competitiveness in drug research and development. The proposed changes include nuanced provisions for extensions, such as additional protection for new therapeutic indications with significant clinical advantages, reflecting a nuanced approach to intellectual property protection in the pharmaceutical sector.

2. Extended market exclusivity for rare disease medications, with potential for up to 11 years of protection.

Market Exclusivity for Rare Disease Drugs: The EU pharmaceutical reform proposes changes to

Contributed by: Camilla Vislie, Magnus Hauge Greaker, Martin Guldbrandt Hansen and Nora Solberg Bjørnnes, **Advokatfirmaet Thommessen AS**

market exclusivity for orphan drugs. Currently, these medications have ten years of exclusivity, plus additional time for processing generic applications. The European Parliament suggests a new structure with a base period of nine years exclusivity, with a potential extension up to 11 years for drugs addressing significant unmet medical needs. This approach aims to incentivise research and development in rare diseases, ensuring that companies can profit despite limited patient populations. By extending exclusivity for drugs that meet critical needs, the reform seeks to balance innovation with patient access to essential treatments.

3. Stricter requirements for supply security to prevent medicine shortages.

Supply Chain Security: The EU pharmaceutical reform aims to enhance supply chain security for critical medicines. The European Parliament's amendments require marketing authorisation holders to explain and report supply disruptions, with at least six months' notice for predictable interruptions. The proposal also refines access requirements, allowing for targeted pricing and reimbursement applications, and strengthening the European Medicines Agency's role in monitoring shortages. These measures collectively seek to improve supply chain resilience and ensure consistent availability of essential medicines across the EU.

4. Introduction of mandatory environmental risk assessments when applying for a market authorisation.

Environmental Risk Assessment (ERA): The EU pharmaceutical reform emphasises environmental considerations and sustainability, expanding the scope of Environmental Risk Assessments (ERAs) for marketing authorisation applications. The European Parliament's proposal extends ERAs to cover the entire life cycle of medicines, including production risks, and requires descriptions of emission reduction strategies. Member states must develop national plans to inform the public and healthcare professionals about proper disposal of unused or expired medicines, monitor disposal rates, and implement measures to increase correct disposal. These new requirements aim to integrate environmental considerations more thoroughly into the regulatory process, addressing the environmental impact of pharmaceuticals throughout their life cycle and ensuring a more comprehensive approach to drug development and management.

5. New incentives for developing antimicrobial agents to combat resistance.

To combat anti-microbial resistance, the EU pharmaceutical reform introduces transferable exclusivity vouchers (TEVs) for priority anti-microbials, offering extended data protection. The European Parliament supports TEVs with stricter conditions, proposing 12, nine or six months of additional protection for critical, high, or medium-priority anti-microbials, respectively. TEVs cannot be applied to products already benefiting from maximum data protection (8.5 years). Additionally, a milestone payment scheme for new antimicrobial development is proposed, though manufacturers cannot benefit from both this scheme and TEVs for the same product. These measures aim to incentivise the development of new antibiotics and antimicrobials to address resistant infections, while also implementing stricter requirements for antimicrobial use, including prescription limitations.

As an EEA member, Norway will need to implement these changes in national legislation. This could affect various aspects of the pharmaceu-

tical sector, including incentives for medicinal product development, supply chain security, and environmental considerations. While final adoption of these changes is not anticipated until 2026, stakeholders in Norway's pharmaceutical industry and healthcare systems should proactively prepare for the forthcoming changes.

Trends in pharmaceutical patent litigation

In 2024, there have been notable developments in two cases within the Norwegian life science patent landscape, in particular in the field of antithrombotic agents: the Apixaban case concerning Bristol-Myers Squibb's blockbuster drug Eliquis and the Rivaroxaban case concerning Bayer's blockbuster drug Xarelto. These cases address important issues regarding inventive step, and they provide insights into how Norwegian courts interpret and apply patent law, particularly in relation to an alleged technical effect substantiating inventive step.

The Apixaban case, previously discussed in last year's Chambers Trends and Developments article, was decided by the Court of Appeal in 2024. The case concerned the validity of Bristol-Myers Squibb's (BMS) Norwegian patent NO 328 558 and supplementary protection certificate SPC/NO 20110021, which protects apixaban, the active substance in BMS's blockbuster thrombosis drug Eliquis®.

On 3 June 2024, the Borgarting Court of Appeal issued its ruling in the case (Case No LB-2023-141798). Teva Pharmaceutical Industries Ltd. and Teva Norway AS had appealed Oslo District Court's ruling, arguing that the patent lacked inventive step because the technical effect of the invention was not sufficiently demonstrated in the patent application to support reliance on this technical effect in the assessment of inventive step.

The Court of Appeal addressed the requirements for demonstrating a technical effect in a patent application. It concluded that the standards for establishing a technical effect are not particularly stringent; it is sufficient that it appears credible to a skilled person that the claimed technical effect is achieved based on the application.

The court assessed what a skilled person would derive from the application in light of common general knowledge. It found that a skilled person would consider it likely that apixaban is a potent and selective factor Xa inhibitor based on the application and the common general knowledge. The court determined that the application contained more than enough information to support reliance on this technical effect in assessing inventive step.

Ultimately, the Court of Appeal unanimously found both the patent and the SPC to be valid, dismissing Teva's appeal. Following this decision, Teva appealed to the Supreme Court; however, this appeal was not granted leave by the Supreme Court's Appeals Selection Committee. As a result, the Borgarting Court of Appeal's judgment is now final and legally binding, effectively concluding the legal proceedings and affirming the validity of BMS's patent and SPC for apixaban in Norway. Thommessen represented BMS before both the Court of Appeal and the Supreme Court.

This decision provides further clarity on how Norwegian courts interpret and apply criteria for assessing technical effects in patent cases, particularly following the European Patent Office's Enlarged Board of Appeal decision in G 2/21.

Also the Rivaroxaban case, previously reported on last year, has seen developments in 2024. Initially, the Oslo District Court upheld the valid-

ity of Bayer's Norwegian patent NO 344 278 for rivaroxaban (the active substance in Bayer's thrombosis drug Xarelto), despite Sandoz's arguments. Notably, Sandoz had invoked the "several obvious steps" approach as part of the problem and solution method in assessing what was obvious to the skilled person.

Following the District Court's decision, generic manufacturers signalled their intention to enter the market, challenging the patent's strength. In response to these threats, three ex parte preliminary injunctions were issued to prevent generic market entry pending further legal proceedings. In the autumn of 2024, oral hearings were held in the PI cases, shedding more light on the complex issue at stake. The appeal case regarding the patent's validity is scheduled for May 2025.

In addition to the Apixaban and Rivaroxaban cases, a new case involving Merck Sharp & Dohme LLC (MSD) has brought attention to the intricacies of administrative patent limitations in Norway.

The case concerned MSD's request for administrative limitation of patent NO 321 999, pertaining to the pharmaceutical substance sitagliptin. MSD, having obtained a Supplementary Protection Certificate (SPC), sought to limit the patent claims to ensure SPC protection under Article 3(1) of the SPC Regulation.

The Norwegian patent authorities had initially rejected MSD's request for administrative patent limitation, arguing that the proposed limitation only affected dependent claims. This decision brought to the forefront a central issue: whether a patent limitation requires amendments to an independent patent claim, rather than just dependent claims.

The Oslo District Court, in its judgment of 8 March 2024, interpreted Section 39a of the Norwegian Patent Act (which corresponds to Article 105a of the European Patent Convention) and concluded that a genuine limitation of patent scope requires changes to the independent patent claim. The court determined that changes to dependent claims alone were insufficient, thereby upholding the patent authorities' decision.

MSD subsequently appealed to the Borgarting Court of Appeal. On 21 October 2024, the appellate court reached the same conclusion as the district court, rejecting the appeal. As a result, the patent authorities' decision to dismiss MSD's request for patent limitation was upheld.

This ruling provides important clarification regarding the requirements for patent limitations in Norway. It emphasises that to be considered a valid limitation, changes must be made to independent claims, not just dependent ones. This decision may significantly influence future strategies for pharmaceutical companies seeking to adjust their patent protection, particularly in cases involving SPCs.

Decision on pharmaceutical advertising practices in Norway

On 7 June 2024, the Norwegian Ministry of Health and Care Services (the HOD) issued a significant ruling in favour of Novo Nordisk, overturning a previous decision by the NoMA dated 11 October 2023. The NoMA had imposed a fine of NOK1.5 million on Novo Nordisk for alleged illegal advertising related to its medicinal products Ozempic, Wegovy and Saxenda. However, upon reviewing Novo Nordisk's appeal, the HOD found substantial legal and procedural flaws in the NoMA's decision.

Contributed by: Camilla Vislie, Magnus Hauge Greaker, Martin Guldbrandt Hansen and Nora Solberg Bjørnnes, **Advokatfirmaet Thommessen AS**

One significant criticism from the HOD was the NoMA's failure to inform Novo Nordisk about its communications with the Norwegian Association for General Practice (NFA), which the NoMA had cited as supporting evidence for the decision. The HOD concluded that this lack of notification violated Novo Nordisk's right to challenge the evidence presented against it, resulting in the dismissal of the NFA's statements in the NoMA's evaluation.

Additionally, the HOD concluded that all advertisements in question adhered to the Norwegian Medicinal Products Regulation, thus not constituting any breach of advertising rules. Key findings from the HOD's assessment are as follows.

- Advertisement analysis – the HOD found that the advertisements provided adequate information aligned with product descriptions, enabling recipients to form informed opinions about the therapeutic value of the medicinal products.
- Off-label use concerns – the HOD noted that the NoMA had raised concerns regarding off-label use but failed to demonstrate a direct connection between Novo Nordisk's advertisements and any such off-label use.
- Imposition of penalties – given the absence of any violations of advertising regulations, the HOD determined that no penalties should be imposed on Novo Nordisk.

In summary, the HOD ruled that the errors made by the NoMA significantly impacted the validity of its decision, rendering the NoMA's decision null and void. This ruling represents a significant development in the administrative oversight of advertising regulations for medicinal products in Norway, highlighting a trend toward a more thorough examination of regulatory actions. The HOD's decision is final.

Novo Nordisk was represented by Thommessen in this matter.

POLAND

Law and Practice

Contributed by:
Krystyna Szczepanowska-Kozłowska, Marcin Ziarkowski, Krzysztof Popławski and Kacper Sobolewski
A&O Shearman, A. Pedzich Sp. k.

Contents

Contributed by: Krystyna Szczepanowska-Kozłowska, Marcin Ziarkowski, Krzysztof Popławski and Kacper Sobolewski, **A&O Shearman, A. Pedzich Sp. k**.

A&O Shearman, A. Pedzich Sp. k. was formed in 2024 via the merger of Allen & Overy and Shearman & Sterling and is a fully integrated elite global firm with around 7,000 people and nearly 4,000 lawyers, including almost 800 partners working across 47 offices in 29 countries. A&O Shearman has the depth of experience and diversity of talent to operate at the forefront of business across every industry sector, market, and geography. The firm's strength comes from its global capabilities and unyielding standard of excellence, supported by deep local roots, relationships, experience, and knowledge. A&O Shearman's Poland team features over 70 Polish and foreign lawyers. The IP practice in Warsaw is focused mainly on IP litigation, with special attention paid to patent litigation. However, the firm has also built a stable transactional and advisory, non-contentious IP practice. It advises on some of the most technically complex and commercially important litigation cases, as well as market-shaping transactions. In patent litigation, A&O Shearman handles most of the major disputes in Poland.

Authors

Krystyna Szczepanowska-Kozłowska is a partner at A&O Shearman, heading the firm's IP and commercial litigation department. She is an attorney-at-law with over 20 years of experience, and provides clients with cutting-edge advice on a wide range of IP issues relating to patents, trade marks and copyrights, both contentious and non-contentious. Krystyna advises on a wide range of complex cases, working with both national and international clients on high-profile and strategic matters. She represents major international companies in their high-profile and exceptionally complex patent and trade mark disputes, which require a significant amount of technical expertise. Additionally, she is a professor and author of publications.

Marcin Ziarkowski is an advocate and senior associate in the IP and commercial litigation department at A&O Shearman. He frequently advises on IP/IT aspects of M&A transactions involving the IT, e-commerce and new technologies sectors. He has been involved in various commercial cases, as well as in numerous patent invalidation proceedings. Marcin has been representing clients in many proceedings for the invalidation of industrial property rights before the Patent Office of the Republic of Poland. Marcin joined A&O Shearman in 2016 and has climbed the corporate ladder to the level of senior associate. In 2017, he graduated from the Intellectual Property Postgraduate Studies at the University of Warsaw.

Contributed by: Krystyna Szczepanowska-Kozłowska, Marcin Ziarkowski, Krzysztof Popławski and Kacper Sobolewski, **A&O Shearman, A. Pedzich Sp. k**.

Krzysztof Popławski is an advocate and an associate in the IP and commercial litigation department at A&O Shearman. He advises on a wide range of commercial issues, including IP, M&A and arbitration. Krzysztof has been involved in high-profile IP, M&A, real estate court and patent invalidation proceedings, as well as arbitration disputes.

Kacper Sobolewski is an associate in the IP and commercial litigation department at A&O Shearman. Kacper graduated from the Faculty of Law at the University of Warsaw in 2022, and he is currently doing his advocate traineeship at the Warsaw Bar Association. With his experience involving commercial and patent invalidation disputes, Kacper aims to become a versatile litigator. In 2023, he was admitted to the Doctoral School of Social Sciences of the University of Warsaw, where he is now also pursuing a PhD in administrative law.

A&O Shearman

ul. Grzybowska 56
00-844 Warsaw
Poland

Tel: +48 22 820 6000
Fax: +48 22 820 61 99
Email: warsaw_reception@aoshearman.com
Web: www.aoshearman.com

A&O SHEARMAN

Contributed by: Krystyna Szczepanowska-Kozłowska, Marcin Ziarkowski, Krzysztof Popławski and Kacper Sobolewski, **A&O Shearman, A. Pedzich Sp. k**.

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

An infringement action should be brought by the patent holder. If several entities own the patent, each co-holder can bring an action independently. An exclusive licensee who is registered in the patent register can also bring an action. The patent holder does not have to participate in the proceedings if the action is brought by an exclusive licensee.

Any entity, including the alleged infringer, can bring a motion for patent invalidation. A motion for invalidation in the public interest can also be brought by the Attorney General of the Republic of Poland or the President of the Polish Patent Office (the PPO).

1.2 Defendants/Other Parties to an Action

The decision to sue a particular entity for patent infringement depends on many factors, which may vary depending on the type of patent (product patent, process patent or use patent), as well as the mode of distributing the medicinal product. The most sued entities are those that offer medicinal products for sale.

Although pharmacists, doctors, and HRAs can theoretically be sued, such cases do not occur in practice.

In the case of patent infringement, there is no obligation to notify HRAs or the PPO. In the case of invalidation, the PPO knows about the ongoing proceedings ex officio because the application for patent invalidation is filed with this body.

1.3 Preliminary Injunction Proceedings

In matters of patent infringement, the court usually grants a preliminary injunction (PI) after hearing the party that is obliged to cease the infringing activities. The proceedings are, therefore, inter partes, meaning that both parties are involved. The court should hold the hearing within one month from the date of receiving the motion for a PI. The obliged party may respond to the motion and present relevant evidence within the time limit set by the court.

There are two exceptions to this rule, as outlined below.

- The court may grant a PI without hearing the obliged party if an immediate decision on the application is necessary.
- Moreover, the court decides without the participation of the obliged party in the case of those methods of injunction that are entirely subject to execution by the court bailiff. One such method of injunction is the seizure of goods infringing the patent.

In cases where the court rules on an injunction without the participation of the obliged party, they may learn about the pending proceedings by monitoring court dockets. It is within the discretionary power of the judge to consider the party's position in a situation where the injunction is ex parte. In the case of an injunction executed by a court bailiff, when proceeding to the seizure, the decision on the injunction is delivered, which the obliged party may appeal against.

An appeal against an injunction must be filed within one week from the date of delivery of the decision granting a PI with a justification.

The entitled party who requests an injunction to prevent patent infringement must prove the existence of a patent infringement claim and demonstrate a legal interest in granting the PI. However, a legal interest only exists if the motion for a PI was filed six months before the expiry date on which the applicant became aware of the patent infringement. The applicant is also required to notify the court of any invalidation proceedings. When assessing the validity of a patent infringement claim, the court is bound to take into account the likelihood of the invalidation of the patent.

Claims for patent infringement may be pursued after the grant of a patent. In the case of European patents, this is possible after their validation in Poland, ie, after the publication of the translation of the European patent into Polish. Claims for patent infringement cannot be pursued based on a patent application.

Polish law also allows a claim to cease actions that threaten to infringe the patent right. Such a claim may also be secured. To prove such a claim, one must show that patent infringement in the future is inevitable. Likewise, as in the case of securing a claim for patent infringement, one must demonstrate a legal interest.

Obtaining a marketing authorisation is insufficient to obtain an injunction, as the decision to authorise a medicinal product for marketing does not constitute patent infringement. It is necessary to show that the marketing authorisation holder (MAH) will undertake actions that constitute patent infringement.

1.4 Structure of Main Proceedings on Infringement/Validity

The infringement proceedings are independent of the invalidity proceedings. In civil cases, the Regional Court in Warsaw, which handles intellectual property matters, is responsible for recognising patent infringement. Meanwhile, the Polish Patent Office (PPO) has the authority to invalidate a national or European patent.

The court is not required to pause its proceedings when there are ongoing patent invalidity proceedings. However, suspending the infringement proceedings cannot be completely ruled out due to the large margin of discretion of the court in this matter.

The patent invalidation proceedings can be initiated independently of the ongoing opposition proceedings.

1.5 Timing for Main Proceedings on Infringement/Validity

Claims for patent infringement are subject to a three-year limitation period, which begins when the entitled entity becomes aware of both the infringement and the infringer's identity. This three-year period applies to each separate infringement. However, claims are barred after five years from the date the patent infringement occurred.

A lawsuit for infringement is served on the defendant by the court. The court sets a deadline for responding when serving the complaint and the defendant may request an extension of this deadline. The deadline cannot be shorter than two weeks. As a rule, the court requires that a party present all allegations and evidence in response to the complaint. Failure to do so may result in losing the right to invoke them later unless it can be justified that the party could not raise those points due to new facts or circumstances or that the need to raise them arose at a later stage.

A request for invalidation is served on the patent holder by the PPO. If the patent holder resides or is based in Poland, the PPO sets a response deadline of no less than one month. If the patent holder is based outside of Poland, the deadline is extended to two months. This deadline can be extended further if the patent holder notifies the PPO in writing, explaining the reasons for the delay before the original deadline expires.

In the case of patent infringement, the first hearing is usually scheduled within eight to ten months from the date of filing the response to the claim and the proceedings in the first instance last about two to three years. Usually, before the first hearing, the court orders the exchange of further preparatory pleadings.

In cases of requests for invalidation, the first hearing is typically scheduled within six months from the filing date. The invalidation proceedings before the PPO usually last about one to two years.

1.6 Requirements to Bring Infringement Action

Claims for patent infringement can be initiated once the patent has been granted. If the infringer acted in good faith, claims can be pursued starting from the day the PPO announced the invention application. However, if the patentee had previously notified the infringing party about the filed application, claims can be pursued from the date of that notification.

In the case of European patents, the patentee must submit a Polish translation of the European patent to the PPO within three months from the date of publication by the European Patent Office (the EPO) of the information about the European patent being granted.

Claims for infringement of a European patent can be pursued starting from the date when the translation of the claims of the European patent application is published in the bulletin of the Polish Patent Office. This translation must be filed by the applicant with the PPO.

In cases involving patents for a process, the burden of proof is shifted. When it comes to new products, if the patent holder can demonstrate that they were unable to determine the actual method used by another person to produce the product, despite making due efforts, they may rely on the assumption that the product was made using the patented production method.

1.7 Pre-Action Discovery/Disclosure

The Polish procedure in patent infringement cases provides for two types of discovery/disclosure proceedings:

- request for information; and
- request for disclosure or delivery of evidence.

Request for Information

A request for information can be filed both before and during the infringement proceedings.

The scope of information and the manner of the proceedings in the case of a request for information does not differ depending on whether the request is filed before or during the infringement proceedings. The entitled party is obliged to demonstrate the circumstances indicating the infringement credibly. Within these proceedings, only information on the origin and distribution networks of goods or services can be demanded if it is necessary to pursue the claim.

If the request for information was filed before the commencement of the proceedings, and the court ordered the entity to provide information,

then the party requesting information shall commence the infringement proceedings within the time limit set by the court, not longer than one month from the date of the decision on providing information. If such proceedings have not been initiated, the required party has a claim for damages. This claim also applies in cases where the lawsuit was dismissed, withdrawn or discontinued.

Request for Disclosure or Delivery of Evidence

A request for disclosure or delivery of evidence is possible only during ongoing infringement proceedings and can be made if the plaintiff has substantiated their claim. The requesting party must specify the evidence they seek to disclose or deliver and provide reasons for such a request. In particular, they must show that the defendant holds the evidence in question.

Polish civil procedure does not address the use of evidence or information obtained in proceedings conducted abroad. Therefore, there is no formal prohibition on using such information. However, when using such information, one should avoid disclosing the defendant's trade secrets in another jurisdiction. This means that the disclosure of information obtained abroad would be possible in practice only if the proceedings in both Poland and abroad involved the same parties.

1.8 Search and Seizure Orders

Evidence can be secured before the proceedings start or at any point until the trial ends in the first instance. The application for securing evidence should be examined within one week from the date of its submission. Both before the initiation of the proceedings for infringement and during their course, the entitled party must demonstrate the claims and show the existence of a legal interest in securing evidence. A legal interest exists when:

- not securing evidence would make it impossible or severely hamper the presentation or proof of facts relevant for reaching the decision;
- there is a risk of evidence being destroyed;
- a delay in obtaining evidence could hinder the achievement of the goal of the evidentiary proceedings; or
- there is a need to ascertain the existing state of affairs for other reasons.

The court decides on the application without the parties' participation. If it rules before the initiation of the proceedings, it sets a deadline for filing an infringement lawsuit within a period of not less than two weeks and not more than one month from the date when the decision becomes final.

The court only sends its decision on securing evidence to the entitled party. The other party gets this decision from the court bailiff, who executes it. The execution of this decision, at the request of the obliged party or the defendant, may take place with the participation of a court expert. A complaint against the decision on securing evidence is admissible.

Polish civil procedure is silent on the use of evidence or information obtained in proceedings conducted abroad. Therefore, there is no formal barrier to using such information. However, when using such information, one should avoid disclosing the defendant's trade secrets in another jurisdiction. This means that the disclosure of information obtained abroad would be possible only if the same parties were involved in the proceedings in both Poland and abroad.

1.9 Declaratory Relief

Polish law provides for an action to establish that the actions taken or intended do not infringe a patent. Such an action can be brought by an entity with a legal interest. According to Polish law, legal interest occurs in two cases:

- the patent holder has asserted that the actions covered by the action constitute an infringement of the patent. This assertion is usually made by sending a cease and desist letter to the entity; or
- the legal interest arises when the entity asks the patent holder to confirm that the actions covered by the lawsuit do not infringe their patent, but the patent holder has not confirmed this within a reasonable deadline.

The law also provides that, to be duly set, the deadline for the patent holder to respond must:

- be in writing;
- not be shorter than two months from the date of delivery of the request;
- clearly indicate the actions that may infringe the patent and the extent of possible infringement; and
- ask the patent holder to expressly confirm that these actions do not infringe the patent.

1.10 Doctrine of Equivalents

Polish law does not expressly provide for the doctrine of equivalents. However, Polish courts sometimes refer to the doctrine of equivalents. In particular, the Supreme Court confirmed in its judgment (V CSK 149/15) that they cannot rely on a literal interpretation of the claims. According to the methodology proposed by the Supreme Court, the answer to whether there has been an infringement is based on the following stages of examination:

- determining the subject matter of the patent on the basis of its claims, description and drawings, taking into account the technical problem underlying the invention and the essence of its solution, as well as the type of the protected solution;
- determining the technical features of the disputed solution, including the technical problem underlying it and the essence of the disputed solution;
- determining which of the technical features of the disputed solution reflect functionally the solutions already existing in the prior art (determining the closest prior art for the disputed solution);
- comparing the determined subject matter of the patent with the technical features of the disputed solution to verify which features of the protected solution have been reflected in the disputed solution in the form of their obvious equivalents; and
- determining, in case the technical features (obvious equivalents) reproduced in the disputed solution are essential for the technical solution protected by the patent, whether these features could have been developed by a person skilled in the art without knowledge of the patent.

1.11 Clearing the Way

Polish law does not provide for an obligation to "clear the way" ahead of a new product launch.

1.12 Experts

In patent infringement cases, the court uses written expert opinions as evidence. The court appoints experts at the request of the parties. The parties must make such a request in the claim or the reply to the claim.

The party requesting the admission of an expert opinion may suggest persons or institutions that

have the appropriate knowledge, but the final decision on who will become an expert in the case belongs to the court. The parties may ask questions to the experts at the hearing if they make such a request after familiarising themselves with the expert opinion. If the party disagrees with the content of the opinion, it may file a motion for the appointment of another expert. The admission of another opinion from a different expert depends on the discretion of the court.

The parties may also attach expert opinions prepared at their own request. Such opinions are, however, treated as statements of the parties themselves. Such opinions are often used by the parties in patent infringement proceedings. They allow them to better explain to the court the complex issues of a technical nature.

In patent invalidation proceedings, evidence from an expert opinion is usually not admitted unless the PPO (seldom) deems it necessary. As in infringement proceedings, the parties often submit private expert opinions to corroborate their claims.

1.13 Use of Experiments

Experiments are allowed in patent infringement proceedings. An experiment can also be part of expert opinion evidence if conducting it or assessing its results requires expert knowledge. The court determines the manner of conducting the experiment.

The results of the experiments carried out outside the court proceedings can also be attached as so-called private documents. In such cases, they are subject to evaluation according to the rules applicable to other evidence.

Theoretically, there are no obstacles to admitting evidence in the form of an experiment in the invalidation proceedings before the PPO. However, in practice, this would involve admitting an expert, which the PPO is generally reluctant to do. On the other hand, it is not uncommon for the parties to submit documents describing the conduct and results of experiments, which, of course, the PPO can take into account when deciding the case.

1.14 Discovery/Disclosure

The party claiming infringement is required to provide evidence that the patent has been violated, which entails proving that the defendant engaged in actions that constitute patent infringement. For instance, this could involve presenting samples of the goods made available in the market, along with documents confirming their purchase, or providing evidence of such products being offered, such as relevant information regarding the availability of medicinal products. To establish infringement, it is essential to demonstrate that these goods possess the features protected by the patent, which may include documents containing relevant analyses or expert opinions.

The defendant must show that the products introduced to the market do not have the features protected by the patent by presenting descriptions of products, processes, or documents in the form of private opinions or analyses.

1.15 Defences and Exceptions to Patent Infringement

Polish law does not contain a closed list of defences that can be raised in patent infringement proceedings. Patent infringement is precluded by the consent of the right holder (eg, in the form of a licence agreement) or by a statutory right to use the patent.

Polish law allows the use of the patent in the following cases:

- transit privilege (transit);
- use of the invention for state purposes (subject to a decision by the relevant public authority);
- use of the invention for research and experimental purposes to assess, analyse, or teach it;
- Bolar exception; or
- preparation of the medicine in a pharmacy based on an individual medical prescription.

The accused infringer may invoke exhaustion as a defence. The defence cannot be based on the so-called free state-of-the-art.

Due to the principle of bifurcation, the court cannot examine the invalidity of the patent on its own initiative, but of course, raising the invalidity defence may – if the court deems it appropriate – lead to the suspension of the infringement proceedings until a decision on the invalidity claim is issued.

1.16 Stays and Relevance of Parallel Proceedings

The court that adjudicates the infringement is bound by the decision to grant the patent. In theory, a parallel proceeding for the invalidation of the patent does not affect the examination of the infringement case. However, the court may sometimes suspend the infringement proceeding in such a situation. This is a matter of the court's discretion.

There are no legal grounds to suspend the proceeding because of a parallel proceeding in another jurisdiction. The judgments of courts from other jurisdictions may only have a psychological impact. The court does not refer to the reasoning contained in the rulings issued in other jurisdictions in its justification.

1.17 Patent Amendment

The PPO can limit a patent upon the patentee's request. A patentee can file such a request even if there is an ongoing infringement proceeding, but this is not a common practice. The court that hears the infringement case has to respect the patent as granted unless the PPO changes it. Alternatively, a patentee can request the limitation of a patent during an invalidity proceeding but only before the first hearing. The PPO will not accept any requests for limitation after the first hearing.

1.18 Court Arbiter

The Regional Court in Warsaw – the Court for Intellectual Property Matters – has exclusive jurisdiction in matters concerning inventions in both PI and infringement proceedings. The judges deciding in this court are specialised in intellectual property matters. They do not have a technical background or expertise. The cases and appeals are, respectively, decided and heard by a single judge.

2. Generic Market Entry

2.1 Infringing Acts

A lawsuit for infringement may be filed if actions that constitute an infringement of the patent right are taken, ie, making, offering, using, putting on the market, importing, exporting, or storing or keeping for those purposes.

Obtaining a marketing authorisation alone does not constitute an infringement of the patent right, as it does not yet amount to an offering. However, the Polish courts considered entering a medicinal product on the reimbursement list as

an offering. An offering also includes submitting a bid in a tender procedure.

In the case of patents for use, the trigger point that allows for filing a lawsuit for infringement is offering the product for protected use, even if that use has been removed from the SmPC. In practice, such a case may occur when a product is reimbursed outside the protected use or when a bid is submitted in a tender concerning the protected use despite skinny labelling.

2.2 Regulatory Data and Market Exclusivity

The data exclusivity period is eight years from the date of granting the first marketing authorisation in Poland, the EU or a state party to the agreement on the European Economic Area (the EEA). However, the market exclusivity is ten years. This period is calculated in the same way as for the data exclusivity period.

The market exclusivity period may be extended for up to 12 months if an approval or authorisation is issued to add a new indication or indications within the eight-year data exclusivity period. The extension of the market exclusivity is conditional on a positive assessment by the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (the Polish Drug Authority), which shows that the new indications constitute significant clinical benefits.

An application for registration of a product containing a substance with well-established medical use in the territory of an EU state or a state party to the EEA agreement may be submitted after at least ten years have elapsed since the first systematic and documented use of this substance in a medicinal product and its proven efficacy and acceptable level of safety. If the application includes new therapeutic indications based on significant non-clinical or clinical studies for such a substance, an additional one-year exclusivity period is granted from the date of the decision on this matter.

The data exclusivity periods described above, resulting from Polish law, apply to reference medicinal products for which a marketing authorisation has been obtained in the national or mutual recognition procedures. In the case of authorisations obtained in the centralised procedure, Regulation 726/2004, laying down community procedures for granting authorisations, applies directly. This Regulation provides for a similar eight-year period of data exclusivity and a ten-year period of market exclusivity, which may be extended to eleven years if, during the first eight years of exclusivity, the holder obtained authorisation for one or more therapeutic indications that bring significant clinical benefits compared to existing therapies.

2.3 Acceptable Pre-Launch Preparations

Polish law provides for the so-called Bolar exemption. The Bolar exemption is defined very broadly in Polish law and allows for the use of an invention consisting of making, using, storing, keeping, offering, putting on the market, exporting or importing. These activities can be undertaken to perform the acts that are required by law to obtain marketing authorisation. According to the law, the Bolar exemption can be invoked not only by the person who applies for the registration of a medicinal product but also by a third party, eg, a manufacturer of an active substance. The Bolar exemption can be invoked if the application was filed in the countries constituting the territory of the EEA, as well as in other countries.

2.4 Publicly Available Drug and Patent Information

The Polish Drug Authority maintains the Register of Medicinal Products Authorised for Marketing in Poland. The following are entered into the Register:

- medicinal products with a marketing authorisation issued by the President of the Polish Drug Authority in national (NAR), mutual recognition (MRP) and decentralised (DCP) procedures;
- medicinal products with a marketing authorisation issued by the European Commission in the centralised (CEN) procedure; and
- medicinal products with a parallel import authorisation (IR).

Once a month, The Polish Drug Authority announces a list of medicinal products that have obtained marketing authorisation. In principle, information on the registration of a medicinal product is available after the marketing authorisation is granted. As part of the access to public information, the Polish Drug Authority usually refuses to provide detailed information, only stating the fact that there are ongoing proceedings for marketing authorisation and indicating the number of ongoing proceedings.

The MAH for the reference product registration does not get notified about the ongoing procedure concerning marketing authorisations for generic products or biosimilars. However, they can request access to the files of the ongoing procedure. Although the Polish Drug Authority refuses access to the files, invoking the necessity of demonstrating a legal interest, according to the latest jurisprudence of administrative courts, the MAH of the reference product should receive access to the files of the ongoing proceedings.

2.5 Reimbursement and Pricing/Linkage Markets

As a rule, the procedure for granting a marketing authorisation does not take into account the existence of patent protection. Similarly, in the case of reimbursement, patent protection is irrelevant. An exception is a situation when the responsible entity applying for the registration of a generic medicinal product submits a request to remove from the SmPC data relating to therapeutic indications or pharmaceutical forms covered by patent protection. In the procedure for granting authorisation, such an entity submits a statement about the existence of patent protection for the specified indications or forms from which it wants to withdraw. The authority issuing the authorisation is not obliged to examine whether the patent protection of these indications or forms exists.

Therefore, a generic drug can be added to the list of reimbursed drugs despite the existence of patent protection. However, in practice, drugs whose reference equivalents are protected by patents are rarely entered on the list of reimbursed drugs due to the possibility of the patent holder initiating a patent infringement proceeding and the possibility of obtaining a prohibition of introducing the generic product to the market in the PI proceeding.

The Minister of Health publicly announces the reimbursement list every three months. The list is announced in the month preceding the next three-month period in which it will be valid. Monitoring the Minister of Health's announcements is the only way to determine if a given medicinal product will be reimbursed because the MAH of the reference drug is not notified of the inclusion of the generic/biosimilar drug on the reimbursement list. The reimbursement list indicates the range of indications covered by the reimburse-

ment for each drug, distinguishing situations for individual preparations, whether they are all registered indications or just some of them.

3. Biosimilar Market Entry

3.1 Infringing Acts

For biosimilars, the situation is much like that of generic drugs.

3.2 Data and Regulatory Exclusivity

The data exclusivity periods for biosimilars are the same as for generic drugs. To use the data of the reference product, the biological product must meet the same criteria as the generic products for equivalence to the reference medicinal products. If these criteria are not met, especially because of differences in the starting materials or manufacturing processes of these products, the responsible entity must present the results of clinical or non-clinical studies

3.3 Acceptable Pre-Launch Preparations

For biosimilars, the situation is much like that of generic drugs.

3.4 Publicly Available Drug and Patent Information

For biosimilars, the situation is much like that of generic drugs.

3.5 Reimbursement and Pricing/Linkage Markets

For biosimilars, the situation is much like that of generic drugs.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

SPCs are available in Poland on the basis of EU Regulation 469/2009. This protection is, therefore, identical in all EU member states.

Granting an SPC is possible if:

- the product constituting the active ingredient or a mixture of active ingredients of the medicinal product is protected by a basic patent remaining in force;
- a marketing authorisation has been issued for the product as a medicinal product in accordance with the relevant EU regulations (ie, Directive 2001/83 for medicinal products for human use and Directive 2001/82 for veterinary products);
- the product has not been previously the subject of a certificate; and
- the marketing authorisation is the first authorisation to market the given product as a medicinal product.

An SPC is granted to the entity entitled to the basic patent. The subject matter of SPC protection is any medicinal product protected by a basic patent in Poland (national or European).

The basic patent can be a patent for a product, a process or an application of the product. However, the theoretical possibility of obtaining an SPC for a product protected by a patent for use was significantly limited by the CJEU's interpretation of the concept of the first marketing authorisation in the Santen case (C-673/18). According to this judgment, marketing authorisation for a new use of an active ingredient or a combination of active ingredients, which had already been the

subject of a marketing authorisation for another therapeutic use, cannot be considered the first marketing authorisation. In practice, this means that only in the case of a patent for the first medical use can an SPC be granted.

A medicinal product is a product consisting of a substance or a mixture of substances used for treatment, prevention, therapy or diagnosis. A product is protected by the basic patent as long as the product in its chemical form mentioned in the marketing authorisation remains protected by the basic patent.

An application for an SPC must be filed in the country in which protection is sought within six months from the date of the marketing authorisation for the medicinal product. If the marketing authorisation was issued before the patent was granted, then the application for the certificate must be filed within six months from the date of granting the patent.

As explained by the CJEU, if the same patent protects several products, then several supplementary protection certificates can be obtained, provided that each of these products is protected by the basic patent and is contained in the medicinal product for which marketing authorisations have been issued.

If the patent protects a mixture of products and each product separately, then on the basis of the same patent and marketing authorisation, a certificate can be issued both for the mixture of active ingredients and for the active ingredient, considered individually. An SPC can only be granted for those active ingredients that have been mentioned in the claims of the basic patent. If the patent only protects a mixture of active substances and does not protect the individual substances separately, then it is impossible to issue an SPC that protects one of the substances in the mixture.

An SPC applies after the expiry of the basic patent. The duration of the SPC cannot exceed five years from the date on which the SPC takes effect. The term of the SPC in a specific case is determined by calculating the period that elapsed between the date of filing of the basic patent and the date of the first marketing authorisation granted for the product in the EU, subtracting five years from it.

4.2 Paediatric Extensions

Regulation 469/2009 allows for the extension of the SPC by six months. The granting of the so-called paediatric extension depends on whether the application for marketing authorisation of the medicinal product in the EU includes the results of all the studies conducted and the details of all the information collected in accordance with the approved paediatric investigation plan, pursuant to Article 36 of Regulation 1901/2006 on medicinal products for paediatric use.

4.3 Paediatric-Use Marketing Authorisations

Paediatric use marketing authorisation (PUMA) is available in Poland on the basis of Regulation (EC) No. 1901/2006; therefore, the procedure to obtain it is identical in all EU member states. PUMA is granted through existing marketing authorisation procedures and only applies to medicinal products developed exclusively for paediatric medicines that are no longer covered by intellectual property rights. However, the application must include a paediatric investigation plan regarding the quality, safety and efficacy of the medicine among children. PUMA benefits from eight years of data exclusivity plus an additional two years of marketing exclusivity.

4.4 Orphan Medicines Extensions

According to the provisions of Regulation (EC) No. 141/2000, medicinal products designated as orphan medicines benefit from a ten-year market exclusivity period, which is granted for a specific clinical indication, meaning that each indication with an orphan designation confers an independent ten-year exclusivity period. Once the period of market exclusivity for all the orphan designations has expired, the product ceases to be classified as an orphan medicine.

Regulation (EC) No. 1901/2006 allows for an extension of this period. Two additional years can be granted if the requirements for use in the paediatric population are fully met. Extensions are granted following a positive compliance assessment conducted by the Paediatric Committee and Committee for Medicinal Products for Human Use.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

Under the provisions of the code of civil procedure, a party subject to a wrongful injunction is entitled to claim damages from the patentee. Third parties cannot claim such compensation.

Generally, a PI is immediately enforceable. If the PI entails the seizure of goods, it is served by a bailiff. Otherwise, it is the court who serves the injunction. Although it is not a standard requirement, the court can condition the enforcement of the issued PI on the entitled party paying a bond, either on its own initiative or at the request of the obliged party.

While granting a PI, the court sets a deadline (no longer than two weeks) for the claimant to bring the main action — failure to do so results in the revocation of the PI.

It is at the court's discretion to stay a PI pending appeal on the request of a party subject to the PI.

5.2 Final Injunctive Relief

Final injunctions are enforceable after the court's ruling becomes final, which means it is not subject to further appeal or cassation.

However, the court may order the immediate enforceability of the injunction, even if it is still appealable if it finds that the delay will impede or seriously obstruct the enforcement of the judgment or put the claimant at risk of harm. In such cases, the court may also require the claimant to provide a bond to cover the defendant's potential damages if the injunction is reversed or modified on appeal.

The enforcement of the injunction is based on the enforceable ruling and an enforcement clause issued by the court. The enforcement is carried out by a bailiff, who acts upon the claimant's request.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

The court may award damages in lieu of a final injunction:

- at the infringer's request;
- if the infringement was not culpable (ie, neither intentional nor negligent) conduct;
- where awarding the injunction would place an undue burden on the party subject to it; and
- only if pecuniary compensation is sufficient to satisfy the infringed party's interest.

In practice, the applicability of this measure is fairly limited, and Polish courts rarely use this discretion. While deciding on a PI, the court is always under a general obligation not to place an undue burden on the party subject to injunction.

5.4 Damages

General Considerations

Two main pecuniary claims can be raised against a patent infringer.

First, there is a classic claim for damages where the claimant is required to demonstrate that:

- the infringement is attributable to the infringer (it was either intentional or caused by the infringer's negligence); and
- damage was inflicted on the claimant, and that damage is a result of the infringement (there is a so-called ordinary/adequate causal relationship between the two).

Both the actual damage (damnum emergens) and hypothetical but highly probable lost profits (lucrum cessans) are subject to compensation. The claimant should demonstrate the value of the damages, which is especially troublesome with respect to lost profits.

The claimant may also choose to have the compensation calculated as an amount of a hypothetical licence fee or other remuneration that would have been due for authorising the infringer to exploit the invention (reasonable royalty).

Second, there is a claim to hand over any benefits unlawfully obtained by the infringer (corresponding to the "recovery of profits" as described in Article 13(2) of Directive 2004/48). Therefore, this is not exactly a claim for hypothetical profits lost by the patent holder (or by the licensee) but for the infringer's actual profits resulting from the unlawful exploitation of the invention. It is not clear, however, to what extent the infringer is allowed to deduct their expenses, ie, whether the claim is limited to the infringer's net profit or whether they have to hand over literally any benefits, ie, all the income resulting from exploiting the inventions. The claim to hand over unlawfully obtained benefits does not require the claimant to demonstrate damage on their side and does not depend on whether the infringement is attributable to the infringer.

The claim for damages and the claim for unlawfully obtained benefits are independent and can be raised together. However, the court will likely limit the damages by the amount awarded as unlawfully obtained benefits.

Claiming lost profits is usually the least preferred patent infringement claim, as it is exceptionally troublesome from an evidentiary perspective. Claimants would rather claim unlawfully obtained benefits since once the infringer's business records are secured, tracking how the infringer profited from the infringement is relatively easy.

Awards

The royalty on revenues for units sold is determined on a case-by-case basis, albeit, in legal literature, values between 1% and 10% are usually indicated. Polish law provides no basis for the court to aggravate the damages awarded depending on whether the infringement was intentional or negligent. It has been a subject of controversy whether the statutory interest for default in payment can only accrue from the moment the damages are awarded by the court or from the moment the infringed party issues a call for payment.

Procedural Issues
Damages are generally considered together with liability, although it is possible for the court to issue a partial award on liability and only then continue the proceedings to determine the exact compensation.

Damages for Wrongful Injunction
An alleged infringer can claim damages for a wrongful injunction. See **5.1 Preliminary Injunctive Relief** for more details.

5.5 Legal Costs
The rule is that the party who loses the dispute has to pay the legal costs, including court fees, attorney fees and certain other expenses (eg, the remuneration of a court-appointed expert).

Costs before filing actions are usually not recoverable. And so are many expenses incurred during the proceedings (eg, commissioning a private expert opinion).

Generally, the legal costs awarded by the court are usually but a fraction of a party's actual expenses. This is especially true with respect to attorney fees.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief
The claimant's conduct may lead to a reduction of the legal costs awarded but will generally not affect the scope of the final relief.

6. Other IP Rights

6.1 Trade Marks
Trade mark disputes in the life sciences and pharma sector are uncommon in Poland.

However, in 2022, the Supreme Administrative Court issued two judgments concerning a long-standing dispute between Swiss Pharma International AG (Polpharma Group) and Hasco TM (Hasco Group) over the "ANACARD PRO" trade mark (Hasco's trade mark) and its similarity to the "ACARD" trade mark (Swiss Pharma). Both companies produce drugs containing acetylsalicylic acid, which is used in the prevention of heart diseases. Swiss Pharma filed an invalidation application for the "ANACARD PRO" trade mark, claiming that it was similar to the "ACARD" trade mark, which is a reputable trade mark, and therefore Hasco's trade mark was detrimental to its reputation. Hasco, on the other hand, argued that the "ACARD" trade mark had not been used for five years and filed a motion to invalidate it on that basis. The PPO issued a decision on the invalidation of the "ACARD" trade mark and dismissed the invalidation motion for "ANACARD PRO", stating that the trade marks were not similar. Both these cases were appealed to the administrative courts. The decision to invalidate the "ACARD" trade mark was set aside, and the decision to dismiss the invalidation application for the "ANACARD PRO" trade mark was upheld. Both judgments were appealed to the Supreme Administrative Court, which set them aside and referred them back for re-examination. The authors anticipate that the final judgments of both cases will be issued within the next few years.

The applicable laws are mainly the Act on Industrial Property Law of 2000, the Act on Pharmaceutical Law of 2001, the Act on Medical Devices of 2022 and the Act on Combating Unfair Competition of 1993.

6.2 Copyright
Copyright disputes in the life sciences and pharma sector in Polish jurisdiction are not very

common, and so far, no significant dispute has reached its final decision in court. The most prominent case of GSK against Celon ended with a settlement. In this case, GSK claimed that the shape of its inhaler for treating asthma had sufficient originality to be a work within the meaning of copyright law. Celon argued that the shape of the inhaler was necessary to obtain a technical result and was described in such a way in an earlier expired patent, and therefore, it cannot be protected by copyright law. However, because of the settlement, the court did not decide on the merits of the dispute.

Some typical copyright issues which may arise in the life sciences and pharma sector are:

- the protection and enforcement of copyrights in the originality, expression, and form of life sciences and pharma products;
- the transfer of copyrights to works such as the packaging of a drug, its shape, or its trade mark; or
- claims related to advertising activities when a drug manufacturer infringes on someone else's copyrights.

The relevant sources of Polish law that regulate copyright are the Act on Copyright and Related Rights of 1994.

6.3 Trade Secrets

Trade secret disputes are relatively rare in the Polish life sciences and pharma sector. They happen occasionally, especially when former employees, competitors, or third parties unlawfully access confidential information through hacking, espionage, or contract breaches. In Poland, a trade secret is valuable information that is not widely known or easy to obtain by others in the same field and that must be protected by the owner with reasonable measures.

The main legal source for trade secret disputes in the Polish life sciences and pharma sector is the Act on Combating Unfair Competition of 1993, which stipulates that the breach of a trade secret as defined in this act is an act of unfair competition. On a separate note, Polish law does not define "know-how" separately, and it is basically treated as a trade secret within the meaning of the aforementioned act.

7. Appeal

7.1 Timeframe to Appeal Decision

In the Polish legal system, due to the principle of bifurcation, there are two different appellate proceedings:

- from a judgment of the court of first instance in a patent infringement case, the party may file an appeal to the court of second instance; and
- from a decision of the PPO in patent invalidation proceedings, the party may file a complaint to the Voivodeship Administrative Court.

Patent Infringement Cases

In patent infringement cases, the appeal is filed to the court of the second instance (through the court that issued the challenged judgment) within a two-week period from the delivery of the judgment with the reasoning to the appealing party (the deadline may be extended to three weeks). Filing an appeal prevents the challenged judgment from becoming final and transfers the examination of the case to the higher instance court.

In the appeal, the party may raise objections relating to the factual findings made by the first instance court, such as violations of substantive

or procedural law. The appellant has full freedom to present the grounds of appeal.

The appellate proceedings consist of a re-examination of the case by the court of second instance on the basis of the material collected both before the court of first instance and the court of second instance. The court of the second instance may admit new evidence and facts invoked by the party if the possibility of invoking them arose only in the course of the appellate proceedings. The examination of the case takes place within the scope of the grounds specified in the appeal. However, if the proceedings in the court of first instance are invalid, the court will consider it ex officio. The court may examine the case at a non-public session if holding a hearing is unnecessary. However, a court hearing must take place if the party has filed a motion for it.

Second-instance decisions can be appealed to the Supreme Court within two months of the delivery of a reasoned judgment. An appeal on a point of law to the Supreme Court can only be based on points of law or procedural violations that could have affected the outcome of the case. The Supreme Court accepts an appeal on the point of law for examination only in exceptional cases, such as if there is a significant legal issue or there is a need for interpretation of legal rules that raise serious doubts in the courts' jurisprudence. The Supreme Court can uphold, quash, or amend the second-instance decisions or remand the case to the lower courts for reconsideration.

PI Proceedings

An appeal against a PI decision must be filed by a party to the court of second instance (the appellate court). In cases of patent infringement, the competent court will always be the Court of Appeal in Warsaw. However, if the court of second instance issues a PI decision, it must be filed with and reviewed by another panel of judges of the same court.

The obliged party must file an appeal against the decision within seven days of receiving it, along with a justification (the only exception to this is when the court dispenses with the need for a justification of the decision). The appeal is not examined by the court that issued the challenged decision, but that court can review its own decision and amend it before sending the case files to the court of second instance.

During the appeal proceedings, the obliged party has the right to present its arguments. The court of the second instance examines the motion for PI by considering all the circumstances. The court of the second instance should examine the appeal against a PI decision without delay but no later than one month from the date of its receipt. In practice, however, the courts often exceed the one-month deadline, and the appeal may take several months to be reviewed.

In the event of a final dismissal of the motion for a PI, the injunction ceases to be effective.

Patent Invalidation Proceedings

A complaint against decisions on patent invalidity can be filed with the Voivodeship Administrative Court within 30 days from the date of delivery of the decision to the complainant, together with a written justification. The complaint to the administrative court is filed through the PPO. The PPO may exercise self-control over the issued decision, ie, accept the complaint in full within 30 days from the date of its receipt and revoke the contested decision.

In the proceedings, the administrative court does not establish the factual circumstances

of the case, nor does it conduct evidentiary proceedings or assess the evidence collected to determine which facts can be considered proven. Instead, the court focuses on reviewing the actions of the administrative authorities to ensure they were performed correctly. It checks whether the authorities adhered to the relevant provisions of administrative procedure and substantive law, including whether they thoroughly examined and assessed the evidence presented.

The administrative court issuing a judgment is not bound by the scope of the complaint or the legal basis invoked by a party.

A cassation appeal against the judgment of the Voivodeship Administrative Court may be filed with the Supreme Administrative Court within 30 days from the date of service of the judgment. A cassation appeal can be based on a violation of substantive law or a violation of the provisions of the proceedings if the infringement could significantly impact the outcome of the case.

7.2 Appeal Court(s) Arbiter

Patent Infringement Cases

An appeal against a court judgment or a PI decision is examined by one judge specialising in intellectual property matters.

Patent Invalidation Proceedings

Typically, the panel of the Voivodeship Administrative Court that reviews the PPO's decision consists of three judges who may (but do not have to) specialise in patent law, depending on their availability and allocation.

7.3 Special Provisions

A separate procedure for IP cases was introduced in 2020 to ensure high-quality judgments and facilitate evidence gathering for claimants to pursue claims for infringement of intellectual property rights.

The IP cases are examined by intellectual property divisions within the Regional Courts, where judges specialising in intellectual property adjudicate. Particularly complex cases, such as those concerning computer programs, inventions and utility models, are adjudicated exclusively by the Regional Court in Warsaw.

In IP cases, in principle, it is mandatory for the parties to be represented by a professional attorney (an advocate, an attorney-at-law or a patent attorney).

The IP procedure introduced a wide range of possibilities, such as securing evidence, requesting disclosure of evidence and requesting information from the other party (see **1.7 Pre-action Discovery/Disclosure** and **1.8 Search and Seizure Orders** for more details).

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

There are no other relevant forums or procedures with respect to life sciences & pharma IP litigation in Poland.

9. Alternative Dispute Resolution

9.1 ADR Options

In Poland, patent litigation continues to be the norm. ADR forms in life sciences disputes in Poland are rare and face several obstacles. These are particularly attributable to the following factors: the lack of awareness of ADR options, the preference for court litigation (specialised

courts), the bifurcated patent litigation system that prevents the arbitrability of patent disputes concerning patent validity, and the invalidity of settlements concerning patent validity.

Regardless of the above, the following ADR forms are available in Poland.

Arbitration

Life sciences disputes are rarely resolved in arbitration proceedings. This results largely from the necessity of concluding an arbitration clause by the parties to the dispute (and some disputes concern infringement of rights by entities with whom no contract was concluded) and the lack of the arbitrability of disputes concerning patent validity. A decision by an arbitral tribunal on the validity of a patent would be invalid – this is a competence reserved exclusively for the PPO. Nevertheless, it is possible to conclude an arbitration agreement between the parties in the remaining scope and resolve the dispute, for example, on patent infringement.

Mediation

Depending on the type of proceedings, court proceedings or before the PPO, there are instruments encouraging the parties to reach a settlement on their dispute. Nevertheless, mediation is not a common option for life sciences disputes in Poland.

In court proceedings, mediation is regulated by the Civil Procedure Code, which provides for both court-annexed and out-of-court mediation. Court-annexed mediation may be initiated by the parties or suggested by the court at any stage of the proceedings, and the parties may choose their own mediator or accept one appointed by the court. The parties may initiate out-of-court mediation before or after the commencement of litigation, and they may select their own mediator and rules.

The PPO offered a way to resolve amicable disputes arising from opposition to trade mark applications through voluntary mediation proceedings conducted jointly with the WIPO and following the WIPO's mediation rules.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

Some specific settlement/antitrust considerations in Poland may affect pharma/biopharma settlements.

Poland is a member of the EU and, therefore, subject to EU competition rules, including Article 101 of the Treaty on the Functioning of the European Union, which prohibits agreements that restrict or distort competition within the internal market. This means that pharma/biopharma settlements that involve potential or actual competitors and affect trade between EU member states may be subject to EU antitrust enforcement and national enforcement by the Office of Competition and Consumer Protection.

In addition to EU competition rules, Poland has its own national competition law, which is largely aligned with EU law but may differ in interpretation or application. The main national competition law provisions of the Act on Competition and Consumer Protection prohibit agreements that restrict or distort competition within the Polish market (Article 6) and the abuse of a dominant position (Article 9).

The European Commission has shown an increasing interest and activity in the pharma/biopharma sector in recent years, especially in

relation to potential anti-competitive practices, such as patent settlements, pay-for-delay agreements and the abuse of patent rights. For example, in Lundbeck v Commission (2021), the European Court of Justice held that the pay-for-delay agreements at issue constituted restrictions of competition and affirmed/vindicated the EC's decision to fine Lundbeck and the other parties EUR146 million.

11. Collective Redress

11.1 Group Claims

The Enforcement of Claims in Group Proceedings Act and the Code of Civil Procedure provide for a statutory collective redress procedure. Collective proceedings can be initiated by a group of at least ten individuals or legal entities whose claims are based on the same factual basis and can be pursued within a collective redress regime. Class actions are brought to the court by the group's representative, who acts in their own name but on behalf of the whole group and must be represented by a professional attorney.

Claims that can be examined include:

- liability claims for damages caused by hazardous products;
- claims for damages;
- liability claims for non-performance or improper performance of contractual liability;
- claims for unjust enrichment;
- claims regarding customer protection; and
- claims regarding bodily injury or health disorders.

Claims for the protection of personal rights are not allowed in group proceedings, except for those arising from bodily injury or health disorders. However, pecuniary claims related to bodily injury or health disorders, including claims of the immediate family of an injured person who died, can only be pursued to establish the defendant's liability.

Each member of the group must have damages and causation clearly established. Any monetary claims should be standardised within the group as equal lump-sum compensation payments, though smaller subgroups can be created if needed.

During the preliminary stage of group proceedings, the court determines the group claim's admissibility and decides to pursue the case as a class action or reject the lawsuit. A decision to examine the case is followed by an announcement to commence group proceedings. Individuals who were not original claim holders can join the group, but the defendant can also file an objection to the inclusion of certain members. The merits of the claims are examined during the main stage of the group proceedings, which ends with the court issuing a judgment.

Group proceedings in the life sciences and pharma sector are uncommon in Poland.

However, there have been cases in which the claim holders used a mechanism of collective redress. In November 2024, a class action lawsuit was filed by a group of Polish entrepreneurs regarding the establishment of liability of the State Treasury for losses arising from regulations that have created significant barriers for Pharmacies to enter and exit the pharmaceutical market.

Trends and Developments

Contributed by:
Krystyna Szczepanowska-Kozłowska, Marcin Ziarkowski, Krzysztof Popławski and Kacper Sobolewski
A&O Shearman, A. Pedzich Sp. k.

A&O Shearman, A. Pedzich Sp. k. was formed in 2024 via the merger of Allen & Overy and Shearman & Sterling and is a fully integrated elite global firm with around 7,000 people and nearly 4,000 lawyers, including almost 800 partners working across 47 offices in 29 countries. A&O Shearman has the depth of experience and diversity of talent to operate at the forefront of business across every industry sector, market, and geography. The firm's strength comes from its global capabilities and unyielding standard of excellence, supported by deep local roots, relationships, experience, and knowledge. A&O Shearman's Poland team features over 70 Polish and foreign lawyers. The IP practice in Warsaw is focused mainly on IP litigation, with special attention paid to patent litigation. However, the firm has also built a stable transactional and advisory, non-contentious IP practice. It advises on some of the most technically complex and commercially important litigation cases, as well as market-shaping transactions. In patent litigation, A&O Shearman handles most of the major disputes in Poland.

Authors

Krystyna Szczepanowska-Kozłowska is a partner at A&O Shearman, heading the firm's IP and commercial litigation department. She is an attorney-at-law with over 20 years of experience, and provides clients with cutting-edge advice on a wide range of IP issues relating to patents, trade marks and copyrights, both contentious and non-contentious. Krystyna advises on a wide range of complex cases, working with both national and international clients on high-profile and strategic matters. She represents major international companies in their high-profile and exceptionally complex patent and trade mark disputes, which require a significant amount of technical expertise. Additionally, she is a professor and author of publications.

Marcin Ziarkowski is an advocate and senior associate in the IP and commercial litigation department at A&O Shearman. He frequently advises on IP/IT aspects of M&A transactions involving the IT, e-commerce and new technologies sectors. He has been involved in various commercial cases, as well as in numerous patent invalidation proceedings. Marcin has been representing clients in many proceedings for the invalidation of industrial property rights before the Patent Office of the Republic of Poland. Marcin joined A&O Shearman in 2016 and has climbed the corporate ladder to the level of senior associate. In 2017, he graduated from the Intellectual Property Postgraduate Studies at the University of Warsaw.

Contributed by: Krystyna Szczepanowska-Kozłowska, Marcin Ziarkowski, Krzysztof Popławski and Kacper Sobolewski, **A&O Shearman, A. Pedzich Sp. k.**

Krzysztof Popławski is an advocate and an associate in the IP and commercial litigation department at A&O Shearman. He advises on a wide range of commercial issues, including IP, M&A and arbitration. Krzysztof has been involved in high-profile IP, M&A, real estate court and patent invalidation proceedings, as well as arbitration disputes.

Kacper Sobolewski is an associate in the IP and commercial litigation department at A&O Shearman. Kacper graduated from the Faculty of Law at the University of Warsaw in 2022, and he is currently doing his advocate traineeship at the Warsaw Bar Association. With his experience involving commercial and patent invalidation disputes, Kacper aims to become a versatile litigator. In 2023, he was admitted to the Doctoral School of Social Sciences of the University of Warsaw, where he is now also pursuing a PhD in administrative law.

Allen Overy Shearman Sterling, A. Pędzich sp.k.

Allen Overy Shearman Sterling, A. Pędzich sp.k.
ul. Grzybowska 56
00-844 Warsaw
Poland

Tel: +48 22 820 6000
Fax: +48 22 820 61 99
Email: warsaw_reception@aoshearman.com
Web: www.aoshearman.com

A&O SHEARMAN

Contributed by: Krystyna Szczepanowska-Kozłowska, Marcin Ziarkowski, Krzysztof Popławski and Kacper Sobolewski, **A&O Shearman, A. Pedzich Sp. k.**

Overview

2024 has seen significant changes in Poland's regulatory landscape for life sciences and pharmaceutical IP litigation.

Key amendments to the Polish Civil Procedure Code (KPC) in 2023 introduced new requirements for preliminary injunctions in IP cases, including urgency in filing motions and a more adversarial process. These changes have made it more time-consuming and challenging for rights holders to obtain preliminary injunctions in patent enforcement cases, with a noticeable decline in successful motions in 2024. This applies particularly to patent cases concerning the pharmaceutical sector.

Additionally, below, one can find an overview of the most interesting case law in patent matters issued by the Supreme Administrative Court (the NSA), which concerns several fundamental issues regarding the assessment of an invention's patentability by the Polish Patent Office (UPRP).

Polish IP Court's Increasing Unwillingness to Grant PIs in Patent iInfringement Cases

On 30 June 2023, significant amendments to the KPC came into force regarding PI proceedings in IP matters. After one and a half years, we can see the first results of this legislation. There is a general trend of increased scepticism and reluctance among the IP court to grant PIs in patent infringement cases. See below for an outline of the key changes introduced by these amendments:

Assessment of patent invalidation risk by the IP court

The amendments impose new formal requirements for PI motions. Rights holders must now provide information about any ongoing invalidation proceedings or declare a lack of knowledge about such proceedings. Courts are now required to consider the likelihood of an exclusive right being invalidated when assessing the probability of a claim. This means that if there are ongoing invalidation proceedings, the court must take this into account when deciding on the PI.

Unfortunately, we have observed a tendency for the IP court to assume from the outset that the risk of patent invalidation is high solely because invalidation proceedings are underway, without conducting a proper analysis of whether the request for patent invalidation has any substantive grounds.

Urgency criterion

The amendments have introduced a requirement for urgency in filing motions for PIs. Motions must now be filed within six months from the date the rights holder becomes aware of the infringement. This is intended to ensure prompt action and prevent delays in seeking legal protection.

The introduction of such a restrictive approach, which does not foresee any exceptions, must be assessed negatively. In complicated patent infringement cases, the preparation of proper evidence, including private expert opinions, can sometimes take a very long time. The six-month urgency criterion that was introduced means that rights holders now have to be very vigilant and think far ahead when devising their strategy for defending their patent portfolio. They must also prepare the necessary materials and evidence 'blindly' as soon as they hear any rumours about a possible infringement. Preparing for legal action only when an actual infringement activity materialises may result in the rights holder hav-

ing insufficient time to prepare a well-founded PI application.

Contradictory nature of PI proceedings

The amendments have shifted the nature of PI proceedings to be more adversarial. Courts are generally required to hear both parties before granting a PI, except for cases where immediate action is necessary or when the injunction involves actions fully executable by a bailiff.

Unfortunately, this change has significantly prolonged the duration of proceedings for granting interim relief, which by definition should be swift, and has caused the nature of PI proceedings to be distorted. In the current legal environment, there is a concern that the infringer will learn about the application for interim relief in advance and may, for example, transfer goods from one warehouse to another or transfer their ownership to another entity. This would make, for instance, the seizure of infringing products within the PI proceedings much more difficult, ultimately leading to a decrease in the effectiveness of the patent enforcement system in Poland.

For the reasons described above, the IP court has adopted a very cautious and conservative approach to granting PIs in patent infringement cases, especially in situations where any invalidation proceedings are pending against the patent. Unfortunately, the aforementioned changes regarding the requirement for the IP court to consider the likelihood of patent invalidation have caused a significant breach in the principle of bifurcation that is in force in Poland, where the IP court decides on patent infringement cases, and the UPRP resolves issues related to patent invalidity. Under the current legal framework, patent enforcement proceedings before the IP court increasingly involve issues strictly related to the alleged invalidity of the patent, significantly prolonging the duration of patent infringement cases.

We fear that the above-presented changes in the KPC will encourage Gx entities to file more and more invalidation requests, regardless of the existence of any substantive grounds for their submission, solely to convince the IP court that there are no grounds for granting a PI due to the likelihood of patent invalidation — which, despite the filing of an invalidation request, is often only theoretical and lacks substantive justification.

Patent Validity Assessment Based on National Regulations

The NSA confirmed that the "could-would" principle adopted by the European Patent Office (EPO) as part of the "problem-solution" method used for analysing patent applications is not binding on the UPRP because the assessment of patent validity is based on national regulations. The NSA accepted the UPRP's legal interpretation of the Industrial Property Law of 30 June 2000 (the IPL).

A recent NSA ruling (dated 4 April 2023, II GSK 1534/19) stated that the UPRP had properly used the "problem-solution" approach to objectively assess the inventive step and avoid analysing prior art ex post facto. In its justification, the NSA clarified that the UPRP's approach is different and more stringent than the EPO's but is not erroneous.

By using the "problem-solution" method to assess the criterion of non-obviousness of the solution, the UPRP conducts a three-stage assessment of the inventive step of the disputed invention. Firstly, it identifies the closest prior art, then it defines the problem that should be solved, and lastly, it considers whether a spe-

cialist familiar with the prior art would be able to arrive at the claimed solution by addressing the problem in a professional and non-creative manner.

The version of the "problem-solution" method used by the EPO is based on the "could-would" principle. The EPO considers an invention obvious if the information derived from the prior art is sufficient to make the invention and simultaneously encourages attempts to solve the problem in the manner described in the patent application. Thus, for the EPO, it is pivotal to establish if the information and tools presented by the prior art would create a strong incentive whereby an expert not only could but would solve the posed problem in the same exact way as it was disclosed in the patent specification.

In the Polish patent system, it is considered appropriate to analyse whether a specialist familiar with the closest prior art could obtain the effects achieved by the invention by modifying or adapting the prior art in a professional and routine manner. Therefore, in the UPRP's policy regarding assessing a patent's validity determination, the question of whether the specialist would indeed create the solution described in the application is not a decisive factor for establishing the non-obviousness of an invention.

Unlike the EPO, the UPRP does not evaluate whether the information in the prior art would sufficiently motivate an expert to develop the invention described in the submitted patent application, especially when other options were also available. This approach has been noted in the court rulings and UPRP decisions that were issued in 2024.

Sufficiency of Presenting Examples of An Invention's Practical Implementation With No Need for Creating a Physical Embodiment

Over the last few years, pursuant to various NSA rulings and UPRP decisions, a new consistent approach regarding the recognition of sufficient disclosure of inventions has been developed within the Polish system. The need to establish a coherent approach that would provide legal certainty among patent system users has arisen from the debate concerning the extent of disclosure that should be sufficient for a reasonable patent system.

Insufficient disclosure may result in positive and negative consequences. Not disclosing all the details allows a patent holder to protect information such as know-how and company trade secrets. However, providing too little information may result in a patent application being rejected or invalidating the patent.

In case No. II GSK 677/20 (ruling dated 26 September 2023), the NSA stated that presenting any examples of an invention's practical implementation and use is sufficient to meet the criterion of the completeness of the disclosure of the invention and its industrial applicability. The NSA emphasised that examples do not need to represent the most advantageous embodiment of the invention.

Moreover, the NSA points out that the proper conduct of the evidentiary proceedings does not require an analysis of physical evidence in the form of a product embodying the invention. This is consistent with the rule that the patent holder is not obliged to utilise the solution disclosed in the patent application.

Therefore, in invalidation proceedings, the UPRP does not determine whether the patent holder's

products sold on the market conform to the specifications and construction described in the patent specification. The assessment of the industrial applicability of the invention is made solely in relation to the patent's disclosure in the documents that have been submitted during the application process. The perspective of the product's physical form resulting from the invention's specification is irrelevant to the outcome of the assessment process.

Applicant's Reference to Their Previous Non-published Applications

The recent ruling issued by the NSA in case No. II GSK 1034/20 (dated 16 April 2024) clarified the reasons why the state of the prior art is and should be assessed differently for the purposes of examining the novelty of the submitted invention (Article 25 of the IPL) and differently to examine the inventive step and the non-obviousness of the invention (Article 26 of the IPL).

The importance of this judgment is significant, especially for those users of the patent system who are seeking a favourable UPRP decision regarding the granting of a new patent but have previously filed patent applications for similar inventions.

The main legal issue to be resolved was whether the information disclosed by the applicant in earlier unpublished applications became part of the prior art by virtue of its mere indication in the subsequent application. The NSA resolved this issue negatively: from the perspective of assessing the inventive step, this information will not become part of the state of the art until the UPRP publishes it.

When evaluating the inventive step, the state of the art presented in a previously submitted application that has not yet been published by the UPRP is not taken into account, even if the applicant is completely aware of the content of that earlier application.

In its justification, the NSA explained that the interpretation of the IPL's provisions, which leads to the conclusion that the applicant cannot refer to their previous applications and previously submitted documents in a new patent application, even though they have not been published in the UPRP's bulletin, is erroneous. Therefore, there is no legal basis for the UPRP to question this practice.

The NSA indicated that a patent can be granted for an invention that does not exhibit an inventive step in relation to an invention previously submitted but not yet published. The justification for such regulation is to create conveniences for entities conducting research on improving inventions, which can be successively submitted for patent protection without the risk of challenging their inventive step and, thus, their patentability. Moreover, the mentioned regulation does not block the possibility of patenting inventions by other entities conducting appropriate research and submitting inventions entering the state of the art in close temporal proximity. This regulation is an exception to the prevailing principle in patent law of "first come, first served" and applies only to the issue of the inventive step of a given invention.

At the same time, there is no risk of granting the same person multiple patents for very similar or even identical solutions because the applicant must also meet the novelty requirement, to which the "first come, first served" principle fully applies. Granting a patent requires meeting all the conditions for its granting. Therefore, if a later submitted invention were to be considered

Contributed by: Krystyna Szczepanowska-Kozłowska, Marcin Ziarkowski, Krzysztof Popławski and Kacper Sobolewski, **A&O Shearman, A. Pedzich Sp. k.**

identical or very similar to an earlier one, the UPRP could recognise a lack of novelty.

In light of the above, the court's new approach results in the non-examination of unpublished previous patent applications when assessing the inventive step of the disclosed invention, which may be convenient for pharmaceutical companies conducting research on improving their inventions.

SAUDI ARABIA

Law and Practice

Contributed by:
Dr Saud Alromi, Mostafa Ihab, Mohamed Ramadan and Saleh Albadry
Mohammed Al Dhabaan & Partners Eversheds Sutherland

Contents

Contributed by: Dr Saud Alromi, Mostafa Ihab, Mohamed Ramadan and Saleh Albadry,
Mohammed Al Dhabaan & Partners Eversheds Sutherland

Mohammed Al Dhabaan & Partners Eversheds Sutherland is a Chambers and Partners top five Saudi Arabian practice and is affiliated with a global top 15 law practice. The firm provides legal services to a local and global client base ranging from small and mid-sized businesses to the largest multinationals. It acts for 73 of the US Fortune 100, 120 of the US Fortune 200 and 66 of the FTSE 100. It is one of the largest full-service legal brands in the world with more than 70 offices across 32 countries. Its global reach allows it to work with clients across numerous jurisdictions. In jurisdictions where it does not have an office, it works with its partner law firms.

Authors

Dr Saud Alromi is a partner and has headed the litigation and dispute management practice at Mohammed Al Dhabaan & Partners Eversheds Sutherland since 2015. He has more than 28 years of experience of practising law in the Kingdom and has advised on the preparation and amendment of numerous Saudi Arabian regulations, such as the legal pleadings system, the penal procedures system, and several regulations related to arranging the legal structure and litigation procedures. He has gained extensive legal experience from his work as an Attorney General at a number of the most important and largest governorates for more than 21 years in Saudi Arabia.

Mostafa Ihab is a legal director at Mohammed Al Dhabaan & Partners Eversheds Sutherland. He is a dual qualified (civil law/common law) bilingual disputes resolution lawyer. He has been practising law for approximately 15 years, five of which have been in Saudi Arabia. He advises and represents clients in disputes before local courts and arbitral tribunals. He also advises clients on all forms of commercial and construction disputes management in addition to handling financial crime cases and internal investigations. Before joining Mohammed Al Dhabaan & Partners Eversheds Sutherland, he spent eight years working as a prosecutor in the Egyptian judiciary at the Financial Crimes Prosecution Office.

Contributed by: Dr Saud Alromi, Mostafa Ihab, Mohamed Ramadan and Saleh Albadry,
Mohammed Al Dhabaan & Partners Eversheds Sutherland

Mohamed Ramadan is a senior associate in the litigation and dispute resolution team at Mohammed Al Dhabaan & Partners Eversheds Sutherland. With over 14 years of legal expertise, he leverages his bilingual capabilities to counsel clients on a broad spectrum of commercial disputes in both courts and arbitration tribunals. Before joining Mohammed Al Dhabaan & Partners Eversheds Sutherland, he was a pivotal senior lawyer in the legal department at one of Egypt's largest holding companies, managing a team handling a diverse array of legal matters and judicial disputes, emphasising his extensive legal background and commitment to securing positive and favourable outcomes.

Saleh Albadry is an associate at Mohammed Al Dhabaan & Partners Eversheds Sutherland. He earned a Bachelor's in Law from Dar Al Uloom University (Saudi Arabia), a Master's from Emory University School of Law (USA), and a JD from Indiana University Maurer School of Law (USA). His practice encompasses matters before general jurisdiction, commercial, and labour courts. His work involves advising corporate clients on various legal matters and drafting a wide range of contracts, including, among others, contracts for contractors, engineers, real estate developers, investment funds, and corporate clients. He handles FIDIC contracts for Saudi Arabian projects. His corporate law practice includes IPO due diligence, prospectus drafting for the Saudi Exchange, and governance policy review and compliance oversight.

Mohammed Al Dhabaan & Partners Eversheds Sutherland

Offices No 9-10-11; Home Offices
PO Box 245555; Riyadh 11312
Saudi Arabia

Tel: +966 11 277 9800
Fax: +966 11 281 6611
Email: DAPESprojects@aldhabaan-es.com
Web: www.aldhabaan-es.com

MOHAMMED ALDHABAAN
& PARTNERS
EVERSHEDS SUTHERLAND

Contributed by: Dr Saud Alromi, Mostafa Ihab, Mohamed Ramadan and Saleh Albadry,
Mohammed Al Dhabaan & Partners Eversheds Sutherland

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Infringement Actions

In an action for patent infringement in Saudi Arabia, the primary parties involved are:

- the patentee: the owner of the patent who holds the exclusive rights to the invention; and
- the alleged infringer: the party accused of infringing the patent rights.

If a patent is co-owned, each co-owner has the right to use the patent independently. However, co-owners must agree to bring an infringement action jointly.

An exclusive licensee, who has been granted the exclusive rights to use the patent within a specific territory or field, can bring an infringement action. The licence must be registered with the Saudi Arabian Authority for Intellectual Property (the "SAIP") to be enforceable.

Generally speaking, non-exclusive licensees do not have the standing to bring an infringement action unless explicitly granted this right in the licence agreement.

If the patentee does not consent to being a claimant/plaintiff, they must be joined as a defendant in the action brought by an exclusive licensee.

Nullity/Revocation Actions

To file a nullity/revocation action, the plaintiff must have legitimate interest. This typically applies to:

- alleged infringers: parties accused of infringement who seek to invalidate the patent as a defence; and
- other interested parties: any party that can demonstrate a direct and legitimate interest in the invalidation of the patent.

The SAIP can provide opinions on infringement. However, these opinions are not binding and serve as guidance. Actions for revocation can be brought before the Committee for Reviewing Patent Disputes, which has the authority to issue binding decisions.

1.2 Defendants/Other Parties to an Action

The parties who are usually sued in infringement actions are:

- manufacturers: they are often the primary target in infringement cases due to their role in producing the patented product;
- suppliers and importers: they can be sued for distributing or importing infringing products; and
- local distributors/wholesalers: they are frequently involved in the supply chain and can be held liable for selling infringing products.

Revocation actions are usually filed against patentees.

In Saudi Arabia, healthcare regulatory authorities and intellectual property offices are not required to be notified of or given an option to join infringement and nullity proceedings. However the SAIP will be notified with the final decisions issued by the Committee for Reviewing Patent Disputes.

1.3 Preliminary Injunction Proceedings

Preliminary Injunctions

Key details

In Saudi Arabia, preliminary injunctions (PIs), including ex parte injunctions, are available under the Law of Commercial Courts. The key details are as follows.

PIs

Both ex parte and inter partes PIs are available. Ex parte injunctions can be granted without notifying the opposing party, typically in urgent situations where immediate action is necessary to prevent irreparable harm.

A PI is to be decided on by the court within three working days as from the date it was filed.

Practical considerations

When deciding whether to grant a PI, Saudi Arabian courts consider:

- balance of convenience: the court assesses whether the benefits to the plaintiff outweigh the potential harm to the defendant;
- adequacy of damages: the court evaluates whether monetary compensation would be sufficient to remedy the plaintiff's harm. If not, an injunction is more likely to be granted;
- validity: the court considers the likelihood of the plaintiff's success on the merits of the case; and
- urgency: the plaintiff must demonstrate that there is an urgent need for the injunction to prevent irreparable harm.

There are special requirements for an applicant to file a PI. Practically speaking, a quia timet relief is available in Saudi Arabia. For example, it might apply to acts that amount to a threat to infringe, including any preparatory steps that indicate an imminent infringement, such as manufacturing or marketing preparations.

There is no consideration specific to patent litigation in life sciences cases in Saudi Arabia.

Court notifications are sent by the court via SMS to the mobile phone of the addressee. The alleged infringer is given an opportunity to file evidence and submissions in defence of a PI. In ex parte requests the right of the defence will be considered at the appeal stage.

Protective letters are not recognised in Saudi Arabian law.

1.4 Structure of Main Proceedings on Infringement/Validity

Practically speaking, infringement and validity proceedings are to be bifurcated. An infringement proceeding will usually be stayed until a validity proceeding is concluded.

Filing Nullity Proceedings

It is possible to file nullity proceedings while there are ongoing patent office opposition proceedings in Saudi Arabia. The legal framework allows for both types of actions to be pursued simultaneously. This means that a party can challenge the validity of a patent through opposition proceedings at the SAIP while also initiating nullity proceedings in court.

1.5 Timing for Main Proceedings on Infringement/Validity

Article 7 of the Patent Law

Under Article 7 of the Saudi Arabian Law of Patents, Layout Designs of Integrated Circuits, Plant Varieties, and Industrial Designs (the "Patent Law"): "If the subject matter claimed in the application or in the protection document is derived from a subject matter owned by a per-

son other than the applicant or the owner of the protection document, then this person may request the Committee to transfer the ownership of the application or protection document to him. The case for the transfer application shall not be heard after the lapse of five years of granting the protection unless bad faith on the part of the applicant is established."

Notification of Main Action

The notification process for the alleged infringer (in the case of an infringement action) or the patentee (in the case of a nullity action) is as follows.

- The notification is typically carried by the court through SMS (if the defendant is located in Saudi Arabia).
- The service takes place once the first hearing is scheduled.
- The location of the infringing entity can impact the service process. If the entity is located outside Saudi Arabia, international service procedures may apply, potentially causing delays.

Usual Time to a First Instance Hearing and Decision

The time to a first instance hearing and decision can vary, but it generally takes several months from the filing of the action.

1.6 Requirements to Bring Infringement Action

Although the Patent Law doesn't explicitly specify when an infringement action can first be filed, in practice, a main infringement action can only be filed once the patent has been granted. The patent must be validated, and any necessary translations must be filed before it can be asserted.

Important Factors/Difficulties with Asserting Different Types of Patents

Process patents

Asserting process patents can be particularly challenging due to the difficulty in proving that the infringing party is using the patented process. This often requires detailed technical evidence and expert testimony to establish infringement.

Product patents

These are generally easier to enforce as the infringing product can be directly compared to the patented invention.

Biotechnology and pharmaceutical patents

These patents often involve complex scientific data and regulatory considerations, making enforcement more complicated.

Reversal of Burden of Proof for Certain Types of Patents

In Saudi Arabia, there is a reversal of the burden of proof for process patents. According to Article 48 of the Patent Law, if the subject matter of a patent is a process for obtaining a product, the defendant must prove that the identical product was not manufactured by this process without the consent of the owner of the patent, under two specific conditions:

- when the product obtained through a patented industrial process is a new product; or
- when there is a substantial probability that the identical product was manufactured through the patented industrial process and the owner of the patent was unable to determine the method actually used despite reasonable efforts.

This provision is designed to address the inherent difficulties in proving infringement of process patents.

1.7 Pre-Action Discovery/Disclosure

The Saudi Arabian legal system lacks a formal process for pre-action discovery similar to those found in common law jurisdictions. Instead, the focus remains on the claimant proving their case without obliging the defendant to disclose or build evidence before the commencement of formal proceedings.

It is possible to use materials obtained in other jurisdictions in Saudi Arabian legal proceedings. However, there are procedural requirements to ensure the admissibility of such evidence.

Authentication and Translation

Documents obtained from other jurisdictions must be attested and translated into Arabic to be admissible in Saudi Arabian courts.

1.8 Search and Seizure Orders

Seizure orders are available in Saudi Arabia as a form of interim/summary measures under the Law of Commercial Courts.

The main requirements for seeking the issuance of a seizure order is to prove to the court the urgency for issuing the order and specify the items that need to be seized.

The main action needs to be filed within seven days as from the date of issuing the seizure order.

1.9 Declaratory Relief

Saudi Arabian courts are willing to grant declaratory relief. Declaratory relief can be sought to clarify the legal rights and obligations of the parties without necessarily seeking coercive enforcement.

Declaratory Relief Requirements

To obtain declaratory relief, the following requirements must be met.

- Existence of a legal dispute: there must be a genuine legal dispute between the parties that requires clarification.
- Legal interest: the party seeking declaratory relief must have a legitimate legal interest in obtaining the declaration.
- Specificity: the request for declaratory relief must be specific and clearly define the legal rights or obligations in question.

Types of Declaratory Relief Available in Life Sciences Patent Proceedings

In life sciences patent proceedings, the types of declaratory relief that may be available include the following.

- Declarations of non-infringement: a declaration that a particular product or process does not infringe on the patent in question.
- Validity declarations: a declaration regarding the validity of a patent.

Parties' Burden

The party seeking the declaration must demonstrate:

- direct and personal interest: the party must have a direct and personal interest in the outcome of the declaration; and
- potential impact: the declaration must have a potential impact on the legal rights or obligations of the party seeking relief.

1.10 Doctrine of Equivalents

The Patent Law implicitly supports the application of the Doctrine of Equivalents (DoE) by allowing for the protection of the essential elements of a patented invention. This doctrine

allows for a finding of infringement even when the accused product or process does not literally infringe the express terms of a patent claim, provided that the differences are insubstantial.

The relevant legal test for determining equivalence in Saudi Arabia involves assessing whether the accused product or process performs substantially the same function in substantially the same way to achieve substantially the same result as the patented invention. This is similar to the function-way-result test used in other jurisdictions.

1.11 Clearing the Way

In Saudi Arabia, there is no legal obligation to "clear the way" ahead of a new product launch. However, it is a prudent practice for companies to conduct thorough due diligence to ensure that their new products do not infringe on existing patents or other intellectual property rights. This practice helps to mitigate the risk of legal disputes and potential infringement claims.

1.12 Experts

Frequency

It is common for Saudi Arabian courts to use evidence from experts to determine issues of infringement and validity in patent cases. Expert evidence is crucial in providing technical insights that the court may not possess.

Forms

Experts typically submit detailed written reports outlining their findings and opinions. Experts also often prepare reply reports to address points raised by either party. Additionally, experts may be called to testify in court and answer questions raised by the court or either party.

Significance

Expert evidence is highly significant in the decision-making process, especially in complex technical cases.

Court-Appointed Experts

The court appointing the expert will specify the time limit for the expert to prepare its report while allowing both parties to submit their comments, which is then followed by a final version of the report. After filing the final version of the report, the court can ask the expert to submit oral testimony or address any other points the court sees fit.

Court-appointed experts owe a duty to the court to provide impartial and unbiased opinions.

Party-Appointed Experts

It is not common for both sides to have their own experts as the court will eventually appoint its own expert when needed. However, in very complex technical issues, parties appoint experts independently so that they can have a reference when they are working with the court-appointed experts.

Khibra Portal

Courts appoint experts through the Khibra portal, which is a portal operated by the Saudi Arabian government and includes a list of registered experts in different fields. Whenever the court decides to appoint an expert in a specific case, it electronically refers the decision to appoint the expert to the Khibra portal while specifying the scope of the expert mission. The Khibra portal will then refer the scope to relevant registered experts while asking them to submit their technical and financial proposals to complete the mission. Once the Khibra portal receives the technical and financial proposals they will send them over to the parties to the case who will be granted the

opportunity to exclude one of the proposals. The Khibra portal will then automatically choose one of the experts to complete the mission.

Technical or Scientific Advisors

Courts in Saudi Arabia do not appoint technical or scientific advisors and only appoint experts when needed.

PIs

Practically speaking, PI proceedings do not involve the appointment of court experts.

1.13 Use of Experiments

There is no mechanism to adduce results from experiments in order to prove or disprove infringement or validity. Additionally, using experiments is not common in Saudi Arabian courts.

1.14 Discovery/Disclosure

There is no specific discovery and disclosure process for patent litigation in Saudi Arabia. Discovery and disclosure are not actually specifically addressed in Saudi Arabian law. However, parties are required to prove their cases by submitting the evidence they have in their possession either in the form of documents or submitting dispositions (as to be accepted by the court). Additionally, a party can ask the court to order the counterparty to submit documents proving evidence in their possession in certain circumstances.

1.15 Defences and Exceptions to Patent Infringement

Defences and Exceptions

In Saudi Arabian law, several defences and exceptions are available in infringement actions. Some of the key defences and exceptions are as follows.

- Invalidity: a common defence where the defendant argues that the patent or intellectual property right in question is invalid. Article 32 of the Patent Law provides that any party with an interest may challenge the decision granting a protection document before the Committee for Reviewing Patent Disputes, and seek total or partial revocation, relying upon the violation of the stipulated conditions for granting the protection document.
- Consent/licence: if the alleged infringer has obtained permission or a licence from the rights holder, this can serve as a defence against infringement claims under Article 21 of the Patent Law.
- Exhaustion: once a patented product is sold by or with the consent of the patent owner, the patent owner's control over the product is exhausted, and the buyer is free to use or resell the product.
- Compulsory licence: under certain conditions, the government can grant a compulsory licence to use a patented invention without the consent of the patent owner, typically to address public health needs under Article 24 of the Patent Law.

Special Considerations for Life Sciences Cases

Life sciences products, including pharmaceuticals and medical devices, must comply with regulations set by the Saudi Arabian Food and Drug Authority (the "SFDA"). This includes obtaining necessary approvals and adhering to guidelines for clinical trials.

All clinical studies must be registered with the SFDA and comply with guidelines for good clinical practice and ethical standards. The SFDA has provisions for the emergency or compassionate use of unapproved medical products,

which can be a critical factor in infringement cases.

1.16 Stays and Relevance of Parallel Proceedings

Other Relevant Proceedings

Infringement and validity proceedings can be stayed pending the outcomes of other proceedings. If there are ongoing opposition or intellectual property rights proceedings, the court may decide to stay the infringement or validity proceedings until the outcome of these proceedings is determined.

Local nullity proceedings, where the validity of a patent or intellectual property right is challenged, can also form a basis for a stay. The court handling the infringement case may wait for the nullity proceedings to conclude before making a decision.

Recognition of Foreign Court Orders

Saudi Arabian courts can recognise foreign court orders or judgments when the conditions under the Saudi Arabian Enforcement Law are met.

Key conditions for recognition include:

- non-contradiction with Saudi Arabian public policy; and
- reciprocity between Saudi Arabia and the foreign country regarding recognition and enforcement of court orders.

Staying Local Proceedings Pending Foreign Proceedings

Saudi Arabian courts have discretionary power to stay the local proceedings if they conclude that deciding on the local proceedings is dependent on the outcome of the foreign proceedings.

Legal Basis for Granting a Stay

Under Article 87 of the Saudi Arabian Law of Civil Procedure, a stay may be granted if the requested proceedings will resolve an issue that will significantly impact the decision in the case sought to be stayed.

1.17 Patent Amendment

Permissibility of Amendments

Patents can be amended during litigation in Saudi Arabia.

Legal Framework

The Patent Law allows for amendments to be made to the claims of a patent, provided that the amendments do not extend the scope of the protection conferred by the patent.

Frequency

These types of applications are not uncommon.

Reasons for Amendments

Patent holders may seek to amend their patents to clarify claims or address issues raised during litigation.

Court Approach

Courts in Saudi Arabia are generally receptive to amendment applications, especially if the amendments are made to address specific issues raised during the litigation process.

Legal Requirements

The amendments must comply with the legal requirements and should not extend the scope of the original claims.

Conditional Amendments

Amendments can be conditional, meaning that they may be subject to certain requirements or limitations imposed by the court. For example, the court may allow amendments on the condi-

tion that they do not introduce a new matter or broaden the scope of the original claims.

1.18 Court Arbiter

In Saudi Arabia, there are no specialised judges for pharma/life sciences cases. All Saudi Arabian judges have the same background. That being said, actions for patent revocation are to be brought before the Committee for Reviewing Patent Disputes which includes two technical members.

Forum shopping is not permitted in Saudi Arabia. The principle of avoiding forum shopping is upheld to ensure judicial efficiency and consistency in rulings.

2. Generic Market Entry

2.1 Infringing Acts

The Patent Law and its implementing regulations do not contain specific provisions regarding patented pharmaceutical products. In addition, there are no published Saudi Arabian court decisions addressing when infringement rights crystallise, what constitutes infringing, special considerations for second medical use patents and skinny labelling, or rules governing parallel imports.

In Saudi Arabia, tender submissions for pharmaceuticals are accessible to the public. The Government Tenders and Procurement Law requires all public tenders, including those from the Ministry of Health and other governmental agencies, to follow principles of publicity (Article 6) and be published through a designated unified electronic portal (Article 16).

2.2 Regulatory Data and Market Exclusivity

Data and Market Exclusivity

The Patent Law does not contain specific provisions regarding data and market exclusivity periods for pharmaceutical products, including orphan drugs, paediatric formulations, new indications, combinations, or reclassifications. However, under Article 19 of the Patent Law, patents receive 20 years of protection from the filing date.

Challenges and Frequency

Frequency of challenges cannot be reliably assessed due to the lack of a specific legal framework for data/market exclusivity, limited publicly available records, and no dedicated challenge process in the Patent Law.

Regulatory Authority

The SFDA serves as the regulatory authority for pharmaceuticals and health-related products.

Forum and Timeframes

The Patent Law doesn't provide for a specific forum regarding data and market exclusivity. However, in general, commercial courts have jurisdiction over intellectual property law claims and violations according to Article 16(3) of the Law of Commercial Courts.

2.3 Acceptable Pre-Launch Preparations

Article 47 of the Patent Law only mentions a limited exemption for "non-commercial activities relating to scientific research", but does not explicitly address Bolar-type exemptions for generic manufacturers' pre-launch activities. The regulatory framework does not provide clear guidance on what preparatory acts are permitted before patent expiry.

2.4 Publicly Available Drug and Patent Information

Saudi Arabia does not have an Orange Book equivalent system. The SFDA maintains a public list of the approved drugs and those awaiting approval.

While the SFDA issued a Regulatory Framework for Drugs Approval (the "Regulatory Framework"), it does not include a system for notifying marketing authorisation (MA) reference product holders about generic/biosimilar applications. Monitoring is probably needed as there is no sufficient data on the existence of an automatic notification system.

2.5 Reimbursement and Pricing/Linkage Markets

There is no formal patent linkage system in Saudi Arabia that connects MA or pricing/reimbursement decisions to patent status. However, the SFDA's Pricing Rules for Pharmaceutical Products (the "Pricing Rules") provide some relevant guidelines.

Patent Status Considerations

For innovative and biological products manufactured locally under licence from international companies during the patent term, they must be priced at the same price as the innovative product (Article 3(D) and 3(E) of the Pricing Rules).

Once patents expire, products are treated as generics for pricing purposes.

Pricing Process

The pricing process is handled by the Registration Committee for Pharmaceutical Companies, Manufacturers and their Products.

Pricing decisions are based on multiple factors outlined in Article 2 of the Pricing Rules, including therapeutic value, prices of alternatives, and economic studies.

There is insufficient data on the existence of an automatic notification system to originators about generic pricing applications.

Second Medical Use Patents

The Pricing Rules do not contain specific provisions on indication-specific pricing. All concentrations and pack sizes of the same product are subject to unified pricing rules.

Administrative Appeals

According to the Policy of Appeal to Drug Sector Decisions, a first appeal to pricing decisions can be submitted within 60 days from notification, with a 60-day review period.

A second appeal to pricing decisions can be filed within 30 days of the first appeal decision, with a 30-day review period.

Appeals must follow the procedures outlined in the Policy of Appeal to Drug Sector Decisions.

There is insufficient data as to how common appeals are.

Monitoring Requirements

Monitoring is probably needed as there is no sufficient data as to the existence of a notification system. Pricing information for registered drugs is publicly available through the SFDA's website.

3. Biosimilar Market Entry

3.1 Infringing Acts

There are no differences in how infringing acts are treated between biologics or biosimilars and small molecule pharmaceuticals in Saudi Arabia.

The Patent Law does not make any specific distinctions regarding infringement rights between biologics and small molecules.

3.2 Data and Regulatory Exclusivity

The key differences for biologics and biosimilars compared to small molecules are as follows.

Price Impact

According to Article 6 of the Pricing Rules, when the first biosimilar enters the market, the price of the reference biological product is reduced by 20% (compared to a 25% reduction for small molecule generics under Article 4).

Pricing Structure

According to Article 7 of the Pricing Rules, the pricing structure is as follows.

- First biosimilar: maximum 75% of the reference biological product's pre-reduction price.
- Second biosimilar: maximum 65% of the reference biological product's pre-reduction price.
- Third and subsequent biosimilars: maximum 55% of the reference biological product's pre-reduction price.

3.3 Acceptable Pre-Launch Preparations

There are no specific differences in pre-launch preparation exemptions between biologics or biosimilars and generics. Article 47 of the Patent Law provides the same limited "non-commercial activities relating to scientific research" exemption without distinguishing between product types.

3.4 Publicly Available Drug and Patent Information

There are no differences. Saudi Arabia does not have an Orange Book equivalent system. The SFDA maintains public lists of approved drugs and products pending approval.

3.5 Reimbursement and Pricing/Linkage Markets

The key difference is in the pricing rules, as outlined in Article 15 of the Pricing Rules. The price of biological products manufactured locally under licence from foreign companies can be fixed for up to seven years if all manufacturing phases are transferred to Saudi Arabia. Beyond the pricing differences noted in **3.2 Data and Regulatory Exclusivity**, the same basic reimbursement and pricing procedures apply to both biologics or biosimilars and small molecules.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Availability and Legal Framework

In Saudi Arabia, supplementary protection certificates (SPCs) or similar patent term extension instruments are available. These are governed by the Patent Law and its implementing regulations, which aim to extend the protection of patents beyond their standard term to compensate for the time taken to obtain regulatory approval.

Applicable Laws and Main Provisions

The main provisions related to SPCs in Saudi Arabia are found in the Patent Law. This law provides the framework for extending the patent term for pharmaceuticals and other regulated products to account for the time required for regulatory approval.

Patents Eligible for SPCs

Patents that can form the basis of an SPC include those covering:

- active pharmaceutical ingredients (APIs);
- medicinal products;
- processes for manufacturing medicinal products; and
- medical devices.

Identity of the Applicant

The identity of the applicant for an SPC matters. Typically, the originator or the patent holder is the one who applies for the SPC. However, third parties can also apply for an SPC if they have obtained the necessary rights from the patent holder.

The originator can be denied an SPC if a third party has already obtained an SPC based on the originator's basic patent, provided the third party has the legal rights to do so.

Rules for Different Products and Same Patent

In terms of different products and same patent, an SPC can be granted for each product covered by the same patent, provided each product meets the criteria for SPC eligibility.

In terms of one product, multiple patents, if a single product is protected by multiple patents, an SPC can be granted for each patent, but the total duration of the SPCs cannot exceed the maximum extension period allowed.

Rules for Combination Products

For combination products, the SPC can be granted if the combination is covered by the basic patent and meets the regulatory approval requirements. The combination must be specifically claimed in the patent or be clearly derivable from the patent claims.

Specific Considerations and Jurisdictional Nuances

Saudi Arabia does not currently have specific provisions for SPC manufacturing waivers. However, the general principles of patent law and regulatory approval processes apply.

The time taken for regulatory approval by the SFDA is a critical factor in determining the duration of the SPC.

4.2 Paediatric Extensions

Availability

In Saudi Arabia, paediatric extensions are available as part of the broader framework for patent term extensions. These extensions are designed to encourage the development of medicines specifically for paediatric use by providing additional market exclusivity.

Applicable Laws and Main Provisions

The primary legal framework governing paediatric extensions in Saudi Arabia includes the Patent Law and its implementing regulations. The main provisions are as follows.

Patent Law

The Patent Law provides the basis for extending the term of a patent to compensate for the time taken to obtain regulatory approval, including for paediatric medicines.

Implementing regulations

The implementing regulations to the Patent Law outline the specific procedures and requirements for obtaining a patent term extension, including paediatric extensions.

Regulatory approval

The extension is contingent upon obtaining regulatory approval from the SFDA. The SFDA evaluates the safety and efficacy of paediatric

medicines and grants approval, which is a prerequisite for the extension.

Additional exclusivity

Paediatric extensions provide additional market exclusivity beyond the standard patent term. This is intended to incentivise pharmaceutical companies to invest in the development of paediatric formulations.

4.3 Paediatric-Use Marketing Authorisations

In Saudi Arabia, MAs are available for medicines that are already authorised but are developed specifically for children, even if they do not have a patent or SPC. The SFDA oversees the regulation and approval of these medicines.

Applicable Laws and Main Provisions

The SFDA is the primary regulatory body responsible for the approval of pharmaceuticals, including paediatric medicines. The SFDA's regulations ensure that medicines are safe, effective, and of high quality.

Regulatory Framework

The SFDA has specific guidelines for the approval of paediatric medicines. These guidelines require that the medicines meet stringent safety and efficacy standards tailored to paediatric use.

Clinical Trials and Data Requirements

For a medicine to receive an MA for paediatric use, the applicant must provide clinical trial data demonstrating the safety and efficacy of the medicine in children. This data must comply with the SFDA's requirements for clinical trials.

Labelling and Packaging

The SFDA also mandates specific labelling and packaging requirements for paediatric medicines to ensure proper usage and dosage.

4.4 Orphan Medicines Extensions

Extensions for Orphan Medicines in Saudi Arabia

Availability of extensions

Extensions are available for orphan medicines in Saudi Arabia. The SFDA provides a framework for orphan drug designation and offers incentives, including potential extensions, to encourage the development of treatments for rare diseases.

Applicable laws and main provisions

The Saudi Arabian Patent Law and its implementing regulations provide the basis for patent term extensions, including those for orphan medicines. The extensions aim to compensate for the time taken to obtain regulatory approval.

The SFDA Guidance for Orphan Drug Designation outlines the criteria and procedures for obtaining orphan drug designation. It includes provisions for incentives to support the development and availability of orphan drugs.

The SFDA offers various incentives for orphan drugs, including regulatory support, fee reductions, and potential extensions of market exclusivity. These measures are designed to make it more feasible for companies to invest in the development of treatments for rare diseases.

Key provisions

To qualify for orphan drug designation, a medicine must be intended for the diagnosis, prevention, or treatment of a rare disease or condition. The disease must be life-threatening or seriously debilitating, and the prevalence must be low, or the development must not be financially viable without incentives.

Companies must submit an application to the SFDA, providing detailed information about the

drug, its intended use, and evidence supporting its designation as an orphan drug. The SFDA reviews these applications and grants designation based on the criteria outlined.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

Undertakings in the form of a financial guarantee can be requested by the court ahead of issuing a PI. This undertaking serves as a guarantee to compensate the defendant for any damages incurred if it is later determined that the injunction was wrongfully granted. The undertaking typically remains in force until the final resolution of the case.

PIs are enforced as per the terms of the Saudi Arabian Enforcement Law. Enforcement takes place through an application to be filed to the competent enforcement court and the method of actual enforcement will differ depending on the nature of the injunction. Once an enforcement application is accepted by the enforcement court, the respondent will be notified to voluntarily comply with the injunction within five days. If the five days lapse before the respondent voluntary complies with the injunction, the enforcement court will proceed with compulsory enforcement.

If a financial guarantee is required before the PI is issued, the court may decide the quantum of such guarantee. However, there are no guidelines on how this quantum will be determined. It will usually be an amount sufficient to compensate the defendant for the potential harm should the plaintiff lose the case.

If a PI is issued, the plaintiff will file the main claim within seven days as from the date of issuing the injunction.

Appealing the decision imposing the PI does not result in the PI enforcement being stayed.

5.2 Final Injunctive Relief

There is no distinction in Saudi Arabian law between PIs and final injunctions as both are dealt with as per as a form of interim/summary relief. The same provisions which apply to PIs apply to final injunctions.

In terms of enforceability of final injunctions in Saudi Arabia, final injunctions in Saudi Arabia become enforceable upon the issuance of a written decision by the court. The enforcement process begins once the judgment is final and binding.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

Courts in Saudi Arabia are granted the power to award damages in lieu of an injunction.

5.4 Damages

Damages are awarded according to the Civil Transactions Law to the extent required to remedy the sustained harm and compensate the aggrieved party for the lost profit. Saudi Arabian law does not recognise punitive damages or legal interest. There is no prescribed way to be followed by judges in awarding damages for patentee/exclusive licensees, and Saudi Arabian judges will apply the general rules prescribed in the Civil Transactions Law while calculating damages.

There is no typical court judgment for the pharma/biopharma/medical device industry, as

courts are not bound by previous court decisions issued in similar cases.

Damages are awarded to remedy actual sustained harm or compensate lost profit from the date at which harm was sustained or the date at which the profit was lost. Damages are awarded by virtue of the court decision and there is no separate quantum hearing or proceedings. Damages are also not awarded via interim awards.

If an injunction was issued and the plaintiff lost the case, the defendant will be at liberty to claim damages for the harm it sustained as a result of the wrongful injunction. There are no special considerations to take into account in this respect and the general rules for awarding damages (wrongful act, harm and causal link) will apply.

The patentee is usually the only person to claim damages against an alleged infringer. It is not usual for national health services to claim damages in these cases.

5.5 Legal Costs

Legal fees incurred by the winning party can be claimed in Saudi Arabia as per the principles of Islamic Sharia. However, as a matter of practice, legal fees are not usually awarded in full as a fraction of the incurred legal fees is usually awarded. There is no prescribed fraction to be decided by the Saudi Arabian courts as each judge will be able to exercise their discretion in this respect.

Court fees are prescribed by virtue of the Saudi Arabian Judicial Fees Law which imposes a maximum of 5% of the amount claimed as court fees (with a maximum amount of SAR1 million) on the losing party.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

Saudi Arabian law does not recognise punitive damages, so the conduct of the parties is not usually considered when deciding on the relief to be granted by Saudi Arabian courts.

6. Other IP Rights

6.1 Trade Marks

Commonality of Trade Mark Disputes

Trade mark disputes in the life sciences and pharmaceutical sectors are relatively common in Saudi Arabia.

Primary Sources of Law

The primary sources of law governing trade marks in Saudi Arabia include:

- the Trade Marks Law: this law provides the framework for the registration, protection, and enforcement of trade marks in Saudi Arabia;
- the GCC Trade Marks Law: this law was implemented in Saudi Arabia through Royal Decree No M/51. It harmonises trade mark regulations across the Gulf Cooperation Council (GCC) states; and
- the SFDA oversees the registration and regulation of pharmaceutical products, including trade mark considerations.

Additional Considerations for Pharma/Medical Devices Marks

Restrictions on naming

Pharmaceutical trade marks must not be misleading or suggest unapproved therapeutic claims. The SFDA has specific guidelines on the naming of pharmaceutical products to ensure they are not confusing or deceptive.

Issues around confusion

The likelihood of confusion is a significant factor in trade mark disputes. Courts consider the similarity of the marks, the similarity of the goods or services, and the likelihood of consumer confusion.

Anti-counterfeiting measures

The SFDA regulations include provisions to combat counterfeiting. These measures are critical in the pharmaceutical sector to ensure the safety and efficacy of medical products.

6.2 Copyright

Copyright disputes in the life sciences and pharmaceutical sectors are not as common as trade mark or patent disputes, but they do occur. These disputes often involve issues related to the unauthorised use of copyrighted materials such as product labels, instructions for use, and other proprietary content.

Relevant Sources of Law

Saudi Arabian Copyright Law

The primary legislation governing copyright in Saudi Arabia is the Copyright Law. This law protects literary, scientific, and artistic works, including those in the life sciences and pharmaceutical sectors.

The SAIP

The SAIP oversees the enforcement of the Copyright Law and provides a framework for the registration and protection of copyrighted works.

6.3 Trade Secrets

Frequency

Trade secrets disputes in the life sciences and pharmaceutical sectors are relatively common in Saudi Arabia. These disputes often arise due to the high value of proprietary information and the competitive nature of the industry.

Common Issues

Employee mobility

One of the most common issues is the movement of employees between competing firms, which can lead to the unauthorised disclosure of trade secrets.

Cybersecurity threats

With the increasing reliance on digital data, cybersecurity breaches pose a significant risk to the protection of trade secrets.

Collaboration and partnerships

Joint ventures and collaborations in the pharmaceutical sector can lead to disputes over the ownership and use of shared proprietary information.

Regulatory compliance

Ensuring compliance with local and international regulations while protecting trade secrets can be challenging, especially in a highly regulated sector like pharmaceuticals.

Relevant Sources of Law

Regulations for the Protection of Confidential Commercial Information

The primary regulation governing trade secrets in Saudi Arabia is the Regulations for the Protection of Confidential Commercial Information, which provides protection for confidential business information and outlines the legal remedies available in case of misappropriation.

The SAIP

The SAIP oversees the enforcement of intellectual property laws, including trade secrets, and provides a framework for the registration and protection of proprietary information.

7. Appeal

7.1 Timeframe to Appeal Decision

In Saudi Arabia, the right to appeal is guaranteed. Parties have the right to appeal decisions from lower courts to higher courts, including decisions on injunctions and main actions.

Timing and Process for PI Appeals

Filing an appeal

The timing to file an appeal against a PI decision is typically within ten days from the date of receiving a copy of the decision.

PI appeal hearing and decision

The timing for a PI appeal hearing and decision can vary, but it is generally expedited due to the urgent nature of injunctions. The appeal court aims to resolve such matters promptly.

Considerations for an appeal

The appeal court considers whether the lower court correctly applied the law and whether the injunction was justified based on the facts presented. The matter is usually considered de novo.

Timing and Process for Main Action Appeals

Filing an appeal

The timing to file an appeal against a first instance main action decision is 30 days from receiving a copy of the decision.

Main action appeal hearing and decision

The timing for a main action appeal hearing and decision can vary depending on the complexity of the case. The appeal process can take several months.

Considerations for an appeal

Similar to PIs, the appeal court reviews the case de novo. The court considers whether the lower court correctly applied the law and whether the decision was supported by the evidence.

Further rights of appeal

Further appeals to the Supreme Court are possible if there are significant legal or procedural errors.

Bifurcated Proceedings (Infringement and Validity)

If proceedings are bifurcated:

- appeals related to infringement follow the same process and timing as outlined above; and
- appeals related to the validity of a patent also follow the same process and timing.

The appeal court reviews the validity of the patent de novo and considers whether the lower court correctly applied the law and whether the decision was supported by the evidence.

Overturning Preliminary or Final Injunctions

If an injunction is overturned on appeal or the patent is revoked, the court decision will be enforced through the competent enforcement court.

7.2 Appeal Court(s) Arbiter

There are no specialised appeal judges to consider patent litigation appeals.

7.3 Special Provisions

There are no special provisions for intellectual property proceedings in Saudi Arabia.

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

In Saudi Arabia, several forums and procedures are relevant to life sciences and pharmaceutical IP litigation beyond the traditional court system.

Customs Detention Applications

The Saudi Arabian Customs Authority plays a crucial role in preventing the importation of infringing or counterfeit products. Rights-holders can file applications with customs to detain suspected infringing goods at the border. This is particularly important for the pharmaceutical sector to prevent the entry of counterfeit medicines.

The SFDA

Any drugs imported to Saudi Arabia have to be registered with the SFDA.

The SAIP

The SAIP oversees the enforcement of IP rights and provides administrative procedures for resolving IP disputes. This includes handling complaints related to IP infringements and coordinating with other government agencies.

9. Alternative Dispute Resolution

9.1 ADR Options

ADR is not commonly used in life sciences disputes as most of these disputes often arise between parties who are not connected through a binding agreement, so an agreement to resort to ADR does not usually exist. However, these kinds of disputes can still be resolved through an ADR method like arbitration, mediation or expert determination depending on the agreement between the relevant parties.

Court actions are commonly used in Saudi Arabia rather than ADR.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

Specific Settlement/Antitrust Considerations

In Saudi Arabia, the General Authority for Competition (the "GAC") oversees antitrust and competition matters. The Competition Law and its implementing regulations provide the legal framework for addressing anti-competitive practices and ensuring fair competition.

Settlement Procedures

The GAC allows for settlement procedures where parties can negotiate and settle disputes related to anti-competitive practices. This is becoming increasingly common as companies seek to avoid lengthy litigation. However, settlements data is not published.

11. Collective Redress

11.1 Group Claims

Availability of Group Claims

Group claims are available in Saudi Arabia. These claims allow multiple plaintiffs with similar grievances to file a single lawsuit against a defendant if they agree to such arrangement. This mechanism is particularly useful in cases involving defective medicines or medical devices, where numerous individuals may be affected by the same issue.

Commonality in the Life Sciences/Pharma Sector

While group claims are available, they are not yet very common in the life sciences and pharmaceutical sectors in Saudi Arabia. The legal framework for class actions is still developing, and awareness among potential claimants is growing.

Trends and Developments

Contributed by:
Dr Saud Alromi, Mostafa Ihab, Mohamed Ramadan and Saleh Albadry
Mohammed Al Dhabaan & Partners Eversheds Sutherland

Mohammed Al Dhabaan & Partners Eversheds Sutherland is a Chambers and Partners top five Saudi Arabian practice and is affiliated with a global top 15 law practice. The firm provides legal services to a local and global client base ranging from small and mid-sized businesses to the largest multinationals. It acts for 73 of the US Fortune 100, 120 of the US Fortune 200 and 66 of the FTSE 100. It is one of the largest full-service legal brands in the world with more than 70 offices across 32 countries. Its global reach allows it to work with clients across numerous jurisdictions. In jurisdictions where it does not have an office, it works with its partner law firms.

Authors

Dr Saud Alromi is a partner and has headed the litigation and dispute management practice at Mohammed Al Dhabaan & Partners Eversheds Sutherland since 2015. He has more than 28 years of experience of practising law in the Kingdom and has advised on the preparation and amendment of numerous Saudi Arabian regulations, such as the legal pleadings system, the penal procedures system, and several regulations related to arranging the legal structure and litigation procedures. He has gained extensive legal experience from his work as an Attorney General at a number of the most important and largest governorates for more than 21 years in Saudi Arabia.

Mostafa Ihab is a legal director at Mohammed Al Dhabaan & Partners Eversheds Sutherland. He is a dual qualified (civil law/common law) bilingual disputes resolution lawyer. He has been practising law for approximately 15 years, five of which have been in Saudi Arabia. He advises and represents clients in disputes before local courts and arbitral tribunals. He also advises clients on all forms of commercial and construction disputes management in addition to handling financial crime cases and internal investigations. Before joining Mohammed Al Dhabaan & Partners Eversheds Sutherland, he spent eight years working as a prosecutor in the Egyptian judiciary at the Financial Crimes Prosecution Office.

Contributed by: Dr Saud Alromi, Mostafa Ihab, Mohamed Ramadan and Saleh Albadry,
Mohammed Al Dhabaan & Partners Eversheds Sutherland

Mohamed Ramadan is a senior associate in the litigation and dispute resolution team at Mohammed Al Dhabaan & Partners Eversheds Sutherland. With over 14 years of legal expertise, he leverages his bilingual capabilities to counsel clients on a broad spectrum of commercial disputes in both courts and arbitration tribunals. Before joining Mohammed Al Dhabaan & Partners Eversheds Sutherland, he was a pivotal senior lawyer in the legal department at one of Egypt's largest holding companies, managing a team handling a diverse array of legal matters and judicial disputes, emphasising his extensive legal background and commitment to securing positive and favourable outcomes.

Saleh Albadry is an associate at Mohammed Al Dhabaan & Partners Eversheds Sutherland. He earned a Bachelor's in Law from Dar Al Uloom University (Saudi Arabia), a Master's from Emory University School of Law (USA), and a JD from Indiana University Maurer School of Law (USA). His practice encompasses matters before general jurisdiction, commercial, and labour courts. His work involves advising corporate clients on various legal matters and drafting a wide range of contracts, including, among others, contracts for contractors, engineers, real estate developers, investment funds, and corporate clients. He handles FIDIC contracts for Saudi Arabian projects. His corporate law practice includes IPO due diligence, prospectus drafting for the Saudi Exchange, and governance policy review and compliance oversight.

Mohammed Al Dhabaan & Partners Eversheds Sutherland

Offices No 9-10-11; Home Offices
PO Box 245555; Riyadh 11312
Saudi Arabia

Tel: +966 11 277 9800
Fax: +966 11 281 6611
Email: DAPESprojects@aldhabaan-es.com
Web: www.aldhabaan-es.com

MOHAMMED ALDHABAAN
& PARTNERS
EVERSHEDS SUTHERLAND

Contributed by: Dr Saud Alromi, Mostafa Ihab, Mohamed Ramadan and Saleh Albadry,
Mohammed Al Dhabaan & Partners Eversheds Sutherland

Overview

Several trends are shaping the landscape of life sciences and pharma IP litigation in Saudi Arabia.

Increased patent filings and litigation

With the growing pharmaceutical market, there has been an increase in patent filings and related litigation. Companies are keen to protect their innovations and market exclusivity, leading to more disputes over patent infringements.

Focus on generic drugs

The Saudi Arabian Food and Drug Authority's (the "SFDA") guidelines on bioequivalence studies have facilitated the entry of generic drugs into the market. This has led to increased competition and potential litigation over patent rights and bioequivalence standards.

Vaccine development and approval

The SFDA's guidelines on clinical trials for vaccines have streamlined the approval process for new vaccines. This has become particularly important in the wake of COVID-19 and an increased focus on vaccine development and related intellectual property (IP) issues.

Privatisation and PPPs

The privatisation of the healthcare sector and the introduction of public-private partnerships (PPPs) have created new opportunities and challenges for IP litigation. Companies involved in PPP projects must navigate complex regulatory and IP landscapes to protect their interests.

Technological advancements

The adoption of digital health technologies has introduced new dimensions to IP litigation. Companies must protect their technological innovations while ensuring compliance with regulatory standards.

Regulatory Environment

The SFDA plays a crucial role in regulating the pharmaceutical industry in Saudi Arabia. The SFDA ensures drug safety, efficacy, and quality through stringent pharmacovigilance measures. All pharmaceutical products must receive approval from the SFDA before entering the Saudi Arabian market. The SFDA provides comprehensive guidelines to assist manufacturers in registering their products, including bioequivalence studies for generic drugs and clinical trials for vaccines.

The SFDA's guidelines on bioequivalence studies for generic drugs and clinical trials for vaccines are critical for ensuring drug safety and efficacy. These guidelines provide a clear framework for manufacturers to follow, reducing the likelihood of rejected applications and facilitating market entry. The SFDA's approach to developing guidelines involves public consultation, allowing stakeholders to provide feedback and ensuring that the guidelines are comprehensive and practical.

The Saudi Arabian Authority for Intellectual Property (the "SAIP") is another key regulatory body, responsible for protecting and enforcing IP rights in the Kingdom. The SAIP was established in 2018 and oversees patent registrations, trade marks, and copyrights, ensuring alignment with international standards. The SAIP aims to regulate, support, develop, sponsor, protect, enforce and upgrade the fields of IP in Saudi Arabia in line with international best practices, and it is organisationally linked to the Prime Minister.

The SAIP's role in protecting IP rights is equally important. The SAIP ensures that patents are granted for new and innovative pharmaceutical products, providing a period of market exclusivity that allows companies to recoup their invest-

ment and fund future research. The SAIP also plays a crucial role in enforcing IP rights, taking legal action against infringers and ensuring that counterfeit products are removed from the market.

Pricing rules

The SFDA has detailed rules for pricing pharmaceutical products, taking various factors such as therapeutic value, prices of alternatives, and economic studies into account. Key points include the following.

Innovative and biological products

Innovative and biological products are priced based on export prices and comparative studies.

Generic products

Generic products are priced at a percentage of the innovative product's price, with reductions as more generics enter the market.

Re-pricing

Products may be re-priced based on market conditions, therapeutic class reviews, and company requests.

The SFDA guidelines

The SFDA has established comprehensive guidelines for the submission, validation, assessment, and pricing of pharmaceutical products. These guidelines ensure drug safety, efficacy, and quality through stringent pharmacovigilance measures. Key aspects include the following.

Bioequivalence studies

Bioequivalence studies are required for generic drugs to ensure they meet safety and efficacy standards.

Clinical trials

Clinical trials are necessary for vaccines to ensure their effectiveness and safety.

Submission process

The submission process involves online submission, technical and business validation, evaluation/inspection, and pricing review.

Key Players in the Saudi Arabian Healthcare Sector

Several key entities play significant roles in the Saudi Arabian healthcare sector. They are as follows.

The Ministry of Health (MoH)

The MoH regulates all healthcare-related activities and services within the country. It also oversees the implementation of healthcare policies, ensures compliance with regulatory standards, and works to improve the quality of healthcare services. Additionally, it is responsible for launching health clusters and integrating healthcare provider networks that aim to improve access to healthcare services and promote preventive care.

The National Unified Company for Medical Supplies (NUPCO)

NUPCO is responsible for centralised government procurement of pharmaceuticals, medical equipment, and supplies. It collects requirements from government agencies, issues tenders, and manages the supply chain and logistics for public healthcare facilities. This centralised approach ensures that public healthcare providers have access to the necessary medical supplies and pharmaceuticals.

The SFDA

The SFDA monitors and controls imports and distribution of medical devices, pharmaceuticals, and food products.

The Cooperative Council of Health Insurance (CCHI)

The CCHI regulates Saudi Arabia's health insurance sector. It ensures that health insurance providers comply with regulatory standards and provides oversight to protect the interests of insured individuals. Its role is particularly important as Saudi Arabia moves towards a more privatised healthcare system, with increased reliance on private health insurance.

The National Centre for Privatisation (NCP)

The NCP enables the privatisation of certain government assets and services. It works to create a conducive environment for private sector participation, facilitating PPPs and ensuring that privatisation initiatives align with the goals of Vision 2030.

The SAIP

The SAIP regulates, enhances, and protects the Kingdom's IP landscape.

The Health Holding Company (HHC)

The HHC manages day-to-day administration of health services from the MoH and provides services through primary healthcare development programmes, including digital health and virtual medical care. This approach aims to improve the efficiency and quality of healthcare services in Saudi Arabia.

Impact of Privatisation on Life Sciences & Pharma IP Litigation

Vision 2030 aims to transform the healthcare sector through privatisation and increased private sector participation. The government plans to invest billions of dollars to develop healthcare infrastructure, reorganise and privatise health services and insurance, and expand e-health services. This transformation is expected to create significant commercial opportunities for both local and international companies.

Privatisation initiatives include the introduction of PPPs in various healthcare areas, such as primary care, hospitals, medical cities, laboratories, radiology, pharmacies, rehabilitation, long-term care, and home care.

The privatisation of the healthcare sector and the introduction of PPPs have created new opportunities and challenges for IP litigation. Companies involved in PPP projects must navigate complex regulatory and IP landscapes to protect their interests. The shift towards privatisation also means that private companies will need to be more vigilant in protecting their IP rights and ensuring compliance with regulatory standards.

IP Protection and Enforcement

IP protection is critical for fostering innovation and attracting investment in the pharmaceutical sector. Saudi Arabia has made significant improvements in its IP protection and enforcement procedures.

The SFDA and the SAIP have developed guidelines to support pharmaceutical manufacturers in registering their products and protecting their IP. These guidelines include requirements for bioequivalence studies for generic drugs and clinical trials for vaccines.

The SFDA's guidelines on bioequivalence studies for generic drugs and clinical trials for vaccines are critical for ensuring drug safety and efficacy. These guidelines provide a clear framework for manufacturers to follow, reducing the

likelihood of rejected applications and facilitating market entry. The SFDA's approach to developing guidelines involves public consultation, allowing stakeholders to provide feedback and ensuring that the guidelines are comprehensive and practical.

The SAIP's role in protecting IP rights is equally important. The SAIP ensures that patents are granted for new and innovative pharmaceutical products, providing a period of market exclusivity that allows companies to recoup their investment and fund future research. The SAIP also plays a crucial role in enforcing IP rights, taking legal action against infringers and ensuring that counterfeit products are removed from the market.

The IP Litigation Process in Saudi Arabia

Filing a lawsuit

To initiate the litigation process, the party filing the lawsuit must submit a complaint to the commercial courts. This complaint outlines the basis of the dispute, the relief sought, and any supporting evidence. The court then reviews the submission to ensure it meets the necessary legal requirements.

Notifying the defendant

After the lawsuit is filed, the court will notify the defendant. This notification is typically communicated via SMS if the defendant is located within Saudi Arabia. If the defendant is outside Saudi Arabia, international service procedures may apply, potentially causing delays.

Court hearings

The court schedules hearings where both parties present their evidence and legal arguments. The timeframe for a case to reach a final decision can vary significantly, often extending over several months or even years, depending on factors such as court schedules and the complexity of the case.

Issuance of judgment

Once the court has reviewed all the evidence and arguments, it issues a judgment, which can include various forms of relief, such as injunctions, damages, or orders for specific performance.

Appeals

Parties have the right to appeal decisions from lower courts to higher courts, including decisions on injunctions and main actions. The timing to file an appeal against a main first instance action decision is typically 30 days from receiving a copy of the decision. The appeal process can take several months, depending on the complexity of the case.

Infringement actions

In an action for patent infringement in Saudi Arabia, the primary parties involved are the patentee who is the owner of the patent who holds the exclusive rights to the invention and the alleged infringer who is the party accused of infringing the patent rights.

If a patent is co-owned, each co-owner has the right to use the patent independently. However, co-owners must agree to bring an infringement action jointly. An exclusive licensee, who has been granted the exclusive rights to use the patent within a specific territory or field, can bring an infringement action. The licence must be registered with the SAIP to be enforceable. Non-exclusive licensees do not generally have the standing to bring an infringement action unless explicitly granted this right in the licence agreement.

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Mohammed Al Dhabaan & Partners Eversheds Sutherland

Challenges and Opportunities

While the pharmaceutical market in Saudi Arabia presents significant opportunities, it also poses several challenges.

Regulatory compliance

Navigating the complex regulatory environment can be challenging for companies, particularly those new to the Saudi Arabian market. Compliance with the SFDA and the SAIP guidelines is essential for successful market entry.

IP enforcement

Despite improvements in IP protection, enforcement remains a challenge. Companies must be vigilant in protecting their IP rights and pursuing legal action against infringers.

Market competition

The entry of generic drugs and increased competition can impact market share and profitability for innovator companies. Companies must adopt strategies to maintain their competitive edge.

Technological integration

Integrating advanced technologies into healthcare and pharmaceutical operations requires significant investment and expertise. Companies must balance innovation with regulatory compliance.

The Transformative Patent Landscape in Saudi Arabia

Since the announcement of Vision 2030, there has been a significant increase in patent activity in Saudi Arabia. Vision 2030 aims to diversify Saudi Arabia's economy and reduce its reliance on oil revenue by fostering growth in sectors such as renewable energy, biotechnology, healthcare, and information technology. Patents serve as a key indicator of technological advancement and innovation, providing a tangible metric for measuring the output of research and development (R&D) activities.

Analysis of patent data from the Patsnap database reveals a gradual increase in patent registrations across various organisations in Saudi Arabia. Leading the way in patent grants is Saudi Aramco, followed by King Faisal University (KFU), King Fahd University of Petroleum and Minerals (KFUPM), King Abdullah University of Science and Technology (KAUST), and King Abdulaziz University.

SINGAPORE

Law and Practice

Contributed by:
Tony Yeo, Meryl Koh, Rozalynne Asmali and Javier Yeo
Drew & Napier LLC

Contents

Drew & Napier LLC has been providing exceptional legal service since 1889 and is one of the largest full-service law firms in Singapore. It is pre-eminent in dispute resolution, international arbitration, competition and antitrust, corporate insolvency and restructuring, intellectual property (patents and trade marks), tax, and telecommunications, media and technology, and has market-leading practices in M&A, banking and finance, and capital markets. Drew & Napier has represented Singapore's leaders, top government agencies and foreign governments in landmark, high-profile cases. It is also appointed by Fortune 500 companies, multinational corporations, and local organisations. The firm is experienced in international disputes before the Singapore International Commercial Court and covers the full range of commercial litigation matters, including building and construction, constitutional law, debt recovery, defamation, fraud and white-collar crime.

Authors

Tony Yeo is the managing director of Drew & Napier's IP practice, and a director in its dispute resolution department. He also heads the firm's health care and life sciences practice. Tony's expertise lies in litigation; in particular, IP litigation and enforcement comprising patents, trade marks and copyright. He was one of the select few IP practitioners appointed by the Intellectual Property Office of Singapore (IPOS) as an IP adjudicator to hear disputes at IPOS for a two-year term from April 2019. Tony is also the President of the International Association for the Protection of Intellectual Property (AIPPI) – Singapore Group.

Meryl Koh is a director in Drew & Napier's dispute resolution and intellectual property departments. She is one of the leading young commercial disputes and intellectual property disputes practitioners. Her distinctive competency has led her to act for household names, MNCs and listed companies in digital media, video games, sports and entertainment, F&B, agriculture as well pharmaceuticals and healthcare industries in copyright, trade marks, patent disputes as well as corporate litigation and international arbitration. She is a Fellow of the Singapore Institute of Arbitrators, admitted in Singapore and Australia and is fluent in Mandarin.

Rozalynne Asmali is a director in Drew & Napier's intellectual property and dispute resolution departments. With over 16 years of experience in the legal industry as a commercial litigator, an intellectual property litigator and general in-house counsel, Rozalynne specialises in representing her clients through complex and complicated legal issues in both IP litigation and general litigation. She has advised and represented a range of clients stemming from diverse industries such as pharmaceuticals, food and beverage, consumer electronics, cleaning technology, property, healthcare and medical devices, in both contentious and non-contentious matters. Rozalynne is a member of the Bar of England & Wales, and is admitted as an advocate and solicitor in Singapore.

Javier Yeo specialises in intellectual property dispute resolution at Drew & Napier. He has successfully acted for many clients across different industries such as the pharmaceutical, chemical and mechanical engineering as well as semiconductor industries in trade mark and patent matters. Apart from his intellectual property practice, Javier has also practised in a wide array of commercial matters including company law, contract law, defamation and employment law, for both international and local clients.

Drew & Napier LLC

10 Collyer Quay
#10-01
Ocean Financial Centre
049315
Singapore

Tel: +65 6535 0733
Fax: +65 6535 4906
Email: mail@drewnapier.com
Web: www.drewnapier.com

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

A patent proprietor has standing to bring a patent infringement action. An equitable owner of a patent may also bring a patent infringement action although he/she must perfect his/her equitable title before final judgment.

Where there are multiple patent proprietors, any of them may bring an action without the consent of the other proprietors, but they must be named as defendants in the proceedings unless the court orders otherwise.

An assignee or exclusive licensee of a patent also has standing to bring an action in respect of any infringement of the patent committed after the date of the assignment or licence, or for infringements occurring prior to that date if such right is included in the relevant grant of title. The transaction, instrument or event by which the proprietor or exclusive licensee is conferred rights in a patent should be registered within a period of six months of its date, or if registration within that period is not practicable, as soon as practicable thereafter. The failure to do so does not mean that the assignee or exclusive licensee cannot sue, but it will preclude the assignee or licensee from obtaining damages or an account of profits in respect of a subsequent infringement of the patent occurring after the transaction, instrument or event, but before the same was registered.

Licensees under a licence of right or a licence granted compulsorily may request the patent proprietor to bring proceedings to prevent any infringement of the patent, and if the proprietor neglects to do so within two months, the licensee may institute proceedings in his/her own name, making the proprietor a defendant to such proceedings.

Section 82(1) of the Patents Act (PA) provides that the validity of a patent may be put in issue only in the following proceedings:

- a request for examination of the specification of a patent under Section 38A of the PA;
- by way of defence, in proceedings for infringement of the patent under Section 67 or proceedings under Section 76 for infringement of rights conferred by the publication of an application;
- in proceedings under Section 77 (ie, applications for remedies for groundless threats of infringement proceedings);
- in proceedings in which a declaration in relation to the patent is sought under Section 78 (ie, applications for a declaration of non-infringement);
- in proceedings before the court or the Registrar under Section 80 for the revocation of the patent; or
- in proceedings under Section 56 or 58 of the PA (ie, proceedings relating to the use of patented inventions by the government and its authorised parties).

Section 82(2) of the PA further states that no proceedings may be instituted seeking only a declaration as to the validity or invalidity of a patent. A mere declaration means that no further action is taken against the patent apart from the fact that the court has declared that the patent is invalid. Consequently, if any party wishes to launch a standalone action challenging the validity of the patent, it must be for the revocation of the patent.

Infringement and/or validity opinions are not available from IPOS.

1.2 Defendants/Other Parties to an Action

Patent infringement in Singapore is territorial in nature. Consequently, only parties who carry out infringing acts within the jurisdiction can be sued for patent infringement.

If the patent covers a product, then as long as the party makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise, he/she can be sued for infringement.

If the patent covers a method of manufacture, then as long as the party uses the process or he/she offers it for use in Singapore when he/she knows, or it is obvious to a reasonable person in the circumstances, that its use without the consent of the proprietor would be an infringement of the patent, he/she can be sued for infringement. Relatedly, any product made from the said infringement process, would also constitute an infringement of the patent.

In Singapore, the typical defendant in life sciences/pharma cases is the generic that applies for marketing approval in Singapore for the sale of the pharmaceutical drug.

Under Regulation 23 of the Health Products (Therapeutic Products) Regulations 2016 (Regulations), when the Health Sciences Authority (HSA) is determining whether to approve a therapeutic product registration application or grant a product licence for a therapeutic product, it considers:

- whether a patent under the Patents Act 1994 is in force in respect of the product;
- whether the applicant is the patent proprietor, or has obtained the patent proprietor's consent; and
- whether the patent is invalid, or will not be infringed by doing the act for which the licence is sought.

This means that when the generic applies for marketing approval, it is required to notify the patent proprietor that it intends to apply for marketing approval, and submit a declaration that the patent (if there is one in force) is invalid or will not be infringed by doing the act for which the licence is sought. The patent proprietor then has the right to oppose the licence application by commencing a patent infringement action within 45 days from receiving notice of the generic's licence application and declaration. Once the patent proprietor commences the action, it will inform HSA that it has done so, and HSA will not register the therapeutic product for a period of 30 months. At the expiry of the 30-month moratorium period, if the patent proprietor has not obtained an order and/or declaration of infringement from the court, HSA may proceed to register the therapeutic product without further notice to the patent proprietor.

If a generic makes a false declaration to HSA by omitting to disclose the existence of certain patents that were in force at the time of its application for a therapeutic product, the patent proprietor may seek a declaration from the court that the generic has made a false declaration, and pursuant to Regulation 24 of the Regulations, HSA may cancel the registration (see Millennium Pharmaceuticals, Inc v Zyfas Medical Co (sued as a firm) [2020] SGHC 28).

Any person who makes a false declaration may also be liable on conviction to a fine not exceeding SGD20,000 or to imprisonment for a term not exceeding 12 months or to both.

1.3 Preliminary Injunction Proceedings

An application for an interim injunction in patent litigation follows similar principles as those in civil cases.

The applicant must show that there is a serious question to be tried, that damages are not an adequate remedy and that the balance of convenience lies in favour of granting an injunction. The procedure for obtaining an interim injunction is set out in Order 13 of the Rules of Court 2021 (ROC 2021). In exchange for obtaining an interim injunction, the claimant may be required to undertake to the court to compensate the defendant in the event that his/her claim fails and the interim injunction has caused the defendant loss.

An application for an interim injunction must be made by summons together with a supporting affidavit. The supporting affidavit should set out the nature of the alleged infringing acts, whether these acts are impending and/or continuing, the strength of the patent proprietor's case on infringement and the strength of the validity of the patent. It should also provide evidence as to why damages are not an adequate remedy, thereby necessitating an interim injunction.

Most applications for interim injunctions are made with notice (ie, inter-partes). If the application is filed with notice, the alleged infringer will be given the opportunity to file a reply affidavit to set out its response. The court will manage the timelines. The alleged infringer is typically given 2–3 weeks to respond with its reply affidavit, and the application will be fixed for a hearing 4–6 weeks from the date that the application for interim injunction is filed. The application will be heard before a judge.

Where the case is urgent and where notice to the alleged infringer will significantly prejudice the patent proprietor or nullify any benefit of an interim injunction (if granted), the application may be made and heard without notice (ie, ex-parte). Even if the patent proprietor intends to file an ex-parte application for injunction, the Supreme Court Practice Directions 2021 requires the patent proprietor to give notice to the other concerned parties prior to the hearing. The notice may be given by way of email, or, in cases of extreme urgency, orally by telephone. Except in cases of extreme urgency or with the permission of the court, the party must give a minimum of two hours' notice to the other parties before the hearing. The notice should inform the other parties of the date, time and place fixed for the hearing of the application and the nature of the relief sought. If possible, a copy of the originating process, the summons without notice or the originating application without notice (if no originating process has been issued yet) and supporting affidavit(s) should be given to each of the other parties in draft form as soon as they are ready to be filed in court. At the hearing of the application without notice, in the event that some or all of the other parties are not present or represented, the applicant's solicitors should inform the court of:

- the attempts that were made to notify the other parties or their solicitors of the making of the application;
- what documents were given to the other parties or their solicitors and when these documents were given; and
- whether the other parties or their solicitors consent to the application being heard without their presence.

Notice need not be given if the giving of the notice to the other parties, or some of them, would or

might defeat the purpose of the application without notice. However, in such cases, the reasons for not following the directions should be clearly set out in the affidavit prepared and filed in support of the application without notice.

Even if the interim injunction is not granted, a party may apply for an expedited trial of the action.

Although it is not a requirement, the court may take into account the expediency on which the application for interim injunction is filed. If an application for interim injunction is filed long after the alleged infringing product has been released in the Singapore market, then the court may infer that it is not a situation where damages cannot compensate the loss, because if that were true, the patent proprietor should have taken steps to arrest the problem and stop the release of the product as soon as possible.

In specific relation to therapeutic products to be registered in Singapore, pursuant to the Health Products Act (HPA) and the Regulations, a 30-month moratorium on registering the said products is available to patent proprietors who are put on notice that an applicant is seeking to register a therapeutic product which is related to a patent that is currently in force. This moratorium is automatic and will kick in on the date that the patent proprietor commences a patent infringement action against the applicant. In practice, this is a more viable option than the customary qua timet injunction to prevent an imminent threat of infringement.

1.4 Structure of Main Proceedings on Infringement/Validity

Infringement and invalidity are generally heard together due to the need to engage expert witnesses for common issues such as claim construction. It is very rare for the court to agree to bifurcate infringement and validity proceedings. The court will usually agree if there is a very clear case of invalidity. For example, prior to the amendment to the Singapore Patents Act in 2021, there was no grace period of 12 months for prior disclosures to be disregarded, unlike other jurisdictions (eg, USA). Consequently, prior sales within the 12-month grace period might have been excluded in other jurisdictions, but it will be considered as citable prior art in Singapore. In such situations, the court may be of the view that it would be better to bifurcate the infringement and validity proceedings, since the possibility of the patent being invalidated by its own poison prior disclosure is high.

While it is technically possible for another party to file nullity proceedings in court while patent office revocation actions are ongoing, in practice, once IPOS learns that nullity proceedings have been filed in court, IPOS will typically stay proceedings at IPOS pending the court's determination on the matter.

1.5 Timing for Main Proceedings on Infringement/Validity

Proceedings for patent infringement have to be commenced by Originating Claim in the General Division of the High Court. As patent infringement is a statutory tort, the limitation period of six years for an action founded on a tort applies. Where there is ongoing infringement of the patent in question, a fresh cause of action accrues every day. However, the patent proprietor's right to bring an action is restricted to the part of the wrong which was committed in the past six years.

While not mandatory, a letter of demand is usually sent before proceedings are commenced. This depends on whether the patent proprietor

wishes to engage the alleged infringer in negotiations prior to the commencement of proceedings. Under Order 5 of the ROC 2021, the parties have a duty to consider amicable resolution of the dispute before commencement and during the course of any action. A party therefore has to make an offer of amicable resolution before commencing the action unless the party has reasonable grounds not to do so.

That being said, the patent proprietor must be aware that in the event that the court eventually finds that his/her patent has not been infringed, the court has the discretion to award the alleged infringer relief for groundless threats of infringement. Such relief could include a declaration that the threats are unjustifiable, an injunction against the continuance of the threats and/or damages for any loss sustained thereby. Where applicable, it is also prudent to conduct trap purchases before the start of any proceedings. A lawyer may conduct the trap purchases on behalf of its client, or a private investigator may be engaged to do so. A party does not need to wait for the patent proprietor to commence a claim in the General Division of the High Court for patent infringement. If the party wishes to, it may commence a claim in the General Division of the High Court for a declaration of non-infringement of the patent. However, before commencing such an action for a declaration of non-infringement, the party must write to the patent proprietor for a written acknowledgement that it does not infringe the patent proprietor's patent and furnish the patent proprietor with full particulars in writing of the act in question and the patent proprietor must have refused to provide such an acknowledgement.

A rough timeline is as follows.

- The claimant files and serves on the defendant the Originating Claim, Statement of Claim and Particulars of Infringement. The Particulars of Infringement must state which of the claims in the specification of the patent are alleged to be infringed, and must give at least one instance of each type of infringement alleged. The method of service is personal service, unless the defendant's lawyers have written to the claimant's lawyers to state that the defendant's lawyers are instructed to accept service on behalf of the defendant. If the defendant is out of jurisdiction, the claimant must apply to court for permission to serve the Originating Claim out of jurisdiction. Typically, since patent infringement acts are territorial, it is unlikely that the defendant will be out of jurisdiction.
- Within 14 days of the service of the Statement of Claim and Particulars of Infringement, the defendant has to file and serve a Notice of Intention to Contest or Not Contest in the proceedings.
- If the defendant intends to put in issue the validity of the patent (or just asserted patent claims, whichever the case may be), the defendant must give prior notice of his or her intention to put in issue the validity of the patent within 14 days of the service of the Statement of Claim by filing a Notice of Intention to Put In Issue the Validity of the Patent ("Notice").
- If the defendant does not challenge the validity of the patent, its defence (and counterclaim if applicable) will be due within 21 days after the Statement of Claim is served on the defendant. If the defendant files the Notice, the defendant has to file its defence and counterclaim and Particulars of Objection to the Validity of the Patent within 42 days of the service of the Statement of Claim.

- A claimant does not have an automatic right of reply to the defence. If the claimant wishes to file a reply, it will have to seek the court's permission to do so.

Thereafter, the parties will typically proceed to the discovery stage. Once pleadings are filed, the court will hold a case management conference to ask the parties' views on whether, amongst others, this is a case where affidavits of evidence-in-chief (AEICs) should be exchanged before discovery. Although the court may, in some cases, direct that AEICs be exchanged first before discovery, in practice, this is unlikely to happen for patent infringement matters where the parties have no existing commercial relationship (unlike, for example, contract matters). It is also usually on or around this time during the case management conference, that the court will decide whether the proceedings should be bifurcated or not, either on its own volition or pursuant to an application from a party in the proceedings. It is more common for the court to bifurcate the issue of liability/invalidity and the issue of damages. As explained above, infringement and invalidity are generally heard together due to the need to engage expert witnesses for common issues such as claim construction.

If the court directs that discovery proceeds first, then after discovery (and the disposal of all interlocutory applications and/or interim orders), AEICs will be exchanged. It is usually on or around the stage of the exchange of AEICs that the court will deal with whether the issues of claim construction will be considered separately from or together with infringement and/or validity, and in general how the trial of the matter should be conducted.

It typically takes around 1.5 to 2 years or more from the commencement of the proceedings to obtain a first instance decision.

Further, with effect from 1 April 2022, the Supreme Court of Judicature (Intellectual Property) Rules 2022 (IP Rules) introduced a simplified optional track for intellectual property litigation known as the "Simplified Process for Certain Intellectual Property Claims" ("Simplified Process") to resolve intellectual property disputes in a quicker and more cost-effective manner. The Simplified Process is applicable for certain intellectual property claims (including actions of patent infringement under Section 67 of the PA and declaration of non-infringement of a patent under Section 78 of the PA) where (i) the monetary relief claimed by each party in the action does not or is not likely to exceed SGD500,000, or (ii) where all parties agree to the application of the simplified process. A case may also be suitable having regard to:

- whether a litigant can only afford to participate in the proceedings under the Simplified Process;
- the complexity of the issues;
- whether the estimated length of the trial is likely to exceed two days; and
- any other relevant matter.

For claims under the Simplified Process, the total costs recoverable is subject to an overall cap of SGD50,000 for the trial, and an overall cap of SGD25,000 for any bifurcated assessment of monetary relief. In line with the spirit of streamlining intellectual property dispute resolution, the court will also give directions on all matters that are necessary for the dispute to proceed expeditiously and where practicable, will give directions to ensure that the trial is completed within two days.

1.6 Requirements to Bring Infringement Action

An infringement action can be filed the moment the patent is granted in Singapore. All patent applications filed in Singapore must be filed in English, so there is no requirement for patents to be further translated.

Generally, the patent proprietor (ie, the claimant) bears the burden of proving that its patent has been infringed. However, the burden of proof is reversed in patent infringement proceedings involving a process for obtaining a new product. In such proceedings, the alleged infringer bears the burden of proving that the product is not made by that process if (i) the product is new, or (ii) substantial likelihood exists that the product is made by that process and the claimant has been unable through reasonable efforts to determine the process actually used. There is no automatic requirement for the defendant to provide a process description. If the claimant wishes to compel the defendant to do so, the claimant may apply for the defendant to furnish such details by way of an application to court for discovery or interrogatories. In Towa Corporation v ASM Technology Singapore Pte Ltd and anor [2014] SGHCR 16, the Singapore High Court Registrar held that the Singapore High Court has no jurisdiction to order an inspection of a process in a patent infringement action under Order 29 Rule 2 of the Singapore Rules of Court 2014 (equivalent to Order 13 Rule 2 of the ROC 2021). This decision has not been overturned by any appellate decision.

1.7 Pre-Action Discovery/Disclosure

Under Order 11 Rule 11 of the ROC 2021, the claimant may seek pre-action discovery and pre-action interrogatories (collectively referred to as "pre-action disclosure") against a defendant prior to commencement of proceedings against a party to compel it to make disclosures of documents and facts in order to help the claimant ascertain whether he/she has a viable cause of action against a potential defendant. Further, pre-action disclosure may be sought against non-parties to the proceedings in order to identify possible parties to the proceedings.

Pre-action discovery is for the claimant who is unable to plead a case as he/she does not know whether he/she has a viable or good cause of action and requires the discovery to ascertain the gaps in his/her case. Where the claimant has evidence sufficient to commence a claim, he/she is generally not entitled to discovery before action in order to fully plead his/her case. Pre-action discovery is also not designed to allow a party to determine whether it is likely to succeed in its cause of action against a potential defendant. Nor is it designed to allow a claimant, who already has an accrued cause of action, to uncover other causes of action.

An application for pre-action disclosure has to be supported by an affidavit setting out the grounds for the application, the material facts pertaining to the intended action, and whether the person against whom the order was sought was likely to be a party to subsequent proceedings. The applicant also has to prove that the defendant has possession, custody or power of these documents. These documents must also be proved to be relevant to the intended action. In other words, the scope of the pre-action discovery should be substantially similar to the scope of discovery expected during the main action (if launched).

The court must be satisfied that the pre-action disclosure is not frivolous or speculative, and that the claimant is not on a fishing expedition.

The costs for the pre-action discovery is borne by the applicant.

Under Singapore law, there is an implied undertaking by a party who receives documents in discovery not to use these documents for a collateral purpose, which includes proceedings in other jurisdictions.

It may be possible to use materials obtained in other jurisdictions. That is dependent on the laws of the particular jurisdiction from which the party obtained these documents. If there is no similar prohibition for use of these documents, then the party can use those documents in Singapore. If there is a similar prohibition, then the party who intends to use these documents obtained in other jurisdictions must satisfy the court in Singapore that permission was by the court of law in that jurisdiction to use these documents in Singapore.

Under Rule 37 of the IP Rules, there are classes of documents that are exempt from discovery. These classes of documents are likely to be similarly exempted from the scope of pre-action discovery. More details relating to the exempt classes of documents are discussed further in this chapter.

1.8 Search and Seizure Orders

Under Order 13 of the ROC 2021, search and seizure orders (previously known as Anton Piller orders) are available in Singapore. There is no requirement for the main action to be started as part of the application.

In view of the draconian nature of the search order (which is usually made ex-parte in light of the risk that the defendant may destroy or conceal the documents and/or incriminating material), the court will have to balance the claimant's right to seize and preserve evidence against the violation of the privacy of the defendant who had no rights to defend him-/her-self at the ex-parte hearing.

- There must be a very strong prima facie case of a civil cause of action. A scrutiny of the merits of the claimant's case is an essential preliminary to the grant of a search order.
- The damage, potential or actual, to the claimant to be avoided by the grant of an order must be very serious. If an order is sought in order to forestall the destruction of evidence, the evidence in question must be of major, if not critical, importance.
- There must be clear evidence that the defendant has in his/her possession incriminating documents or items.
- There must be a real possibility that the defendant may destroy such material before an application inter partes can be made.

The requirements for a search order therefore goes beyond what is required for pre-action discovery. It is a pre-requisite to a search order that the materials that the claimant intends to seize is relevant and necessary to the action.

It may be possible to use materials obtained in other jurisdictions. See **1.7 Pre-Action Discovery/Disclosure**.

1.9 Declaratory Relief

A claimant may rely on Section 67(1)(e) of the PA to seek a declaration that the patent in suit is valid and has been infringed by the defendant. Conversely, a defendant or any person may rely on Section 78(1) of the PA to seek a declaration that an act or proposed act would not constitute an infringement of a patent if the following conditions are met:

- the patent proprietor has not made any assertion to the contrary;
- the person has applied in writing to the patent proprietor for a written acknowledgment to the effect of the declaration claimed and has furnished him or her with full written particulars of the relevant act; and
- the patent proprietor has refused or failed to give any such acknowledgment.

However, Section 82(2) of the PA further states that no proceedings may be instituted seeking only a declaration as to the validity or invalidity of a patent. A mere declaration means that no further action is taken against the patent apart from the fact that the court has declared that the patent is invalid. Consequently, if any party wishes to launch a standalone action challenging the validity of the patent, it must be for the revocation of the patent.

To date, the Singapore Court has not dealt with "Arrow" declarations. It remains to be seen whether this will be recognised in Singapore.

1.10 Doctrine of Equivalents

The general principle under the doctrine of equivalents is that a device which is functionally equivalent to the patented invention will be held to infringe it, notwithstanding that certain essential features of the patented invention are absent from the device. This doctrine has not been accepted in Singapore on the basis that a wholly functional approach to claim construction objectionably disregards the clear and unambiguous words stated in the patent claims when such words must be given their natural and ordinary meaning.

1.11 Clearing the Way

The obligation for a generic to "clear the way" ahead of a new product launch is statutorily imposed in Singapore pursuant to Regulation 23 of the Regulations.

1.12 Experts

It is very common for parties and consequently the court to rely on expert evidence for patent infringement and validity issues. This is because patent infringement and validity issues often require technical evidence which lawyers and judges require assistance with. In fact, most patent proceedings in Singapore rely heavily on expert-led evidence.

Experts may be called to give opinion evidence on technical matters and scientific information relating to the patent. Parties usually engage their own respective experts. While it is not common for parties to agree on a single joint expert for patent matters, pursuant to the ROC 2021, parties to all civil proceedings (including actions under the PA) commenced on or after 1 April 2022 must agree on a single expert as far as possible. No expert evidence may be used in court unless it is approved by the court. Expert evidence is admissible in relation to matters that ordinary persons are unlikely to have sufficient knowledge to give meaningful evidence.

Specifically, an expert may give evidence on:

- the prior art at any given time;
- the meaning of any technical terms used in the prior art and an explanation as to facts of a scientific kind;
- whether, on a given hypothesis as to the meaning of what is described in the patent specification, the specification can be carried out by a skilled worker;
- at any given time, what a given piece of apparatus or any given sentence on any given hypothesis would have taught or suggested to him/her;

- whether a particular operation relating to the art would be carried out; and
- what is common general knowledge to a person skilled in the art.

It is increasingly common for the Singapore court to appoint a court expert (referred to as a Court Assessor) to assist the court in matters where the subject matter is highly technical.

It is the duty of an expert to assist the court on the matters within his/her expertise, and this duty overrides any obligation owed to the person instructing or paying him/her.

Unless the court otherwise directs, expert evidence is given in a form of a written report. Typically, there are no limits on the length or amount of expert evidence that may be adduced. This report must contain relevant details, including:

- the expert's qualifications showing that he or she has the requisite specialised knowledge on the issues referred to him or her;
- the expert's statement that he or she understands his or her duty is to assist the court in the matters within his or her expertise and on the issues referred to him or her and that such duty to the court overrides any obligation to the person from whom he or she receives instructions or by whom he or she is paid;
- the issues referred to the expert and the common set of agreed or assumed facts that he or she relied on; and
- a list of the materials that the expert relied on and including only extracts of the materials which are necessary to understand the report.

A party may with the court's approval, request in writing that an expert clarify his or her report in any aspect. This report will be sworn by the expert in his/her AEIC, and either party may cross-examine the other party's expert on the contents of his/her report. The court may also order that some or all of the expert witnesses give their evidence concurrently by testifying as a panel (ie, hot-tubbing).

There are no restrictions for parties to rely on expert evidence in PI proceedings. Typically, expert evidence adduced at the trial would address issues of infringement and/or invalidity in-depth, whereas expert evidence adduced at the PI stage would focus on the issue of infringement.

1.13 Use of Experiments

A party which desires to establish any fact by experimental proof (the "Requesting Party") shall serve a notice of experiments on the other party, stating the facts which it desires to establish and full particulars of the experiments proposed to establish those facts. Within 21 days of such service, the other party is to serve upon the Requesting Party a notice stating whether or not he/she admits each fact.

Where any such fact is not admitted, the Requesting Party may seek an order for the experiments to be conducted. At this stage, the court will manage the conduct of experiments and timelines to ensure that there is judicious use of time and costs.

1.14 Discovery/Disclosure

There is no closed list of types of documents that the parties are required to provide in discovery. As long as the category of documents is proved to be material to the issues in the proceedings, and that discovery is necessary, parties must disclose them and the court can order discovery of these documents.

In exercising its power to order discovery, the ROC 2021 state that the court must bear in mind that a claimant is to sue and proceed on the strength of the claimant's case and not on the weakness of the defendant's case.

Types of documents that will have to be disclosed therefore include the following.

- Proof that the alleged infringing samples were obtained from the defendant, ie, provenance and chain of custody of the alleged infringing samples.
- Evidence of infringement, eg, technical analysis, expert reports, and lab reports.
- If the patent is a process patent, the defendant will be required to disclose its method of manufacture. For this, the defendant can apply for a confidentiality order limiting the disclosure of its method of manufacture to named individuals.

The following classes of documents are exempted from discovery.

- Documents relating to the infringement of a patent by a product or process, if before serving a list of documents, the party against whom the allegation of infringement is made has served on the other parties, full particulars of the product or process alleged to infringe, including if necessary drawings or other illustrations.
- Documents relating to any ground on which the validity of a patent is put into issue, except documents which came into existence within the period beginning two years before the claimed priority date and ending two years after that date.
- Documents relating to the issue of commercial success (collectively referred to as the "exempt classes").

Notwithstanding this, however, any party may apply for further and better production or specific production of any document in an exempt class.

Where the issue of commercial success arises in any proceedings relating to an action for infringement of a patent or a declaration of non-infringement of a patent or any proceedings where the validity of a patent is in issue, and where the commercial success relates to an article or product, the proprietor of the patent must serve a schedule containing the following details.

(i) an identification of the article or product (for example, by product code number) which the proprietor asserts has been made in accordance with the claims of the patent;

(ii) a summary by convenient periods of sales of any such article or product;

(iii) a summary for the equivalent periods of sales (if any) of any equivalent prior article or product marketed before the article or product mentioned in (i) above; and

(iv) a summary by convenient periods of any expenditure on advertising and promotion which supported the marketing of the articles or products mentioned in (i) and (iii) above.

Where the commercial success relates to the use of a process, the proprietor of the patent must serve a schedule containing the following details:

(1) an identification of the process which the proprietor asserts has been used in accordance with the claims of the patent;

(2) a summary by convenient periods of the revenues received from the use of such process;

(3) a summary for the equivalent periods of the revenues (if any) received from the use of any equivalent prior art process; and

(4) a summary by convenient periods of any expenditure which supported the use of the process mentioned in (1) and (3) above.

It is not common for the court to grant discovery of inventor lab notebooks. Usually, the inventor's subjective intentions and understanding of the patent and the motivations behind his/her invention are irrelevant. Validity issues and claim construction are always viewed from the lens of a person skilled in the art.

1.15 Defences and Exceptions to Patent Infringement

The two key defences to patent infringement are (i) the invalidity of the patent, which is a complete defence; and (ii) non-infringement.

While rarely relied on, a defendant may also rely on exceptions created by Section 66(2) of the PA for acts which would otherwise constitute infringement by virtue of being prohibited by Section 66(1) of the PA.

The main categories of exceptions in Section 66(2) of the PA are:

- acts which are done privately and for non-commercial purposes;
- acts which are done for experimental purposes relating to the subject-matter of the invention;
- acts which consist of the extemporaneous preparation of a medicine for an individual in accordance with a prescription given by a registered medical or dental practitioner or consist of dealing with a medicine so prepared;
- uses of a patented product or process by aircraft and ships which had temporarily or accidentally entered into Singapore's airspace or territorial waters (as the case may be) or by exempted aircraft or ships; and
- the parallel importation into Singapore, with consent of the foreign patent proprietor or his/her licensee, of any patented product or any product obtained by means of a patented process or to which a patented process has been applied. Further, under Section 71(1) of the PA, a person who in Singapore before the priority date of the invention does in good faith an act which would constitute an infringement of the patent if it were in force, or makes in good faith effective and serious preparations to do such an act, has the right to continue to do that act notwithstanding the grant of the patent.

1.16 Stays and Relevance of Parallel Proceedings

In the event that post-grant opposition proceedings have commenced at the IPOS Registry prior to the revocation action in patent infringement proceedings in the General Division of the High Court, the parties can consider whether any of the proceedings ought to be stayed, and if so, which one. While there are no provisions in the ROC 2021 that provide for an automatic stay of proceedings, it is likely that parties will opt for the IPOS Registry proceedings to be stayed given that any appeal from the IPOS Registry would eventually be heard in the General Division of the High Court.

It is, however, unlikely for the Singapore Court to agree to any stay on the basis of foreign pro-

ceedings since the patent will be different, and the acts are also different (based on territory).

The Singapore Court may take into account the decisions of the Court in other jurisdictions, but the Singapore Court is never bound. Further, the weight that the Court accords to the Court decisions in these other jurisdictions depends on whether the patent language in these other jurisdictions are substantially similar to the patent granted in Singapore and whether the basis of the Court's finding is based on laws that are substantially similar in Singapore. For example, a finding of infringement for a US-equivalent of the patent on the basis of the doctrine of equivalents will not be relevant at all for the issue of infringement of the Singapore patent.

1.17 Patent Amendment

A patent that is the subject of a patent litigation may be amended in the midst of patent litigation. The patent proprietor may only apply to do so if the validity of the patent has been put in issue before the court or the Registrar. This would usually be in a case where there is a counterclaim filed by the defendant in a patent infringement action to invalidate and revoke the patent.

Regardless of whether the amendment is sought before the court or the Registrar, a patent proprietor intending to do so must give notice of his/her intention to the Registrar and a copy of an advertisement containing relevant details of the patent sought to be amended must be published in the patent journal by the patent Registry. Such details include the full particulars of the amendment sought, whether the amendment is by way of deletion or rewriting of claims and the patent proprietor's address for service within Singapore. Any person may oppose the amendment and that person must give written notice of his/her intention to oppose to the patent proprietor within 28 days after the publication of the advertisement. This notice is to be accompanied by a statement of opposition, which is to contain full particulars of all grounds of opposition to the patent proprietor's application to amend. After the expiration of 42 days from the appearance of the advertisement, the patent proprietor must make his/her application to amend by way of summons in the proceedings pending before the court. A copy of the summons and a copy of the specification with amendments marked up in coloured ink must be served on the Registrar, the parties to the proceedings and any person who has given notice of his/her intention to oppose the amendment.

All applications for post-grant amendments will be assessed according to the following criteria:

- whether the patent proprietor had disclosed all relevant information with regard to the proposed amendments;
- whether the amendments comply with the statutory requirements;
- whether the amendments introduce additional matter;
- whether the amendments extend the scope of protection of the patent (ie, the amended patent is broader than the patent in its current form);
- whether there had been undue and inexplicable delay on the patent proprietor's part in taking out the amendment application;
- whether the patent proprietor had sought to obtain an unfair advantage from the patent by delaying the amendments which it knew were needed; and
- whether the patent proprietor's conduct discourages the amendment of the patent.

Following a successful application to amend the patent specifications, the patent proprietor (ie,

the claimant) may be in a better position to resist any claims from the defendant that the patent in the suit is invalid on the ground of anticipation by the prior art. This is generally why a patent proprietor seeks to amend its patent. However, the adverse implication to an application to amend a patent specification is that it indicates to the adverse party and to the court that the unamended patent as granted may not be valid. In cases where the amendment is sought in proceedings before the court, the court has the discretion to direct whether the hearing of the patent amendment application should be at the trial of the patent infringement suit or separately before the trial of the patent infringement suit. While the patent amendment application is considered an interlocutory application where cross-examination of deponents is typically not allowed, given the complexity and the finding of facts involved in a patent amendment application, expert witnesses are usually cross-examined at the hearing of a patent amendment application that is separate from the trial of the suit.

The concept of conditional amendments has not been tested in Singapore.

1.18 Court Arbiter

All patent matters will be heard by judges sitting in the General Division of the High Court of Singapore. Judges chosen to hear patent matters will typically be selected from the list of Intellectual Property Judges.

2. Generic Market Entry

2.1 Infringing Acts

As mentioned in **1.2 Defendants/Other Parties to an Action**, generics are required to obtain marketing approval from HSA before they are allowed to launch the product in Singapore. Regulation 23 of the Regulations provides the patent proprietor a statutory right to commence an action for patent infringement once the patent proprietor is notified of the generic's application for marketing approval.

In relation to second medical use patents (also known as Swiss-type claims), the patent proprietor must be able to prove that the generics intend to market that product for that second medical use.

An issue closely-intertwined with the infringement of patents with Swiss-type claims is whether the exclusion of the patent-protected indications from the product labels of potentially-infringing medical products would preclude a claim of patent infringement. The practice of excluding patented indications is often referred to as "skinny-labelling" or "carving out". This is a developing area of the law, both in Singapore and in the UK. On the one hand, there have been some obiter comments in English case law that the problem of infringement posed by "skinny labels" is more theoretical than real, since product manufacturers often have to provide details of the approved indications on its product information leaflets. On the other hand, there have also been decisions in the UK and the Netherlands which suggest that manufacturers of "skinny-labelled" products may infringe a second medical use claim if there is a subjective intention on the part of the manufacturer that the pharmaceutical composition will be used for treating the patented indication. It should be noted that unlike in the UK Patents Act, there is no provision for indirect infringement in the Singapore PA. As there have been no reported local cases on this issue, it remains to be seen how the Singapore courts will decide on this issue.

2.2 Regulatory Data and Market Exclusivity

Regulation 26 of the Regulations provide for protection of confidential information relating to innovative therapeutic product applications. Confidential information received in support of the registration of an innovative therapeutic product is protected for a period of five years from the date of receipt, during which HSA which will not use the information to determine whether to grant any other registration applications. Confidential information here includes trade secrets and information that has commercial value which will be diminished by disclosure.

Pursuant to Regulation 29 of the Regulations, a five-year period of exclusivity is granted for a therapeutic product for which safety and efficacy data has been generated in support of its registration. During the exclusivity period, a subsequent similar therapeutic product will not be able to rely on such data generated for the earlier therapeutic product to obtain registration.

2.3 Acceptable Pre-Launch Preparations

The research exemption more commonly known as the "Bolar" provision protects generics who may need to conduct research and/or trials to prove that their generic version of the product is the bioequivalent of the patented drug or, who may, in the course of obtaining marketing approval for the release of a drug in Singapore, inadvertently infringe a patent.

All pharmaceutical products have to be approved by the HSA before they can be marketed and/or sold in Singapore. These approval processes can take very long, and a generic may apply for marketing approval near the expiry date of a patent, with the intention of launching immediately once the patent expires.

The Bolar provision is therefore a legal exemption from infringement if the generic can prove that the acts which otherwise would have been infringing, were done for meeting the marketing approval requirements for the pharmaceutical product.

2.4 Publicly Available Drug and Patent Information

There is no equivalent of the Orange Book in Singapore.

2.5 Reimbursement and Pricing/Linkage Markets

Singapore has a patent linkage scheme, which is set out in Regulation 23 of the Regulations. HSA oversees the administration of these regulations.

In specific relation to therapeutic products to be registered in Singapore, pursuant to the HPA and the Regulations, a 30-month moratorium on registering the said products is available to patent proprietors who are put on notice that an applicant is seeking to register a therapeutic product which is related to a patent that is currently in force. This moratorium is automatic and will kick in on the date that the patent proprietor commences a patent infringement action against the applicant. In practice, this is a more viable option than the customary qua timet injunction to prevent an imminent threat of infringement.

There is no public list of applications for marketing approval. Patent proprietors therefore rely solely on the generic's notice identifying the relevant patents relating to the generic product. Patent proprietors can file a court declaration if the generic is found to have falsely declared in its notice by excluding patents that are relevant to the drug for which the generic has applied for marketing approval.

There has been no known suit against HSA for the refusal to list or grant marketing approval. Since HSA is a statutory body imbued with the authority to grant marketing approvals, any administrative suits will be a judicial review of HSA's decision.

3. Biosimilar Market Entry

3.1 Infringing Acts

There are no differences at present in this jurisdiction. See **2.1 Infringing Acts**.

3.2 Data and Regulatory Exclusivity

There are no differences at present in this jurisdiction. See **2.2 Regulatory Data and Market Exclusivity**.

3.3 Acceptable Pre-Launch Preparations

There are no differences at present in this jurisdiction. See **2.3 Acceptable Pre-Launch Preparations**.

3.4 Publicly Available Drug and Patent Information

There are no differences at present in this jurisdiction. See **2.4 Publicly Available Drug and Patent Information**.

3.5 Reimbursement and Pricing/Linkage Markets

There are no differences at present in this jurisdiction. See **2.5 Reimbursement and Pricing/Linkage Markets**.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Under Section 36A of the PA, the proprietor of a patent which subject includes any substance which is an active ingredient of any pharmaceutical product may apply to extend the term of the patent not exceeding five years if there was an unreasonable curtailment of the opportunity to exploit the patent caused by the process of obtaining marketing approval for a pharmaceutical product, being the first pharmaceutical product to obtain marketing approval which uses the substance as an active ingredient; and the term of the patent has not previously been extended on this ground.

4.2 Paediatric Extensions

There are no extended protections provided for paediatric indications over and above the allowable five-year extension.

4.3 Paediatric-Use Marketing Authorisations

Paediatric medicines are considered as therapeutic products which are governed by the HPA. As with all health products, a company seeking to market a therapeutic product in Singapore must obtain marketing approval from HSA by submitting an application for product registration under Section 30(1) of the HPA.

4.4 Orphan Medicines Extensions

There are no extended protections provided for orphan drugs over and above the allowable five-year extension.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

See **1.3 Preliminary Injunction Proceedings**.

It is not common to apply for an interim injunction for patent cases involving pharmaceutical patents or health products in view of the patent-linkage scheme, which gives the patent proprietor a statutory right to, in effect, a qua-timet injunction of 30 months the moment the patent proprietor files a patent infringement suit against the generic.

In exchange for obtaining an interim injunction, the claimant may be required to undertake to the court to compensate the defendant in the event that his/her claim fails and the interim injunction has caused the defendant loss.

Interim injunctions are enforceable from the date the order is made. A breach of the order will entitle the claimant to commence enforcement proceedings and contempt of court proceedings, which may include a custodial sentence for the directors of the defendant company against whom the interim injunction was ordered.

An appeal does not operate as an automatic stay of the interim injunction. The defendant must file an application for a stay pending appeal, and in so doing, the defendant must convince the court that if a stay is not granted, it will nullify the appeal. It is in practice difficult to convince the court of this since an interim injunction is usually a prohibitory injunction rather than a mandatory injunction, unless there is a time limitation of the defendant to do the act which is covered by the interim injunction and the expiry of the said time limitation will cause irreparable prejudice to the defendant should the defendant not act.

5.2 Final Injunctive Relief

Generally, final injunctions are prayed for in the claimant's Statement of Claim. While the court retains discretion as to whether a final injunction should be granted, if the court eventually finds that the patent in the suit has been infringed, the court will generally grant the final injunction. The standard form of final injunction is one which restrains the defendant "from making, disposing of, offering to dispose of, using, importing and/or keeping whether for disposal or otherwise products which infringe the patent in issue, and/or using or offering for use in Singapore processes which infringe the patent in issue".

Final injunctions are enforceable from the date the order is made. A breach of the order will entitle the claimant to commence enforcement proceedings and contempt of court proceedings, which may include a custodial sentence for the directors of the defendant company against whom the final injunction was ordered.

Unlike an interim injunction, there is no requirement for the patent proprietor to give an undertaking as to damages or to pay a bond before it can enforce the final injunction.

An appeal does not operate as an automatic stay of the final injunction. The defendant must file an application for a stay pending appeal, and in so doing, the defendant must convince the court that if a stay is not granted, it will nullify the appeal. For example, if the injunction covers the whole of the defendant's business, and the defendant will no longer be able to finance the appeal if the injunction is in place, the defendant may be able to convince the court that a stay should be granted.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

Injunctions are an equitable remedy. Consequently, the court will have the discretion to decide whether it should award injunctive relief.

In practice, once the court finds that there is infringement, the court will readily order a final injunction unless the defendant has given evidence that it has already ceased with the alleged infringing activities even before the order was made, such that an injunction is of no use.

5.4 Damages

A successful claimant is entitled to damages as compensation for the loss that it suffered due to the infringement. Typically, patent infringement claims are bifurcated, and damages are assessed at a separate inquiry held subsequent to the infringement trial.

In a great deal of cases where the patent proprietor does not have a competing product of its own, the proper measure of damages is a reasonable royalty in respect of each infringement committed. If the patent proprietor habitually grants licences at a particular royalty, quantum is easy to estimate. Even if he/she does not, an estimate can be made.

Claims to larger damages can be made, on the ground that the patent proprietor has lost profits, or, for example, has had to reduce his/her prices. The patent proprietor has to elect whether it intends to claim damages, or loss of profits. It cannot claim both. The onus is on the claimant to prove that his/her lost profit has resulted from the infringing acts and that if those acts had not taken place, he/she would have made the profits. If he/she cannot, the reasonable royalty basis will apply. Claims are often made for other damages (for example, loss of sales of related products not covered by the patent, or loss of orders of spare parts or loss of service contracts).

Damages/loss of profits will be calculated from the date of when the infringing activities occur and when the patent is valid and in force, subject to the limitation period of six years. There will be interest fixed at 5.33% per annum. This interest is determined and fixed by the court for all post-judgment interest.

5.5 Legal Costs

A successful party will be able to recover about 30% to 40% of its legal costs from the losing party and 100% of court filing fees and reasonable disbursements from the other side. These costs are generally awarded on a standard basis (ie, the winning party will be able to recover costs that were reasonably incurred and are reasonable in amount, and any doubts that the court may have as to whether the costs were reasonably incurred or were reasonable in amount shall be resolved in favour of the paying party). Costs are awarded at the discretion of the court, and in exercising its discretion, the court must have regard to all relevant circumstances, including:

- efforts made by a party at amicable resolution;
- the complexity of the case and the difficulty or novelty of the questions involved;
- the skill, specialised knowledge and responsibility required of, and the time and labour expended by, the solicitor;
- the urgency and importance of the action to the parties;
- the number of solicitors involved in the case for each party;
- the conduct of the parties;
- the principle of proportionality; and
- the stage at which the proceedings were concluded. Additionally, the court may disallow

or reduce a successful party's costs or order that party to pay costs if:

(a) that party has failed to establish any claim or issue which that party has raised in any proceedings, thereby unnecessarily increasing the amount of time taken, the costs or the complexity of the proceedings;
(b) that party has done or omitted to do anything unreasonably;
(c) that party has not discharged that party's duty to consider amicable resolution of the dispute or to make an offer of amicable resolution; or
(d) that party has failed to comply with any order of court, any relevant pre action protocol or any practice direction.

In appropriate cases, the court also has the discretion to order costs to be assessed on an indemnity basis (ie, the winning party will be able to recover all costs except those that have been unreasonably incurred or are unreasonable in amount, and any doubts which the court may have as to whether the costs were reasonably incurred or were reasonable in amount shall be resolved in favour of the receiving party). A defendant may apply for a security for costs (SFC) order, which requires the claimant to put up a certain amount of money as security/guarantee for the defendant's legal costs in the event the claimant loses his/her case. For the avoidance of doubt, the legal costs referred to here are Party-and-Party Costs ("P&P Costs"). Usually, a losing party must pay the winning party's P&P Costs. P&P Costs are not the legal fees a party pays to his/her lawyer, which are called Solicitor-and-Client Costs ("S&C Costs"). P&P Costs are not meant to compensate the winning party for his/her S&C Costs and are generally far lower than S&C Costs. However, P&P Costs still go some way towards the winning party recouping its expenses. SFC applications are usually granted when the court is persuaded that the defendant will have difficulty obtaining P&P Costs from the claimant if the claimant's claim fails. The grounds on which an SFC application can be sought is set out in Order 9 Rule 12 of the ROC 2021:

- where the claimant is ordinarily resident out of the jurisdiction;
- where the claimant is a nominal claimant who is suing for the benefit of some other person and that there is reason to believe that he/she will be unable to pay the costs of the defendant if ordered to do so; or
- where the claimant has not stated or has incorrectly stated the claimant's address in the originating claim or originating application, or the claimant changed the claimant's address during the course of the proceedings so as to evade the consequences of the litigation.

Along with the grounds above, the court will still have regard to all the circumstances of the case and order the SFC if the court thinks it just to do so. The process of obtaining SFC is started by the defendant writing to the claimant requesting for security to be provided. If the claimant refuses, the defendant will have to make a formal application to court by way of summons supported by affidavit. This affidavit will contain the defendant's reasons for wanting security to be provided and the amount of security sought. If the court grants an application for SFC, the claimant may provide security by way of depositing the sum of monies into an account held by the Singapore Court, by way of a bank guarantee, or by way of a solicitor's undertaking.

For claims under the Simplified Process, the total costs recoverable is subject to an overall cap of

SGD50,000 for the trial, and an overall cap of SGD25,000 for any bifurcated assessment of monetary relief. In line with the spirit of streamlining intellectual property dispute resolution, the court will also give directions on all matters that are necessary for the dispute to proceed expeditiously and where practicable, will give directions to ensure that the trial is completed within two days.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

See **5.5 Legal Costs**.

6. Other IP Rights

6.1 Trade Marks

A health product is counterfeit if it is presented in such a manner as to resemble or pass off as a registered health product when in fact it is not, or it is presented with any false information as to its manufacturer or origin (Section 2(2)(b), HPA).

The principal regulatory agency tackling the problem of counterfeiting in the pharmaceutical sector in Singapore is the HSA.

All health products (which includes Western medicines – also known as therapeutic products) must be granted a licence by the HSA before they are allowed to be marketed and sold in Singapore. This better enables the HSA to detect counterfeit, adulterated and/or illegal health products at the first instance.

The manufacture, import or supply of a counterfeit health product in Singapore is an offence under the HPA and is punishable by a fine not exceeding SGD100,000 and/or imprisonment for up to three years.

In this regard, the HSA has wide powers of enforcement, including the power to search premises that are suspected to be used for or in connection with the manufacture, import or supply of counterfeit health products. The HSA can also seize any health products that are suspected to be counterfeit.

In addition, the HSA continually monitors the safety, integrity and quality of health products, acting on its own independent surveillance reports as well as in response to reports or complaints from the public. The HSA also maintains a publicly accessible list of illegal health products in Singapore that have been detected and tested.

6.2 Copyright

Copyright disputes in the life sciences and pharma sector are not common.

6.3 Trade Secrets

Trade secrets disputes in the life sciences and pharma sector are not common, save for situations where a patent infringement suit has commenced and the defendant has to disclose its manufacturing process to the patent proprietor to prove non-infringement. The generic's manufacturing process may be a trade secret. In such situations, the generic will typically apply to establish a confidentiality club to limit the disclosure of its manufacturing process to only named individual members of the confidentiality club.

7. Appeal

7.1 Timeframe to Appeal Decision

A party intending to appeal against a preliminary injunction decision has to file an application to the appellate court for permission to appeal within 14 days of the decision. If permission to

appeal is granted by the court, the party has to file and serve on all parties who have an interest in the appeal a Notice of Appeal within 14 days after the date of the decision granting permission. If the matter involves patents, the appellate court hearing the appeal will be the Court of Appeal.

The appeal will be heard by way of a rehearing. The matter will not be heard de novo. There is no further right of appeal after the Court of Appeal.

If the preliminary injunction is overturned on appeal, the preliminary injunction is lifted immediately from the date of the order.

For the substantive suit, the parties have a right of appeal to the Court of Appeal. Appeals to the Court of Appeal are by way of a rehearing. The parties are entitled to appeal on all issues, including findings of facts. When filing the appeal, the party must therefore indicate whether it is appealing against the whole or part of the judgment or order.

If the matter is bifurcated into two tranches on issues of validity and infringement, the parties will have a right to appeal the trial judge's decision in each of these tranches. Procedurally, the matter will not move to the second tranche (assuming the patent is found to be valid) until the issues in the first tranche have been completely disposed of, including the exhaustion of any appeals.

In general, the appellate court will be slow to upset an exercise of discretion by the trial judge. In relation to finding of facts, the appellate court is also generally slow to overturn a trial judge's findings because the trial judge is in a better position to assess the veracity and credibility of the witnesses, unless they can be shown to be plainly wrong or against the weight of the evidence. Similarly, in relation to patent matters, the appellate court will be cautious in differing from the trial judge's evaluation of what was obvious.

On the other hand, there is a distinction between the perception of facts and evaluation of facts, the latter of which the appellate court is in as good a position as the trial court to make an evaluation from primary facts.

If a final injunction is overturned, or if the patent is revoked, the final injunction will be lifted immediately from the date of the order. For completeness, the Court of Appeal will usually include in its orders that all orders by the trial judge (including the order for the final injunction) are set aside, if the appellant is successful on appeal.

7.2 Appeal Court(s) Arbiter

Singapore has specialised Intellectual Property Judges who will be docketed to hear patent matters.

7.3 Special Provisions

The substantive act that governs patents in Singapore would be the Patents Act.

There are two sets of court rules that govern IP matters.

The first set of rules will be the ROC 2021, which applies to all court proceedings regardless of subject matter.

The second set of rules will be the IP Rules, which applies in addition to the ROC 2021, for matters involving IP.

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

No information has been provided in this jurisdiction concerning other forums/procedures relevant to life sciences & pharma IP litigation in Singapore.

9. Alternative Dispute Resolution

9.1 ADR Options

Under Order 5 of the ROC 2021, the parties are obliged to consider ADR options before commencing a claim.

IP disputes are capable of being resolved by arbitration as between parties to that dispute under Singapore law, although this is not a common dispute resolution option for patent matters as it requires both parties to agree to refer the matter to arbitration.

Mediation is another possible, and more common, ADR option. The parties can request to refer the dispute to mediation at any time before the case has been decided. In general, the court and/or IPOS will ask parties to consider ADR options such as mediation to resolve the dispute. This is especially when Order 5 of the ROC 2021 requires the parties to attempt an amicable resolution to the dispute.

There are various mediation service providers in Singapore. Apart from the Singapore Mediation Centre and the Singapore International Mediation Centre that handles general mediation disputes, the World Intellectual Property Organization Arbitration and Mediation Centre is a global mediation provider that specialises in IP disputes.

If parties attempt mediation, the court and/or IPOS will, at the request of the parties, generally allow a stay of proceedings pending the outcome of the mediation. A failure or refusal to genuinely consider ADR options may lead to an adverse costs order being made against the refusing party.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The Competition and Consumer Commission of Singapore has released guidelines on the licensing of SEPs on FRAND terms. Where an owner of an SEP has a dominant position in the market, its refusal to license its SEP on FRAND terms to any application for a licence may give rise to competition concerns under Section 47 of the Competition Act 2004. However, there is no known decision in Singapore regarding SEPs yet.

Further, the life sciences industry has not had to deal with SEPs yet.

11. Collective Redress

11.1 Group Claims

Group claims are available pursuant to Order 4 Rule 6 of the ROC 2021, where numerous persons that have a common interest in proceedings may sue or be sued as a group, with one or more of them representing the group. For claims initiated by a group of persons, all members in the group must give their consent in writing to the representative to represent all of them in the action and they must be included in a list attached to the originating claim or the originating application. Where there is a class of persons and all or any member of the class cannot be ascertained or cannot be found, the Court

may appoint one more persons to represent the entire class or part of the class and all the known members and the class must be included in a list attached to the order of Court. Any judgment or order given in such proceedings is binding on all the persons and the class named in the respective lists.

Group claims are not common in the life sciences/pharma sector in Singapore.

SOUTH AFRICA

Law and Practice

Contributed by:
Russell Bagnall, Danie Dohmen, Sophia Smallbones and Ramon Pereira
Adams & Adams Attorneys

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Contributed by: Russell Bagnall, Danie Dohmen, Sophia Smallbones and Ramon Pereira,
Adams & Adams Attorneys

Adams & Adams Attorneys is a prominent African law firm specialising in IP, commercial law, real estate, and dispute resolution. Recognised locally and internationally, the firm boasts a team of over 100 skilled attorneys and is the largest IP law firm in Africa. With offices in four major South African cities and 24 associate offices across the continent, it serves as a gateway for IP clients, offering comprehensive support in various jurisdictions. The firm's extensive IP services include filing, enforcement, licensing, and anti-counterfeiting, alongside a full range of commercial services like arbitration, regulatory law, and corporate investigations. Adams & Adams is also committed to advancing legal frameworks in Africa, actively contributing to IP policy formulation, providing governance training, and engaging in public interest litigation. Through its diverse expertise, the firm fosters valuable client relationships and promotes legal development across the continent.

Authors

Russell Bagnall has been a partner at Adams & Adams since 1998, and leads the patent and design litigation group. Russell mainly advises on pharmaceutical disputes between multinational originator and generic companies, as well as on licensing, distribution, and regulatory issues. He manages multi-jurisdictional litigation across several African countries and has received international recognition in peer-reviewed publications. Russell holds a BSc in Metallurgical/Chemical Engineering and a BProc. He also advises in other technology areas such as mechanical engineering, and tech/software. Russell is top ranked in Chambers Global for Intellectual Property: Patents.

Danie Dohmen has been a partner at Adams & Adams since 2007 and is the chairperson of the patents department. He specialises in patent, design, PBR and IP transaction litigation, and opinion work. Consistently highly ranked in Intellectual Property: Patents by Chambers, Danie holds a BSc in physics and chemistry and an LLB. He is a past president of the Licensing Executives Society of South Africa and a fellow of the South African Institute of Intellectual Property Law. He represents clients across various sectors, litigates in multiple African jurisdictions, and contributes to IP policy on national and international levels.

Contributed by: Russell Bagnall, Danie Dohmen, Sophia Smallbones and Ramon Pereira,
Adams & Adams Attorneys

Sophia Smallbones specialises in patent and registered design litigation, with 11 years' experience mainly in the life sciences field. At Adams & Adams, Sophia handles high-value cases of global significance and has represented clients before the Patents Court, the Supreme Court of Appeal of South Africa, and the ARIPO Board of Appeal. She holds a BSc in Chemical Engineering and an LLB. She is an admitted attorney and a registered patent attorney.

Ramon Pereira is a senior associate and qualified patent attorney at Adams & Adams, specialising in patent litigation mainly in the life sciences field. He holds an MSc in Molecular and Cell Biology and an LLB from the University of Cape Town, and is passionate about the intersection of commerce and technology. Ramon also advises in the fields of mechanical engineering, mining technologies, and tech/software innovations. He collaborates with overseas multinational enterprises on high-value, cross-border matters. Committed to protecting intellectual property rights in Africa, Ramon provides strategic advice to clients navigating the complex landscape of patent and design enforcement in Africa.

Adams & Adams Attorneys

4 Daventry St
Lynnwood Manor
Pretoria, 0081
South Africa

Tel: +27 12 432 6000
Email: patents@adams.africa
Web: www.adams.africa

Contributed by: Russell Bagnall, Danie Dohmen, Sophia Smallbones and Ramon Pereira,
Adams & Adams Attorneys

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Only the patentee and a very specific type of licensee (a party endorsed as a licensee of right) are entitled to bring proceedings for infringement. To have standing, a licensee's interest must be recorded in the Patent Office Register. The patentee is required to notify licensees recorded in the register (which would include exclusive and non-exclusive licensees) of the intention to bring proceedings and such licensees are entitled to join in the proceedings as co-plaintiffs.

A co-patentee is not entitled to institute infringement proceedings unless there is an agreement to that effect or consent given by the other co-patentee(s).

There are no specific standing requirements to bring a nullity action. The relevant provision of the Patents Act provides that "any person" may do so.

No substantive proceedings relating to infringement or validity take place before the Patent Office.

1.2 Defendants/Other Parties to an Action

The party that is most often sued in South Africa (SA) is the generic company manufacturing or importing the generic product (sometimes including the holding company and subsidiaries). In some cases, national pharmacy groups with wide distribution networks are also joined in the proceedings.

1.3 Preliminary Injunction Proceedings

Inter partes preliminary injunctions are possible, but not ex-parte injunctions. The applicant must show that:

- the right sought to be protected by means of interim relief is clear or, if not clear, is prima facie established, though open to some doubt;
- if the right is only prima facie established, there is a well-grounded apprehension of irreparable harm to the applicant if the interim relief is not granted and the applicant ultimately succeeds in establishing his/her right;
- the balance of convenience favours the granting of interim relief; and
- the applicant has no other satisfactory remedy.

An applicant for preliminary injunction is required to bring the proceedings with some degree of urgency, which will vary depending on the circumstances. For complex matters with voluminous evidence, 4–6 weeks is not unusual to bring proceedings if there is some degree of urgency. SA courts have commented that approximately 3–4 weeks may constitute utmost expedition for patent matters.

The time to a hearing varies, depending on several factors, including the number of days required which impacts the availability of a court. Typically, 3–4 months from instituting proceedings until a hearing date could be expected. A judgment usually takes 2–3 months.

The proceedings may be based on a reasonable apprehension of infringement rather than an actual infringement. However, proceedings may only be brought nine months after grant unless special circumstances are shown to warrant pro-

ceedings being brought after grant but before the nine-month period has expired.

The grant of a Marketing Authorisation (MA) or activities relating to obtaining regulatory approval (other than stockpiling) are not considered to be acts of infringement. There is also no patent linkage system with the MA authority in South Africa.

Preliminary injunction proceedings are commenced by service on the respondents at their place of business and the time periods are calculated from the date of service. The application is accompanied by founding evidence in the form of one or more declarations. Urgent service usually takes one to three days. The respondent is required to file a notice of intention to oppose and, thereafter, file answering evidence. The applicants have the opportunity to file replying evidence in response to the answering evidence.

The respondents are given 15 days from the filing of the notice of intention to oppose to file their evidence and the patentee is required to reply within ten days. Often these timelines are extended by agreement between the parties.

The presiding judge considers the question of infringement and validity and the prospects of the patentee succeeding on these issues at trial. If the court is of the view that the patentee has strong prospects of succeeding at trial, then other factors, such as the balance of convenience, need not necessarily weigh heavily in favour of the applicant. However, if the court finds that the strength of the case is prima facie established but open to some doubt, factors such as the balance of convenience would need to favour the patentee more heavily.

It is common practice for the applicant to provide an undertaking that it will pay any damages to the respondent that it proves to have suffered because of the injunction being wrongly granted. This assists in arguing that the balance of convenience favours the applicant. In some cases, the respondent will provide a cross-undertaking.

Demands from respondents to provide bonds for security for legal costs (for foreign applicants who hold no fixed assets in South Africa) are not uncommon. Security for costs can be effectively provided with limited risk for applicants.

1.4 Structure of Main Proceedings on Infringement/Validity

Infringement and validity proceedings are not bifurcated. A defendant is entitled to raise invalidity by way of defence or by way of a counterclaim in an infringement action.

It is possible to bring a revocation application post grant, but no opposition proceedings are available before or after grant.

1.5 Timing for Main Proceedings on Infringement/Validity

A claim for damages prescribes three years from when prescription starts to run. The issuing of summons interrupts prescription. In practical terms, what this means is that, once successful in an infringement action, it is permissible to claim damages for sales that took place up to three years before a summons was instituted.

An infringement action is commenced by issuing of a summons accompanied by a particulars of claim through the court whereafter the issued summons is physically served through the Sheriff of the Court (usually at the defendant's main place of business or registered address). All relevant time periods are calculated from the date of service.

Since the court of first instance has nationwide jurisdiction for patent infringement matters, service can be made anywhere within South Africa. It is also possible to obtain leave to serve proceedings on foreign entities in foreign jurisdictions through a process of edictal citation to confirm jurisdiction. This is less common in life sciences matters where the generic company is situated in South Africa and is directly involved in the act(s) of infringement.

An infringement action is usually concluded within 18 to 24 months after commencing proceedings. Pleadings usually close within 3–4 months after commencing proceedings. Thereafter, discovery and any interlocutory applications (for example, to compel further or better discovery) take place. This usually takes about 3–6 months to conclude. Once discovery has been concluded, expert summaries are filed. In practice, the parties usually exchange expert summaries 2–3 months before trial.

1.6 Requirements to Bring Infringement Action

An infringement trial action can be instituted nine months after grant of the patent, or after grant and before the expiry of nine months with leave of the court if special circumstances exist. There are no translation or validation formalities that need to be completed.

There are no pre-trial discovery-/seizure-type orders available in SA (apart from Anton Piller-type orders which are very specific ex-parte orders that are rarely invoked because they only apply where there is a reasonable likelihood that evidence will be spirited away).

A trial action is instituted based on a reasonable apprehension of infringement. Relevant information to prove infringement must be obtained through the normal discovery procedures which would be applicable once the trial action has been instituted (at the close of pleadings). Potential challenges arise when the details of the infringement (for example, a process or specific amounts of an excipient) are not readily apparent from public documents and are not in the possession of the defendant who, as importers, allege no knowledge thereof. Expert evidence may be required to examine impurity markers, excipient amounts, or the like to reverse the onus, or documents from foreign proceedings may be relied on if permissible in terms of the law of the foreign jurisdiction.

A claim in respect of a process for making a new product shall be assumed to be made by the patented process unless the contrary is proved.

1.7 Pre-Action Discovery/Disclosure

As indicated previously, there are no pre-trial discovery-/seizure-type orders available in SA (apart from Anton Piller-type orders which are very specific ex-parte orders that are rarely invoked because they only apply where there is a reasonable likelihood that evidence will be spirited away).

Information obtained from foreign jurisdictions may be used if permissible under the laws of the foreign jurisdiction.

1.8 Search and Seizure Orders

No seizure orders are available. However, inspections in loco may be ordered during the discovery process.

Information obtained from foreign jurisdictions may be used if permissible under the laws of the foreign jurisdiction.

1.9 Declaratory Relief

A declaration of non-infringement is possible. The declaration may be sought by any person and requires that the applicant furnish the full particulars of the alleged infringement to the patentee with a request for the declaration which, if refused, permits the applicant to apply to court.

1.10 Doctrine of Equivalents

South African (SA) courts adopt a purposive or contextual approach to the interpretation of claims. Within the framework of this approach, SA courts do apply a form of the doctrine of equivalents. In particular, the courts will determine whether a feature is essential or not. The considerations are broadly as follows.

- To ascertain what are and what are not the essential features or integers of a claimed invention, the specification must be read and interpreted purposively or realistically, with the understanding of persons with practical knowledge and experience of the kind of work for which the invention was intended to be used and in the light of what was generally known by such persons at the date.
- The fact that a particular feature is present in the claim does not alone suffice to make that feature an essential one, otherwise the problem would not arise.
- In general, if the feature is in fact essential to the working of the claimed invention, then it must be regarded as an essential feature. On the other hand, a patentee may indicate in his/her specification, either expressly or by implication, that he/she regards a particular integer as essential; and in that event it must be treated as essential, and it does not matter that it may not be essential to the working of the invention. However, where a feature is not essential to the working of the invention and the patentee has not indicated that he/she regards it as an essential integer, then, in general, it may be treated as unessential.

1.11 Clearing the Way

There is no obligation to clear the way before launching a product. However, a failure to do so is an issue that is relevant during preliminary injunction proceedings in weighing up the balance of convenience if the generic product is launched at risk.

1.12 Experts

Parties routinely rely on expert witnesses to advance their case on validity and infringement. In preliminary injunction proceedings, the evidence takes the form of declaration evidence. In trial proceedings, the party wishing to adduce expert evidence is required to indicate an intention to do so and must provide a summary of the opinion and its reasons for the opinion in an expert summary. The expert witnesses provide oral testimony and are subject to cross examination.

There is no limit to the amount of evidence that may be adduced.

Parties appoint their own expert witnesses and there is no court-appointed expert, technical or scientific adviser. However, the expert has a duty to assist the court in its findings by providing independent and objective views.

Multiple experts are often required, for example, where the notional skilled addressee is a multidisciplinary team.

As mentioned, in preliminary injunction proceedings the evidence takes the form of declaration evidence.

1.13 Use of Experiments

Experimental evidence may be adduced and is often relied on, especially for proving infringement. The normal evidentiary rules apply. A chain of custody should be established when reliance is placed on the analysis of infringing samples.

1.14 Discovery/Disclosure

Any party may be required to make discovery on oath of all documents and tape recordings relating to any matter in question, once pleadings have closed.

The party required to make discovery files a discovery affidavit specifying documents and tape recordings in its possession and identifies those documents and tape recordings it objects to produce.

There is no discovery by way of deposition. However, it is possible to make provision for a party to compel further or better discovery in circumstances in which the discovery is considered inadequate.

A party is required to discover and make available for inspection all documents which may either directly or indirectly enable the party requiring the affidavit of discovery either to advance its own case or damage the case of its adversary. Documents which tend to advance only the case of the party making the discovery need not be disclosed unless such party intends to rely on those documents at trial.

A party is entitled to claim privilege in certain documents, for example, communications with its legal representatives for the purpose of giving or receiving legal advice, without prejudice communications, and the like.

Documents that are confidential but do not enjoy legal privilege, are usually either redacted or disclosed to the legal advisers under suitable restrictions.

SA courts have held that the inventor story is not relevant to an objective determination of inventiveness. Therefore, discovery of inventor notebooks may be resisted as being not relevant. However, if the patentee decides to rely on aspects of the inventor story, then discovery would be required.

1.15 Defences and Exceptions to Patent Infringement

The following may typically be relied on by way of defence.

- Traditional grounds of invalidity.
- The patentee consented or granted a licence.
- The patentee waived its rights or is estopped from asserting them.
- Prior use and Gillette defence.
- The activities fall under the right to reasonable repair.
- Exhaustion of rights.
- The activities fall under legitimate compounding regulations.
- Experimental use.
- Bolar-type exemption.

1.16 Stays and Relevance of Parallel Proceedings

SA courts would not ordinarily stay infringement proceedings (without an agreement between the parties) to await the outcome of foreign parallel proceedings.

Since the Court of the Commissioner of Patents has nationwide jurisdiction, and since there are no substantive proceedings before the Patent Office, parallel proceedings in different tribunals

are not usually encountered. However, a stay could be ordered if there is an issue before the Court of the Commissioner of Patents or a higher court, that would be determinative of the issues and would render the proceedings moot until that issue is decided.

1.17 Patent Amendment

South Africa is a non-examining jurisdiction. The Registrar of Patents does not conduct substantive examination. Therefore, there is an onus on an applicant or patentee to make validating amendments to the claims on becoming aware of relevant prior art.

It is permissible to apply to court for amendment during infringement proceedings. The court will likely stay the infringement proceedings pending a determination of the amendment application. The amendment will be advertised for a two-month opposition period. Filing multiple auxiliary requests would be very unusual. A patentee would need to elect which amendment it wishes to make.

1.18 Court Arbiter

The court of first instance in patent matters is the Court of the Commissioner of Patents. Although the court is named as a specialist court, it is, in practice, convened by a High Court judge (without a jury) who may not have patent experience.

Since the Court of the Commissioner of Patents has nationwide jurisdiction, there is no forum shopping.

2. Generic Market Entry

2.1 Infringing Acts

The patentee must show a reasonable apprehension of infringement. South Africa has a bolar-type provision. Therefore, any acts associated with obtaining an MA or the possession of an MA are not considered acts of infringement. To show a reasonable apprehension of infringement, post MA registration reliance is often placed on number of surrounding circumstances, including pre-launch activities, a pricing approval request and/or obtaining a reimbursement code for medical insurance. The private market sector is often the most relevant market where tender supply does not apply. However, a submission of a tender would be relevant to the public sector and would amount to "offering to dispose of" which is an act of infringement. Tender submissions would typically not be accessible but could be obtained by way of SA access to information legislation (subject to a trade secret defence) or could be obtained by way of discovery in trial proceedings.

There has been no skinny labelling litigation in South Africa. However, it is well settled law that contributory infringement is actionable (for example, by way of inducement).

An originator product that has been put on the market by the patentee or with the consent of the patentee in another jurisdiction (free of restrictions) is subject to the exhaustion of rights defence in South Africa. Therefore, if a licensee supplies a product in another country under a territorially limited agreement, the importation of that product into South Africa may result in an infringement. Importation is a specified act of infringement in South Africa. The Minister of Health is empowered by Section 15C of the Medicines and Related Substances Control Act to prescribe the conditions on which any patented medicine may be parallel imported into South Africa regardless of the provisions of the Patents Act. This is seldom invoked.

2.2 Regulatory Data and Market Exclusivity

There is no data package exclusivity of any kind available in South Africa.

2.3 Acceptable Pre-Launch Preparations

In terms of the South African Bolar provision, it shall not be an act of infringement to make, use, exercise, offer to dispose of, or dispose of, or import a patented invention on a non-commercial scale and solely for the purposes reasonably related to obtaining, development and submission required under any law that regulates the manufacture, production distribution, use or sale of any product. However, stockpiling with a commercial intent is not permissible.

2.4 Publicly Available Drug and Patent Information

No Orange Book or patent linkage system is used in South Africa.

The fact of the registration, including the holder and basic product details, becomes available on grant of the MA. However, no notification is provided.

Underlying documents are not freely available and must be obtained through access to information legislation (which is subject to certain defences including trade secrets defences) or through the discovery proceedings in trial proceedings.

2.5 Reimbursement and Pricing/Linkage Markets

As noted in **2.4 Publicly Available Drug and Patent Information**, no Orange Book or patent linkage system is used in South Africa.

There has been no skinny labelling litigation in South Africa. However, it is well settled law that contributory infringement is actionable (for example, by way of inducement).

Tender supply is limited to the public sector. The most relevant sector in patent disputes is usually the private sector. Best practice in the private sector is to put in an indication code on the script, but that rarely takes place. In practice, the pharmacy will look to fill the script for the drug (even under a general reimbursement code). So, the drug gets prescribed for off-label use and there is no practical prevention measure based on an indication specific code at prescription level. Generic substitution takes place at pharmacy level unless the clinician indicates no generic substitution. If the drug is being prescribed for an approved chronic condition, the clinician will need to submit the prescribed chronic application to the scheme where the indication and justification is set out. However, if chronic approval is denied (because it does not fit within the chronic diseases) then the drug can still be dispensed against the patient's savings portion on the scheme (depending on the level the patient is on).

There is generally no notification made of any listing or reimbursement application, although the MA holder becomes aware when the reimbursement price is lowered to the generic price.

Generally, administration suits to force delisting or listing of products are not filed.

3. Biosimilar Market Entry

3.1 Infringing Acts

There are no differences for infringing acts in biosimilar market entry when compared with the same in **2.1 Infringing Acts**.

3.2 Data and Regulatory Exclusivity

See **2.2 Regulatory Data and Market Exclusivity**.

3.3 Acceptable Pre-Launch Preparations

There are no differences for acceptable pre-launch preparations in biosimilar market entry when compared with the same in **2.3 Acceptable Pre-Launch Preparations**.

3.4 Publicly Available Drug and Patent Information

There are no differences for publicly available drug and patent information in biosimilar market entry when compared with the same in **2.4 Publicly Available Drug and Patent Information**.

3.5 Reimbursement and Pricing/Linkage Markets

There are no differences for reimbursement and pricing/linkage markets in biosimilar market entry when compared with the same in **2.5 Reimbursement and Pricing/Linkage Markets**.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

No patent term extensions including Supplementary Protection Certificates (SPCs) are available.

4.2 Paediatric Extensions

No paediatric patent term extensions including SPCs are available.

4.3 Paediatric-Use Marketing Authorisations

No patent term extensions including SPCs are available for paediatric-use marketing authorisations.

4.4 Orphan Medicines Extensions

No patent term extensions including SPCs are available for orphan medicines.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

There is no requirement for a patentee or licensee to give an undertaking to pay damages in exchange for a preliminary injunction. However, if a patentee volunteers an undertaking that it will pay damages caused by the wrongful grant of preliminary injunction, it strengthens their position in showing that the balance of convenience favours the grant of the preliminary injunction. Typically, such undertakings are in force for so long as trial proceedings, or any appeals, remain pending. Thereafter, the undertaking will either lapse or become enforceable, depending on the outcome. The undertaking is made in such a way as to be personal to the opposing parties to the preliminary injunction application. Third parties not party to the preliminary injunction application would not be beneficiaries of the undertaking.

Preliminary injunctions are enforceable from when the Court of the Commissioner of Patents grants the injunction. A party against whom a preliminary injunction has been granted will be in contempt of court if it continues its conduct after the order has been handed down. Proceedings for contempt of court may be brought against that party.

There is no requirement for a patentee to pay a bond before the preliminary injunction is enforceable. Proceedings for a final order of infringement should be brought simultaneously or shortly after the institution of an application for a preliminary injunction.

The grant of a preliminary injunction is usually not appealable unless the decision has final effect. In that case, if leave to appeal is granted, the order may be suspended pending a determination of the appeal. It would be possible to approach court to have the order kept in place pending the outcome of the appeal. An order which is final in effect in a preliminary injunction application is very unusual in patent cases. Therefore, it is common for the preliminary injunction to remain in place pending the appeal process being completed. A bond will not lift a preliminary injunction.

5.2 Final Injunctive Relief

Final injunctions are enforceable from when the Court of the Commissioner of Patents hands down judgment in final proceedings for infringement. Judgments are typically handed down electronically by email or on the electronic case management platform. There is no formal service process, and no bond is payable to have the order enforced. The filing of an application for leave to appeal against the judgment and order automatically suspends the judgment and order pending a determination of the application for leave to appeal. Should leave to appeal be granted, the judgment and order are stayed pending a determination of the appeal. As noted, an existing preliminary injunction will remain in place during this period. If no preliminary injunction is in place, it is in principle possible to have the final order remain in place pending the appeal, for example, if irreparable harm is in issue. However, such applications are not often granted.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

One of the issues that contributes to a consideration of the balance of convenience in preliminary injunction applications is the public interest. The principle of public interest has not been applied to the grant of a final injunction to date. The provisions of the Patents Act provide that a patentee shall be entitled to an injunction. It is not clear to what extent a court will refuse a final interdict if a valid patent is infringed on the ground of public interest and, in lieu of an injunction, award an amount of damages.

The Patents Act makes provision for the grant of a compulsory licence in limited circumstances. Furthermore, the Minister of Health is empowered by Section 15C of the Medicines and Related Substances Control Act to prescribe the conditions on which any patented medicine may be parallel imported into South Africa regardless of the provisions of the Patents Act. This is interpreted to be limited to the patent owners' "branded" product.

The Patents Act further provides that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee. This is rarely invoked.

5.4 Damages

The purpose of a damages order in South Africa is to, as far as possible, restore the plaintiff to a position that it would have been in but for the infringement. The patentee is required to show that, had it not been for the infringing sales, on a balance of probabilities, it would have made those sales. Only lost profits may be claimed as

damages. There are no punitive damages for wilful infringement nor is the concept of account of profits applied. The question of transfer pricing would become relevant to the damages calculation if used between affiliate and parent company.

Infringement and damages are separated in South Africa. If a court finds that a patent has been infringed, it may order an enquiry into damages suffered by the plaintiff. A plaintiff may then institute an action for damages. Damages are rarely litigated in South Africa and experience has shown that parties usually settle on the quantum.

A patentee or licensee may, at its election, claim a reasonable royalty in lieu of damages. If the patentee has entered into exclusive or non-exclusive licence agreements, the commercial terms of those agreements may be relevant in assisting a court in determining what damages or royalty would be payable.

It is well settled law in South Africa that, in circumstances in which damages are difficult to calculate, a court is required to take a robust approach based on the relevant market and the loss suffered by the patentee to arrive at an appropriate or reasonable estimate.

Damages accrue from when the infringement first took place. However, the prescription period for damages in South Africa is three years, subject to being interrupted by proceedings for infringement. Thus, a party can claim damages for acts of infringement that took place up to three years before proceedings for infringement were instituted. Interim awards are not made in South Africa. Interest is payable from when the damages amount is determined. The Prescribed Rate of Interest Act applies, and the interest rate prescribed is amended from time to time.

There are no reported cases in South Africa where a respondent in a preliminary injunction application has been awarded damages, either on the strength of an undertaking made by a patentee, or otherwise, in circumstances in which the preliminary injunction was wrongly granted. Neither are there any reported cases in South Africa where a third party has claimed damages for the wrongful grant of a preliminary injunction. However, parties have settled damages claims in circumstances in which the preliminary injunction was found to have been wrongfully granted.

5.5 Legal Costs

A successful party in patent litigation proceedings in South Africa is usually entitled to recover from the unsuccessful party what is termed the "taxed party and party costs" through an award of costs made by the court. Legal costs are recoverable only after proceedings have been instituted but may include costs for pre-litigation work. There are no court fees payable in South Africa. If the court is of the opinion that the party to whom costs have been awarded has been put to unnecessary expense, or if the opposing party and/or their legal representatives have not acted with bona fides, alternative costs scales with higher tariffs may be ordered.

Parties can expect bills of costs to be taxed within 3 to 6 months of being submitted to the Registrar. A party can typically expect to recover 30 to 40% of their legal costs.

In some cases, the court may choose to order only a portion of the costs in favour of the successful party. Factors that influence this decision can be whether the successful party succeeded on all grounds and the amount of court time spent on dealing with issues in respect of which it was unsuccessful.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

In preliminary injunction proceedings, conduct-related issues, such as delay in bringing the application or the main action, could impact on the grant of an injunction. The issues of delay are less relevant to the outcome of the merits of a trial action, but the court could take into consideration the conduct of the parties in making a costs order. It would be very unusual in patent matters for a plaintiff to be penalised in a costs order for starting an action without engaging in pre-action correspondence or a delay in bringing the matter. A licensee not recorded in the register does not have standing to join proceedings for infringement.

6. Other IP Rights

6.1 Trade Marks

Brand name applications for medicines form part of the application for marketing approval made to the South African Health Regulatory Authority. There have been occasions where a generic medicine alleged to infringe a patent was also alleged to infringe the patentee's registered trade mark, resulting in parallel patent and trade mark infringement proceedings. More generally, trade mark disputes certainly do take place in the life sciences and pharma sector in South Africa and patentees have successfully enforced trade mark rights.

6.2 Copyright

Copyright issues are uncommon in the life sciences and pharma sector in South Africa. There may be a claim by a patentee against a generic medicine holder relating to the copyright in the package insert and/or the trade dress. However, such actions are usually of limited value.

6.3 Trade Secrets

Trade secret disputes rarely arise in the life sciences and pharma sector that relate to the sale of the allegedly infringing product. However, trade secret issues may arise in access to information or discovery disputes.

7. Appeal

7.1 Timeframe to Appeal Decision

A party against whom the Court of the Commissioner of Patents has made an order, may apply to the Court of the Commissioner of Patents for leave to appeal within 15 days from when the order is handed down. Usually, the same judge that heard the main matter hears the application for leave to appeal.

In patent matters, parties typically ask for the appeal, if granted, to be to the Supreme Court of Appeal, instead of the full bench of the High Court. If leave to appeal is granted, the appellant has one month to file their notice of appeal. If leave to appeal is refused, the party seeking leave to appeal may make a further application for leave to appeal directly to the Supreme Court of Appeal.

Leave to appeal may only be given where the judge or judges concerned are of the opinion that the appeal would have a reasonable prospect of success, or there is some other compelling reason why the appeal should be heard, including conflicting judgments on the matter under consideration.

As noted, a preliminary injunction is not appealable unless the order is final in effect.

If an injunction decision is overturned on appeal or the patent is revoked, the preliminary injunction would most likely be extinguished.

7.2 Appeal Court(s) Arbiter

Patent appeals are most frequently heard in the Supreme Court of Appeal, the highest court on non-constitutional matters. The quorum is five non-specialist judges.

7.3 Special Provisions

There are certain specific procedures prescribed in the Patents Act. For example, patent revocation proceedings are brought on a specific form, with prescribed timelines for the exchange of pleadings and declaration evidence. Specific procedures also apply to oppositions to applications for post-grant amendments of patents and to oppositions to applications to restore lapsed patents. Where specific provision is not made for procedure in the Patents Act or Regulations, the Superior Courts Act and Uniform Rules of Court govern proceedings in the Court of the Commissioner of Patents. Therefore, proceedings for infringement follow the ordinary high court procedural rules.

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

Procedures are available for custom searching and seizing of counterfeit goods and suspected trade mark infringement. However, there are no customs-related procedures especially applicable to patent infringement.

9. Alternative Dispute Resolution

9.1 ADR Options

Arbitration proceedings may be used but they are not relied on in South Africa.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The pharma/biopharma industry has come under recent scrutiny by the Competition Commission where issues such as anti-competitive pricing, abuse of dominance and denying access to an essential facility, and the like, have been considered. The disputes are often settled with the Commission (on pricing-related issues) before a referral to the Competition Tribunal takes place. Settlement agreements are usually made confidential between the parties.

11. Collective Redress

11.1 Group Claims

South Africa has a well-developed class actions regime that is framed by common law principles and recent case law. Class action litigation in principle can be brought in relation to allegedly defective medicines or medical devices. The common law of negligence would usually apply. In addition, the Consumer Protection Act (2008) makes provision for potential liability of any supplier involved in product supply chain and, in specific instances, provides for strict liability (Section 61). Both class actions and strict liability statutory claims are fast developing areas of the law and whilst claims in the life sciences/pharma sector are possible, they are not yet common.

SWITZERLAND

Law and Practice

Contributed by:
Tobias Meili, Damian Schai, André S Berne and Isabel Wahl-Zeller
Wenger Plattner

Contents

Wenger Plattner has been advising and representing clients in all areas of business law for over 40 years, with more than 100 employees in its offices in Basel, Zurich and Bern. The firm's lawyers identify practical, workable solutions and help clients implement these to achieve the best possible commercial outcomes. Many of Wenger Plattner's experts are involved in decision-making as members of public authorities and other bodies, giving them an in-depth understanding of client needs. As a fully integrated partnership, the firm places a strong emphasis on teamwork and co-operation. Wenger Plattner's clients have access to dedicated, highly experienced specialists who offer top-level advice so that they may meet their specific objectives efficiently.

Authors

Tobias Meili is a partner at Wenger Plattner and advises clients, particularly in the life sciences sector, on commercial and corporate law, with a focus on corporate governance, restructuring, M&A, and contract and technology law. He also works on internal investigations as an examiner or investigator appointed by FINMA or companies themselves. Due to his many years of experience in a leading position in the legal department of a formerly SMI-listed multinational corporation and an international consulting and technology company, Tobias is very familiar with the structures, processes, and challenges of large corporations. He combines an authentic, pragmatic, and solution-oriented advisory approach, building upon his solid legal expertise and negotiation skills.

Damian Schai is a partner at Wenger Plattner and is specialised in IP law, with a focus on the protection, defence, and enforcement of trademarks worldwide. He has extensive experience in other IP and related disciplines, such as copyright, personal, name and company law, unfair competition law, IT law, and data protection. Damian's work supports Life Sciences and Health Law practice in several areas, particularly licence and R&D agreements. He also draws on a wealth of experience in (IP) litigation gained as a court clerk and in court proceedings as a lawyer, all of which has contributed to his holistic advisory approach.

André S Berne is a senior associate at Wenger Plattner and primarily handles commercial and regulatory issues. His main areas of focus include life sciences law, health law, competition law, and general contract law. He also advises companies and organisations on Swiss commercial and corporate law, administrative law, and EU law, and represents them before courts and authorities in German and French. In addition to his advisory and litigation activities, André prepares expert opinions in his areas of specialisation. He regularly publishes on and lectures in these fields.

Isabel Wahl-Zeller is an associate at Wenger Plattner primarily working in the areas of contract law, construction and real estate law, and intellectual property law. She also contributes to the work of the employment law team. Isabel advises clients from both domestic and international backgrounds on contentious and non-contentious matters, and represents them in proceedings before state courts of all instances and authorities.

Wenger Plattner

Attorneys at Law, Tax Advisors Public and Notaries
Aeschenvorstadt 55
P.O. Box 462
4010 Basel
Switzerland

Tel: +41 61 279 70 00
Fax: +41 61 279 70 01
Email: basel@wenger-plattner.ch
Web: www.wenger-plattner.ch

WengerPlattner

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

Patent infringements typically grant the patent owner the right to initiate legal proceedings. Where a patent has multiple owners, unless an additional agreement has been reached among the co-owners, they are obliged to exercise their rights collectively. This affects, for instance, the issuance of licences, as the consent of each co-owner is required. Regarding patent infringements, however, the Swiss Federal Patent Act (PA) enables each owner to initiate legal proceedings autonomously (Article 33 et seq PA).

If the licensor grants an exclusive licence to the licensee, solely the licensee is entitled to exploit the patent within the designated territory for the duration of the agreement. Consequently, patent infringement actions can only be filed by the licensee, unless expressly excluded in the licence agreement (Article 75 PA). Litigation does not necessarily require the patent owner's participation and a licence registration in the patent registry is not required for this purpose. Although non-exclusive licensees have no standing to sue on their own, in accordance with the PA, licensees may participate in litigation initiated by patent right holders to receive compensation for their own damages. This rule is of a dispositive nature, meaning that the parties may contractually agree otherwise. The above legislation was introduced in 2008. Hence, the right of licensees to sue infringers requires particular attention in older licence agreements.

The objective of a nullity action is the judicial declaration that the patent has never existed. It is accessible to any person and/or entity which demonstrates an interest in a nullity action (Article 28 PA). There are no specific requirements regarding proof of interest. In most cases, it is sufficient if the parties compete for the same goods, and such goods fall within the patent's scope of protection.

1.2 Defendants/Other Parties to an Action

Numerous activities, including the import, temporary storage, transit, and resale of goods abroad, may constitute infringements. In the pharmaceutical sector, suppliers, manufacturers and regional distributors are typical defendants. Specific actions performed by medical doctors, pharmacists or similar professionals in connection with medicinal products are deemed outside the patent's scope (Article 9 PA). Health authorities and similar entities are not required to participate in infringement or nullity proceedings.

1.3 Preliminary Injunction Proceedings

Preliminary injunctions (both ex parte and inter partes) are of decisive importance because infringing products may have been commercially available for a significant period prior to a final judgment in the main proceedings. Furthermore, during this period, the patented technology may have become outdated, or the patent itself may have expired. Proceedings in Switzerland are, in principle, adversarial – that is, the opposing party is given an opportunity to present its case prior to the handing down of a preliminary injunction. To streamline the preliminary injunction proceedings, a mere exchange of writs is conducted followed by an oral hearing. Ex parte injunctions may be granted in circumstances of extraordinary urgency.

Requirements for a Preliminary Injunction

The following requirements must be credibly demonstrated for a preliminary injunction.

- The plaintiff must demonstrate either ownership or the status of exclusive licensee of a patent that is officially recognised in Switzerland (see **1.1 Claimants/Plaintiffs to an Action**), as well as that the defendant is interfering, or threatening to interfere, with the scope of protection of this patent.
- The infringement threatens to cause the plaintiff to suffer irreparable harm, including due to market confusion, destruction of the patent owner's licensing agreement system, or difficulty in re-establishing a connection with customers who have migrated to another product.
- The plaintiff must have a sense of urgency in initiating proceedings. Absence of urgency is evident when the initiation of main proceedings could have been achieved earlier. Preliminary injunction proceedings before the Federal Patent Court usually take approximately ten months and main proceedings 24 months. The plaintiff forfeits the right to a preliminary injunction when the delay in filing for such an injunction exceeds 14 months from the date of learning of the infringement. Ex parte injunctions require an even higher degree of urgency. Generally, decisions regarding ex parte injunctions are rendered quickly. When necessity dictates, the Federal Patent Court has the authority to render a decision regarding an application on the day it is served.
- Additionally, the extent of the likely damage must be reflected in the measure.

A fact is considered credibly demonstrated when the judge finds the presentation to be "predominantly true", notwithstanding the absence of complete elimination of doubt. Document-based evidence is required. Other types of evidence are deemed admissible only if they can be presented without delay or if they are required for the purpose of the proceedings.

Amendments to Preliminary Injunctions

Preliminary injunction proceedings are independent proceedings that may be initiated either prior or subsequent to the initiation of the main proceedings. They only offer interim legal protection and are of a provisional nature. Therefore, they are subject to amendment if there is a change in the circumstances on which the preliminary injunction is based. If preliminary injunctions have been applied for prior to the commencement of the main proceedings, the interim judgment must be confirmed in the main proceedings. The court that handed down the preliminary injunction must set a deadline for filing such confirmation. If this deadline is missed, the injunction will lapse.

By demonstrating an exceptionally high level of urgency, the court may grant an ex parte injunction without hearing the counterparty in the first step. Concurrent with granting an ex parte injunction, the court either invites the counterparty to a hearing or sets a deadline for the submission of a written statement. After the hearing, or having read the counterparty's statement, the court decides (again) on the preliminary injunctions.

Typically, the defendant becomes aware of the preliminary injunction through either the court order requiring the submission of a statement or the invitation to the hearing. Court orders and summons are delivered by registered mail. If delivery is not possible, the defendant is obliged to retrieve the court documents from the post office. Seven days after an unsuccessful delivery attempt, service is considered to have been effected even if the documents remain uncollected.

Any presumable defendant may file a caveat to the Federal Patent Court if such defendant expects a counterparty to request an ex parte injunction. The caveat will only be notified to the counterparty if it initiates an ex parte proceeding. It expires six months after submission, although an additional six-month renewal is possible.

1.4 Structure of Main Proceedings on Infringement/Validity

It is not mandatory to initiate nullity and infringement proceedings concurrently in the form of a main action and counterclaim. Even if the actions are brought at long intervals, a suspension of one of the proceedings is unusual. Validity is often challenged as a means of defence in infringement proceedings. An initial action brought by the infringer for nullity is rare.

The defence of nullity is examined on a preliminary basis and is inextricably linked to the main proceedings – if the claim in the main proceedings is withdrawn, the defence automatically falls away. Upon confirmation, the defence of nullity enters into force among the disputing parties regarding the ongoing lawsuit. The judgment merely declares the preliminary nullity and does not factor into the judgment dispositive. The patent entry in the register remains intact. Additionally, nullity may be claimed by a counterclaim. Such judgment, if successful, has an erga omnes effect. Consequently, the patent will be revoked.

It should be noted that Swiss patent law provides for a suspension of proceedings under certain conditions for European patents (Article 128 PA; see **1.16 Stays and Relevance of Parallel Proceedings**).

1.5 Timing for Main Proceedings on Infringement/Validity

An Action for Nullity

In principle, an action for nullity can be initiated at any time. In Swiss civil proceedings, the principle applies that two unrestricted statements may be made on the matter. This necessitates that the defendant raises the nullity defence no later than in the second exchange of writs. An instruction hearing is often scheduled prior to the main hearing. Should this occur prior to the second exchange of writs, then the nullity defence should have been raised during the instruction hearing.

Infringement Claims

In the case of infringement claims, it should be noted that claims for damages or for the disgorgement of profits may be subject to defence of the statute of limitations. A relative three-year statute of limitations applies to unauthorised acts, commencing on the date of identification of the infringer and knowledge of the damaging act or actual damage. An absolute statute of limitations of ten years applies, commencing from the damaging event.

Injunctive Relief, Removal and Declaratory Judgment

Claims for injunctive relief, removal and declaratory judgment are not subject to a limitation period.

Timeline of Lawsuits and Hearings

The Federal Patent Court generally sets a deadline of six weeks for a written response to the lawsuit (see **1.3 Preliminary Injunction Proceedings**). Upon reasoned request before expiry of the deadline, an extension of two weeks may be granted. Additional extensions are typically permissible solely with the opposing party's consent.

An instruction hearing usually takes place before subsequent exchanges of writs. In around 50% of the cases, a settlement is reached at (or before) the instruction hearing. If no such settlement can be achieved, an additional exchange of writs occurs. Typically, a four-week timeframe is allocated for the reply and the rejoinder. In this situation, a two-week extension is permissible, provided a valid request is made prior to the deadline's expiration.

Panel of Specialists

The Federal Patent Court relies on a panel of specialists as judges. The parties are given the opportunity to provide written comments on the expert judges' opinions once they become available during the main proceedings.

1.6 Requirements to Bring Infringement Action

The plaintiff may file a complaint once the patent has been validly granted and the plaintiff has established the validity of the claims. The patent owner has the burden of proof regarding the alleged infringement. In the absence of such proof, the action for infringement is dismissed.

An exception applies regarding specific process patents. Until proved otherwise, any product that is identical in nature is presumed to have been produced using the patented process, provided that the invention pertains to a process for the manufacturing of a new product (Article 67 PA). This is especially pertinent in the context of pharmaceutical or chemical process patents.

1.7 Pre-Action Discovery/Disclosure

Even prior to the commencement of the main proceedings, the Swiss Civil Procedure Code permits the court to admit evidence on a precautionary basis, provided a credible interest of protection can be demonstrated, which is typically the case if evidence is in jeopardy of being destroyed, lost or altered. In such proceedings, the court also evaluates the likelihood of success in a legal proceeding.

The expenses associated with the precautionary collection of evidence, which may include compensation for the opposing party, are typically borne by the requesting party. If the requesting party subsequently initiates main proceedings and succeeds, the court may order that the expenses associated with the precautionary collection of evidence have to be borne by the losing counterparty.

There is no discovery/disclosure available that is comparable, for example, with such remedies under US law.

1.8 Search and Seizure Orders

The information in **1.7 Pre-action Discovery/Disclosure** also applies in general during the proceedings.

Patent law does not require a party to hand over evidence in its possession. Nevertheless, a party can request the disclosure of evidence held by the other party. If the opposing party is unwilling or unable to disclose such evidence, it will only have an impact on the evaluation of the evidence by the court. Search orders are not available under Swiss Civil Procedure law. Preliminary injunctions, however, can lead to the seizure of infringing goods, for example, provided that the respective prerequisites are met. The destruction of seized infringing goods, however, can only be awarded in the main proceedings.

1.9 Declaratory Relief

In Switzerland, actions for a declaratory judgment are typically subordinate to actions for performance. The prerequisite for an immedi-

ate declaratory judgment is that the plaintiff can establish a substantial legal interest, such as that the legal relationship between the parties is ambiguous but can be resolved by means of a judgment. Such ambiguity must, however, be so severe that the plaintiff cannot reasonably be expected to endure its continuation.

For instance, the required interest of a plaintiff for a declaratory (negative) judgment regarding an alleged patent infringement was upheld by the Federal Supreme Court (FSC) in a case where the defendant had issued a cease-and-desist letter to prevent the plaintiff from conducting business with an allegedly infringing product (FSC 129 III 295, E 2.4).

It is worth mentioning that in the context of international relations, a party's desire to secure a favourable place of jurisdiction for an upcoming court case may qualify as a sufficient interest in a declaratory judgment (FSC 144 III 175).

1.10 Doctrine of Equivalents

The doctrine of equivalents is used in Switzerland. According to Swiss court practice, the following three questions must be answered in the affirmative to demonstrate an equivalent infringement:

- is the functional feature of the allegedly infringing product – from an objective point of view – the same as that of the original product (same effect)?
- is the replaced feature and its equal objective function obvious to a hypothetical specialist (accessibility)?
- is the patent specification drafted in such a way that a hypothetical specialist would consider the replaced feature to be a solution of equal value (equal value)?

1.11 Clearing the Way

In Switzerland, there is no legal obligation to "clear the way" prior to the introduction of a new product. There is no obligation to challenge another patent in court prior to marketing a pharmaceutical product.

1.12 Experts

Before the revision of the Swiss Code of Civil Procedure at the beginning of 2025, it was clear that court expert opinions were considered as evidence, whereas private expert opinions were merely considered as party statements. A party's expert opinion might have been useful when assessing the chances of winning a legal dispute, attempting to reach a settlement with the opposing party, or initiating a lawsuit that was well founded.

Since the beginning of 2025, it is stipulated that the party's expert opinion is considered a physical record. Physical records, then, are considered evidence. However, it remains to be seen whether this revision will actually have an impact on the probative value of the party's expert opinion.

Since the Federal Patent Court employs specialised judges (see **1.5 Timing for Main Proceedings on Infringement/Validity**), expert opinions are of lesser significance in patent proceedings. Instances where technical expert opinions are requested are exceedingly rare and occur only when the court is unable to decide the case with its own technically proficient judges. After a court has ordered an expert opinion, all parties involved must be given the opportunity to provide their comments on the expert opinion.

1.13 Use of Experiments

The Swiss Civil Procedure Code exhaustively lists the methods of establishing evidence (tes-

timony, physical records, inspection, expert opinion, written statements, questioning and statements of the parties). An experiment might be requested as part of an "inspection".

1.14 Discovery/Disclosure

In principle, no evidence is collected ex officio in Swiss civil proceedings. It is the responsibility of the parties to introduce facts and evidence into the proceedings in due course. There are two unrestricted statements on the matter for each party, in which the presentation of new facts and evidence is allowed. Hence, the parties must introduce all new facts and associated evidence in the second exchange of written submissions at the latest, or at the instruction hearing, if applicable. Thereafter, the presentation of amendments (new facts and evidence) is only possible in limited circumstances, for example, when new facts have arisen, or evidence has surfaced after the submission of the second writ.

However, if one party submits new facts or evidence in its second and final writ, the other party is entitled to provide a response to the newly introduced facts and evidence (unrestricted right of reply in the context of the right to be heard). The court-imposed deadline for this response usually ranges from five to ten days.

1.15 Defences and Exceptions to Patent Infringement

Typically, the assertion that a product or process does not infringe the patent is put forward as a defence. Certain acts are excluded by law from obtaining patent protection (Article 9 PA), such as actions performed in the personal sphere for non-commercial objectives, actions performed at educational institutions for educational purposes, actions performed as part of a medical activity concerning medicinal products and an individual, or the direct preparation of medicinal products in pharmacies to fulfil a prescription (see also **2. Generic Market Entry**).

Swiss patent law grants rights to compulsory licences under specific conditions (Article 36 et seq PA). In all cases involving compulsory licences, it is essential that the applicant has been unable to secure a contractual licence on reasonable market terms within a reasonable timeframe. A compulsory licence may be granted for the manufacture and export of certain patented products. This includes pharmaceuticals, active ingredients, diagnostic kits, and vaccines required in underdeveloped countries to combat health issues such as HIV/AIDS, tuberculosis, malaria, COVID-19, and other epidemics and pandemics. Many of the common defences are available under the PA: nullity of the plaintiff's patent, consent and licences granted to the "infringer", exhaustion, experimental use, "Formstein" defence, "Gillette" defence, etc. While the Swiss courts have not yet expressly ruled on either the "Formstein" or the "Gillette" defences, an analogous application appears possible. In general terms, Swiss case law has for years accepted the state-of-the-art defence. Swiss law has not expressly included the "Bolar" exemption, but it provides a similar research exemption (see **2.1 Infringing Acts**).

1.16 Stays and Relevance of Parallel Proceedings

The Federal Patent Court has exclusive jurisdiction in the first instance for infringement and validity issues. As already mentioned above, preliminary injunctions and ex parte injunctions can also be asserted before the lis pendens in the main proceedings (see **1.3 Preliminary Injunction Proceedings**).

Switzerland's non-membership of the EU precludes the application of the "Brussels Ia"

Regulation (Regulation (EU) 1215/2012), which governs the recognition and enforcement of judgments in civil and commercial affairs. This fact must be considered in an international context. However, Switzerland is a signatory to the Lugano Convention, which was established in accordance with the "Brussels Ia" Regulation. Swiss courts therefore generally adhere to the case law of the European Court of Justice (ECJ) or at least consider it diligently.

If the same parties bring actions before the courts in different member states of the Lugano Convention regarding the same claim, the Lugano Convention stipulates that the court seized in the second order shall stay its proceedings until the court seized in the first order has decided on its jurisdiction. Beyond the scope of application of the Lugano Convention, Swiss international procedural law states that the subsequently seized Swiss court shall stay its proceedings if a competent foreign court is expected to render a recognisable decision within a reasonable period of time.

Swiss patent law provides that the Federal Patent Court may stay its proceedings in certain circumstances, for example if the European Patent Office has not yet rendered a decision on the limitation of a European patent or if an opposition is pending at the European Patent Office (Article 128 PA). So far, such a stay has played a minor role in court practice. If the Federal Patent Court is aware of a pending opposition, it will make an ex officio request to speed up the proceedings before the European Patent Office.

1.17 Patent Amendment

An amendment to the action is admissible if the amended or new claim is factually related to the previous claim or if the opposing party agrees. During the main hearing, an amendment to the claim is only admissible if it is based upon newly discovered facts and evidence that did not previously exist.

An amendment to the claim is generally admissible if it targets the same object of infringement and is founded on the same, potentially restricted patent.

1.18 Court Arbiter

In Switzerland, patent disputes are decided in the first instance before the Federal Patent Court only. The FSC serves as the appellate court. Therefore, forum shopping only occurs in non-patent related IP litigation.

In ordinary proceedings, cases are dealt with by panels of three, five or seven judges. Each panel includes both jurists and technicians (see **1.5 Timing for Main Proceedings on Infringement/Validity**). Preliminary injunctions are dealt with by a single judge. When legal or factual considerations so require, a panel of three judges may render decisions. There are no juries in Switzerland.

2. Generic Market Entry

2.1 Infringing Acts

All actions aimed at obtaining marketing authorisation for a medicinal product (not only for a generic product), including but not limited to acts of scientific research, clinical trials, and the application for reimbursement or engagement in activities related to price fixing, are excluded from the validity of a patent (Article 9(1)(b)(c) PA). Swiss law does not contain any explicit provisions that implement or reference the "Bolar" exemption; however, Article 9(1)(b)(c) PA operates analogously. Thus, in cases involving generic entry, the aforementioned activities

do not generally enable a party to bring an action for infringement.

This exception to the patent's effect is restricted to circumstances where the quantity produced or imported does not exceed the quantity necessary for the marketing authorisation process. Purposeful stockpiling for future market supply is not encompassed within the scope of the privilege. Production is restricted to the quantity specified by the authorisation authority (ie, validation batches). Situations not encompassed by this exemption render actions for infringement conceivable. This also pertains to preliminary injunctions in cases where an imminent infringement has not yet commenced (see **1.3 Preliminary Injunction Proceedings**).

2.2 Regulatory Data and Market Exclusivity

For medicinal products, the Swiss Agency for Therapeutic Products ("Swissmedic") grants the following data exclusivity periods:

- ten years for a medicinal product that includes a novel active substance;
- three years for a modified dosage or route of administration;
- three years for a new indication; however, Swissmedic may grant a period of ten years if the new indication is anticipated to yield a substantial clinical advantage over established treatments;
- ten years for a fixed combination of medicinal products if at least one new active substance is prevalent;
- ten years for medicinal products intended exclusively and specifically for paediatric use, provided that pertinent clinical data substantiates the indication; and
- 15 years for essential medicinal products for orphan diseases.

Swissmedic's decisions regarding data exclusivity are susceptible to appeal to both the Federal Administrative Court and, ultimately, the FSC. Appeals to the Federal Administrative Court can take 12–18 months, although the duration may be extended in cases involving high complexities. In general, decisions regarding appeals to the FSC are rendered within six to 12 months.

2.3 Acceptable Pre-Launch Preparations

See **2.1 infringing Acts**.

2.4 Publicly Available Drug and Patent Information

In Switzerland, no "Orange Book" equivalent exists. Patent rights are neither verified nor considered by Swissmedic prior to the issuance of marketing authorisations. Swissmedic publishes all granted marketing authorisations in its monthly Official Journal. To obtain access to the contents of the marketing authorisations, a Freedom of Information request must be submitted to Swissmedic. However, Swissmedic will refrain from disclosing any personal data, confidential information, or data protected by data exclusivity regulations. Swissmedic does not proactively notify product marketing authorisation holders of any generic or biosimilar marketing authorisations.

2.5 Reimbursement and Pricing/Linkage Markets

The Federal Office of Public Health (FOPH) is the competent authority by default in Switzerland regarding all public health matters concerning the pricing and reimbursement of medicinal products. Pricing and reimbursement, in addition to the issuance of marketing authorisations, are not contingent upon patent status. Thus, in their regulatory supervisory activities, neither Swissmedic nor the FOPH consider patent status. In general, pricing approvals and issuances

of marketing authorisations are determined irrespective of the existence of patents. Nevertheless, the patent status could potentially be considered by the FOPH in the determination of the reimbursement amount.

3. Biosimilar Market Entry

3.1 Infringing Acts

In contrast to other countries, the utilisation of biosimilars in Switzerland has thus far been limited. However, since costly biological active ingredients contribute significantly to increasing expenses in Swiss healthcare, the potential savings from increased use of more cost-effective biosimilars are evident. Generally, the provisions outlined in **2.1 Infringing Acts** with respect to generics, possess a broad applicability to biologics and biosimilars as well.

3.2 Data and Regulatory Exclusivity

Biosimilars may only be authorised with reference to a fully documented biological medicinal product. Consequently, biosimilars cannot be granted marketing authorisation as reference products. First-time-approved biosimilars are not classified as new active substances; thus, they do not receive data exclusivity, apart from in special cases, as outlined in **2.2 Regulatory Data and Market Exclusivity**.

3.3 Acceptable Pre-Launch Preparations

The provisions outlined in **2.3 Acceptable Pre-launch Preparations** with respect to generics are also broadly applicable to biologics and biosimilars.

3.4 Publicly Available Drug and Patent Information

The provisions commented on in **2.4 Publicly Available Drug and Patent Information** with respect to generics are also broadly applicable to biologics and biosimilars.

3.5 Reimbursement and Pricing/Linkage Markets

The provisions outlined in **2.5 Reimbursement and Pricing/Linkage Markets** with respect to generics are also broadly applicable to biologics and biosimilars.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Supplementary protection certificates (SPC) may be granted for active ingredients or for the combination of active ingredients in medicinal products (Article 140a(1) PA). However, this requires that the product (ie, its active ingredients or combination of active ingredients) is protected "as such" and that a medicinal product containing the product is authorised in Switzerland at the time of application (Article 140b(1) PA). The SPC is granted to the owner of the patent (Article 140c(1) PA) and is valid for up to five years (Article 140e(2) PA). Under specific conditions, an SPC may be extended once for an additional six months (Article 140n PA). In general, only one SPC will be granted for each product (Article 140c(2) PA). If several patent owners submit an application for the same product on the basis of different patents and no SPC has yet been granted, each applicant may be granted an SPC (Article 140c(3) PA).

The Swiss Patent Act broadly aligns with the EU Regulation on SPCs for medicinal products (Regulation (EC) No 469/2009). Thus, the FSC generally follows the ECJ case law. However, there are exceptional circumstances where the

Swiss legislator may have intended to establish a different set of rules, which would be the only exception to this rule. As an illustration, the FSC ruled unequivocally, based on the ECJ case C-322/10 "Medeva", that if the basic patent designates only one of two active substances, a product cannot be granted an SPC after marketing authorisation if it is composed of two active substances (FSC 144 III 285).

It is worth mentioning that an application for an SPC must be submitted within six months of the initial authorisation of a medicinal product containing the product in Switzerland, or within six months of the patent grant if the patent was granted subsequent to the marketing authorisation to obtain an SPC (Article 140f(1) PA). Failure to meet the deadline will result in the rejection of the application (Article 140f(2) PA). The aim of this process is to establish legal certainty by informing the public and competitors in advance that a medicinal product will not be released at the end of the patent term, but at a later date. In addition (and unlike in the EU), Switzerland has yet to implement a manufacturing waiver for SPCs.

4.2 Paediatric Extensions

Swiss patent law provides for both independent paediatric SPCs (Article 140t et seq PA) and paediatric extensions of SPCs (Article 140n(1) PA). Both can be granted for a period of six months. A paediatric SPC may only be issued in the absence of an "ordinary" SPC (Article 140t(2) PA). Consequently, ordinary SPCs and paediatric SPCs are mutually exclusive.

4.3 Paediatric-Use Marketing Authorisations

The issuance of marketing authorisations, which is regulated by the Therapeutic Products Act (TPA), is not contingent upon the patent status of a medicinal product or the existence of a patent at all, as outlined in **2.5 Reimbursement and Pricing/Linkage Markets**. However, some links exist – eg, a marketing authorisation holder that no longer intends to market a medicinal product authorised for a paediatric indication or use for which a SPC was granted must publicly announce this intention in an appropriate manner (Article 16a(4) TPA).

Furthermore, a paediatric investigation plan must be formulated for each medicinal product to obtain a marketing authorisation outlining the developmental requirements for paediatric use (Article 54a(1) TPA). The procedure is streamlined up to a certain level due to the possible consideration of a paediatric investigation plan evaluated by a foreign authority (Article 54a(3) TPA) and the alignment of Swiss paediatric investigation plan requirements with regulations of the European Union (Article 54a(2) TPA).

4.4 Orphan Medicines Extensions

Swiss law lacks specific provisions for SPCs applicable to orphan medicines. Consequently, the general provisions, as outlined in **4.1 Supplementary Protection Certificates**, also apply to these medicinal products.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

Should the court-imposed preliminary injunction be deemed unjustified, the plaintiff may be held liable for the payment of damages. The defendant must prove the damage, which may be a challenging task, particularly in cases where the defendant was not selling the product at the time the preliminary injunction was issued. It is difficult, and thus rare, in Switzerland to claim dam-

ages based on unjustified preliminary injunctions. In addition, if the requesting party can prove that it made its request in good faith, the court can reduce or completely release it from its obligation to pay compensation.

The opposing party may request that preliminary injunctions may only be imposed upon the provision of a surety by the plaintiff in order to cover potential damages arising from such a measure. To obtain a surety during the preliminary injunction proceedings, the opposing party must file an application with the court. In ex parte proceedings, the court has the authority to order on the provision of surety ex officio.

Preliminary injunctions in patent law focus on injunctive or removal claims. This prohibits the defendant from committing imminent or actual patent infringing acts for the duration of the main proceedings. At the plaintiff's request, the injunction may be combined with a penalty or threat of a fine if the injunction is disregarded. In exceptional circumstances, the judge may also seize existing infringing products, or the equipment, devices and other components used in their production.

If a preliminary injunction is ordered, the court will require the plaintiff to file an action. Generally, the deadline for bringing such an action is one month. This deadline is extendable upon reasoned request to the court. Damages may be assessed against the plaintiff if the claim is not brought forth in a timely manner (see **1.3 Preliminary Injunction Proceedings**).

Preliminary injunctions are generally enforceable upon receipt by the defendant, unless otherwise stated in the judgment. Service of legal documents is effectuated by the court itself via Swiss post. The court is also responsible for carrying out all measures to fulfil its judgment (eg, seizing orders). In the latter case, the court can entrust national or cantonal police forces to carry out the necessary acts by issuing a corresponding order.

5.2 Final Injunctive Relief

As appeals to the FSC regarding infringement actions typically lack suspensive effect, decisions rendered thereunder are typically enforceable promptly upon issuance. The FSC may, however, issue a different ruling on the suspensive effect ex officio or at the request of a party. In principle, the Federal Patent Court is responsible for enforcing its own judgments using the means outlined in **5.1 Preliminary Injunctive Relief**.

As with preliminary injunctions, the plaintiff may request that the injunction be combined with the threat of a monetary penalty or other penalty should it be disregarded. The court may also seize infringing products, or the equipment, devices and similar materials utilised in their production.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

In patent litigation as well as in most other civil proceedings, the principle of party disposition applies. This stipulates that the court is bound by the requests of the parties and must not award anything in excess of, or different to what the parties have applied for.

Consequently, the court is precluded from awarding damages in lieu of issuing an injunction. When an injunction is requested by the plaintiff due to infringement of a valid patent, the court is obliged to grant the injunction. This remains valid notwithstanding the absence of a public interest injunction.

Compulsory licences may be issued under extraordinary circumstances (see **1.15 Defences and Exceptions to Patent Infringement).**

5.4 Damages

The injured party may seek either traditional damages or the disgorgement of the profits earned by the infringer.

Damage refers to an involuntary reduction of assets, which may consist of a reduction in assets, an increase in liabilities, or a loss of profit. The determining element is the disparity between the injured party's present financial status and the assumed financial status of the injured party in the absence of the detrimental incident. In practice, establishing damages may be difficult. The plaintiff could either prove that: a) income generated by the infringer should have accrued to the patent owner; or b) the plaintiff could have generated a higher profit if the infringement had not occurred. Injured parties are obliged to furnish the most accurate feasible evidence pertaining to particular instances of harm, such as the quantification of transactions omitted as a consequence of the patent infringement.

In Switzerland, the issuance of preliminary injunctions is limited to the prevention of imminent harm. On the contrary, they cannot be utilised to seek compensation for harm that has already occurred. Consequently, the award of damages is limited to the main proceedings. According to established case law, damages encompass interest equal to 5% per annum commencing from the moment the damaging event had a financial impact.

The exclusive licensee and patent owner are the only parties permitted to file a claim for infringement (see **1.1 Claimants/Plaintiffs to an Action**). Other licensees may, however, participate in an action (Article 75(2) PA). Therefore, it is essential for licensees to oblige the patent owner to take action against infringers in non-exclusive licence agreements.

5.5 Legal Costs

Ordinary Costs

The parties typically request that the ordinary and extraordinary costs of the proceedings be borne by the other party. Court expenses are commonly referred to as "ordinary costs". The court costs are proportional to the disputed amount. If the disputed amount does not exceed CHF50,000, a court fee of CHF12,000 may be assessed. If the disputed sum exceeds CHF5 million, the court may assess court costs of up to CHF150,000.

Extraordinary Costs

Attorney's fees and the necessary expenses of the parties are examples of "extraordinary costs". The attorney's fee is also proportional to the disputed amount. Accordingly, for disputes of up to CHF50,000, the attorney's fee is between CHF2,000 and CHF16,000. In cases where the disputed amount exceeds CHF5 million, attorney's fees range from CHF100,000 to CHF300,000. This does not preclude the attorney from reaching an agreement with their client based on hourly rates, which is the common practice. The difference may then be borne by the client.

The Loser Pays

In principle, the losing party is obliged to reimburse the opposing party for all court costs, attorney's fees and expenses, in addition to its own attorney's fees and expenses. Court costs are typically payable in advance by the plaintiff. Payment of the advance on costs by the plaintiff is a condition of the proceedings. If a party

succeeds only partially, the costs of the court and the attorney's fees will be split between the parties proportionately.

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

The court may deviate from the principles outlined in **5.5 Legal Costs** if, for instance, it considers the usual distribution as inequitable due to exceptional circumstances. This may be the case if the plaintiff has made no attempt to find an out-of-court solution with the defendant and the defendant is not resisting the action.

6. Other IP Rights

6.1 Trade Marks

The regulations governing pharmaceutical trademarks consist of the overarching provisions outlined in the Federal Trademarks Act (TmPA) and are supplemented by the guidance documents "Medicinal Product Names" by Swissmedic. Trade mark disputes occur quite frequently in the pharmaceutical sector in Switzerland.

Pharmaceutical product trademarks are required to obtain Swissmedic approval. In its evaluation, Swissmedic does not consider the status of the trademark. Swissmedic is solely responsible for ensuring that the nomenclature of a product does not evoke any confusion with another product, that the name does not convey any incorrect or misleading information concerning the product's indications, quality, risks, or safety, and that it does not encourage improper usage or abuse.

6.2 Copyright

Copyright law in Switzerland is primarily regulated by the Federal Copyright Act (CopA). Copyright concerns are rare within the pharmaceutical sector in Switzerland.

6.3 Trade Secrets

Switzerland does not have specific legislation on trade secrets. Notwithstanding, numerous laws contain provisions in this regard, such as the:

- Federal Act Against Unfair Competition;
- Federal Criminal Code;
- Federal Data Protection Act;
- Code of Obligations (specifically its sections pertaining to corporate law, employment law, and agency law);
- Civil Procedure Code;
- Code of Penal Procedure; and
- Federal Therapeutic Act (TPA) (eg, Article 67(9) TPA).

Furthermore, contract parties (eg, in R&D and product development contracts) may design elaborate contractual clauses, including effective enforcement mechanisms, to protect trade secrets. Thus, depending on the specific situation, trade secrets may be protected in accordance with the principles of contract law, tort law, or criminal law.

7. Appeal

7.1 Timeframe to Appeal Decision

Patent disputes are litigated in the first instance before the Federal Patent Court. Decisions of the Federal Patent Court can be appealed to the FSC. Additional legal conflicts pertaining to intellectual property rights are decided by the competent canton's high court. In such cases, the plaintiff is free to file a request for conciliation with a conciliation authority before filing an action with the canton's high court. Decisions

from the canton's high court can be appealed to the FSC.

The FSC is the highest court in Switzerland and its decisions cannot be appealed. In principle, appeals must be submitted to the FSC within 30 days of service of the reasoned decision of the lower court (Federal Patent Court or higher cantonal court). The appeal period is only ten days against judgments on the granting of a compulsory licence for the export of pharmaceutical products.

However, caution is required when it comes to preliminary injunctions ordered by the Federal Patent Court. In principle, only final decisions can be appealed to the FSC. Since preliminary injunctions must always be reviewed in the main proceedings, the Federal Patent Court's order on preliminary injunctions is not a final decision. Such decisions can only be subject to appeal if they are likely to cause irreparable harm. If the Federal Patent Court rejects an application for provisional measures, and the rejection is considered a final decision, an appeal to the FSC within 30 days is possible. Appeals against decisions on preliminary injunctions can only be challenged on the grounds of a violation of constitutional rights.

In principle, there is only one exchange of writs before the FSC. Typically, the judges decide by way of circulation of the file and there is no hearing. If there is no consent among the judges, or if a judge requests it, the judges will hold an oral debate. The review of a lower court's judgment by the FSC is limited to cases where the lower court has made blatantly erroneous factual findings, or national or international law has been improperly applied.

7.2 Appeal Court(s) Arbiter

Intellectual property law-related appeals are decided by the First Civil Division of the FSC. Divisions typically reach decisions with the participation of three judges. In response to a judge's request or on matters of fundamental importance, five judges render decisions. There are no specialist judges for intellectual property at the FSC.

7.3 Special Provisions

Intellectual property law does not stipulate any procedural requirements for the FSC. Thus, the procedural provisions of the Federal Act on the FSC are applicable.

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

If the customs administration has reason to believe that the import, export or transit of goods may infringe on a valid Swiss patent, it may inform the patent owner (Article 86a ff PA). Such goods may be detained for three working days so that the patent owner can apply for protective measures. In the case of such an application, customs can block the goods for a maximum of 20 working days. Within this period, the patent owner must obtain a decision (ex parte, preliminary or by means of criminal proceedings) to prevent the goods from being put onto the market. If this is not achieved within this period, the customs administration must release the goods.

9. Alternative Dispute Resolution

9.1 ADR Options

In principle, all civil disputes in the field of intellectual property law are arbitrable, even regard-

ing validity claims. The Swiss Federal Institute of Intellectual Property (IPI) accepts arbitration awards on the validity of Swiss intellectual property rights for enforcement, provided they are accompanied by a certificate of enforcement issued by the state court at the seat of the arbitration court.

Since patent disputes are often based on non-contractual grounds and often require rapid initial intervention before the state courts, arbitration agreements prior to the outbreak of a dispute are rare.

Although mediation is available for all sorts of civil cases, including intellectual property matters, it is not commonly used.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The Swiss healthcare market is characterised by competition, which is why it is generally recognised that competition law applies to this sector, including the pharmaceutical markets (FSC 141 III 66). In recent times, the focus of the Swiss competition authorities and courts has mainly been on the pricing of prescription-only medicinal products. Nevertheless, it should be noted that scrutiny may extend to other domains as well, particularly in the context of preventing parallel imports of patented products, in situations involving the blocking of patents, or in cases involving patent trolls.

11. Collective Redress

11.1 Group Claims

In general, group claims are not available in Switzerland. Only associations and other organisations of national or regional importance authorised by their statutes of association to protect the interests of a specific group may use a form of "group action". This group action is limited to personal rights, and includes negatory and non-monetary reparatory claims. Consequently, group claims are of limited relevance. Although the broader implementation of group claims has been a topic of prolonged political discourse in Switzerland for several years, there is currently no indication of an early introduction.

USA

Law and Practice

Contributed by:
Jim Hurst, Jeanna Wacker, Sam Kwon and Ashley Ross
Kirkland & Ellis

Contents

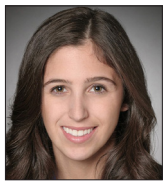
Kirkland & Ellis has a patent litigation practice comprising approximately 220 attorneys in London, Austin, Boston, Chicago, Houston, Los Angeles, New York, Palo Alto, Salt Lake City, San Francisco and Washington, DC. Nearly 75% of Kirkland's patent litigation attorneys are engineers and scientists, who are trained in a variety of technical disciplines. The firm's attorneys have extensive experience of pharmaceutical and biologics patent litigation, coordinating global IP disputes, post-grant proceedings before the US Patent and Trademark Office's Patent Trial and Appeal Board. In addition, Kirkland's lawyers have taken part in appeals of high-stakes cases before the US Court of Appeals for the Federal Circuit and the US Supreme Court, the Court of Appeal of England and Wales, and the UK Supreme Court.

Authors

Jim Hurst is a nationally recognised trial lawyer who serves on Kirkland & Ellis' executive committee. He has been trying cases for more than 30 years and has argued dozens of appeals, including before the US Supreme Court. Jim has represented numerous life sciences clients in matters involving pharmaceutical drugs, biologic drugs, diagnostic products and vaccines. He has significant experience representing clients in matters related to Abbreviated New Drug Applications (ANDA) and the Biologics Price Competition and Innovation Act (BPCIA). Jim is ranked as a Band 1 National Trial Lawyer by Chambers and he is a fellow of the American College of Trial Lawyers.

Jeanna Wacker is a partner in Kirkland & Ellis' New York office. She is an experienced trial lawyer and concentrates her practice on patent litigation in the life sciences field. Jeanna has extensive experience assisting clients in the pharmaceutical, biotechnology, chemical and medical device industries, where she has represented both plaintiffs and defendants at all stages of litigation, including trials (bench and jury) and appeal. She also has experience in inter partes reviews before the United States Patent and Trademark Office. Jeanna has a degree in biochemistry, genetics and cell biology.

Sam Kwon is an IP litigation partner in Kirkland & Ellis' New York office. His practice focuses on patent litigation in a variety of life sciences fields, including medical devices, pharmaceutical and biologic products and biotechnology. He has significant experience representing clients in Hatch-Waxman patent infringement litigation. Sam has a degree in chemical engineering.



Ashley Ross is an IP partner at Kirkland & Ellis. Her work focuses on patent and trade secrets litigation. Ashley has a degree in molecular and cellular biology, and routinely works on Hatch-Waxman, life sciences and high-tech patent cases involving small molecules, pharmaceutical compositions, biofuels, therapeutic antibodies, DNA amplification technology, and mechanical and medical devices. She has been an integral part of multiple district court and International Trade Commission trial teams. She also has extensive experience in conducting all phases of pre-suit and discovery practice, including patent dance proceedings, taking and defending fact and expert depositions, arguing at Markman hearings, and facilitating motions practice.

Kirkland & Ellis

300 North LaSalle
Chicago
IL 60654
USA

Tel: +1 312 862 2000
Fax: +1 312 862 2200
Email: info@kirkland.com
Web: www.kirkland.com

KIRKLAND & ELLIS

1. Life Sciences and Pharma/ Biopharma Patent Litigation

1.1 Claimants/Plaintiffs to an Action

In the US, all parties with substantial rights must be named for plaintiffs to have statutory standing in patent infringement actions. Generally, a party with substantial rights will not have statutory standing if any co-owner is not named in the suit (AntennaSys, Inc v AQYR Techs, Inc, 976 F.3d 1374, 1378 (Fed Cir 2020)).

Those with less than all substantial rights in patents may need permission from the patentees to bring suit. Non-exclusive licensees need to bring suit with the licensor to have standing. However, exclusive licensees can establish standing alone (Aspex Eyewear, Inc v Miracle Optics, Inc, 434 F.3d 1336, 1340 (Fed Cir 2006)). The relevant licence does not need to be registered but the licensee must, at the minimum, hold the exclusive right to sue. The Federal Circuit also requires joinder of any exclusive licensee, given that exclusive licensees are usually necessary parties in actions in equity (BASF Plant Sci, LP v Nuseed Americas Inc, 2017 WL 3573811, at *5 (D Del 17 August 2017)). Generally, courts will also join a patentee, either voluntarily or involuntarily, in any patent infringement suit brought by a party with fewer than all substantial patent rights (Lone Star Silicon Innovations LLC v Nanya Tech Corp, 925 F.3d 1225, 1238 (Fed Cir 2019)).

Those seeking freedom to operate (FTO) around another's patents can file a declaratory judgment action. Federal courts have discretion as to whether to exercise jurisdiction over a declaratory judgment action under 28 USC Section 2201, even when the suit satisfies subject matter jurisdictional requirements (Wilton v Seven Falls Co, 515 US 277, 282 (1995)). The scope of this discretion is unclear, but the Federal Circuit has emphasised that there must be well-founded reasons to decline exercising jurisdiction over a declaratory judgment action (Mitek Sys, Inc v United Services Auto Ass'n, 34 F.4th 1334, 1347 (Fed Cir 2022)).

To establish standing in declaratory judgment actions:

- the plaintiff must have suffered an injury in fact;
- there must be a causal connection between the injury and the defendant's conduct; and
- it must be likely that the plaintiff's injury would be redressed by a favourable decision (3M Co v Avery Dennison Corp, 673 F.3d 1372, 1377 (Fed Cir 2012)).

There is no standing requirement for an inter partes review (IPR) before the Patent Trial and Appeal Board. However, there is a standing requirement to appeal a PTAB's decision in an IPR. Specifically, parties appealing to the Federal Circuit must show (and maintain throughout the appeal):

- injury in fact;
- that is "fairly traceable to the challenged action"; and
- it is likely that "a favourable judicial decision will redress the injury" (Lujan v Defenders of Wildlife, 504 US 555, 560 (1992)).

Such standing may be lost if there is an intervening abandonment of the controversy, such as settlement (ModernaTx, Inc v Arbutus Biopharma Corp, 18 F.4th 1352, 1362 (Fed Cir 2021)). Therefore, a petitioner may not be able to challenge the PTAB's decision – even if they could have at the outset of the petition.

1.2 Defendants/Other Parties to an Action

Typically, the entities named in life sciences lawsuits are those that are named as sponsors of US Food and Drug Administration (FDA) filings such as New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), abbreviated Biologics Licence Applications (aBLAs), and Biologics Licence Applications (BLAs). In a typical Hatch-Waxman suit, for example, patentees will sue the entity that filed the ANDA.

Beyond this, determining which entities will be sued is fact-dependent. Entities such as suppliers, distributors and doctors are rarely sued in typical Hatch-Waxman or Biologics Price Competition and Innovation Act (BPCIA) actions because these actions often occur before the accused products are approved and distributed. Suppliers are more likely, for example, to be the subject of subpoenas for discovery where the accused product is not approved.

1.3 Preliminary Injunction Proceedings

PIs are available in ANDA proceedings. Under the ANDA framework, a 30-month stay ensues if a brand product patent owner files an infringement suit against generics applicants within 45 days of receiving an ANDA notification (21 USC Section 355(j)(5)(B)). In addition, infringement by submitting an ANDA under Section 505(j) of the Federal Food, Drug and Cosmetic (FD&C) Act could result in a court-ordered delay of product approval until at least the expiration of the infringed patent under 35 USC Section 271(e)(4)(A).

Otherwise, PIs are ordered if the four-factor test is met. A plaintiff must establish that:

- they are likely to succeed on the merits;
- they are likely to suffer irreparable harm in the absence of relief;
- the balance of equities tips in the plaintiff's favour; and
- an injunction is in the public interest (Winter v Natural Res Def Council, 555 US 7, 20 (2008)).

The Federal Circuit has held that "no one factor, taken individually, is necessarily dispositive" (Chrysler Motors Corp v Auto Body Panels of Ohio, Inc, 908 F.2d 951, 953 (Fed Cir 1990)). A strong showing of likelihood of success and irreparable harm can overcome a weaker showing, for example, on balance of hardship or adverse public interest.

Demonstrating a tendency that is somewhat peculiar to life sciences cases, a court may consider whether the accused product provides a patient population with a unique role that cannot be replaced (Hybritech Inc v Abbott Laboratories, 849 F.2d 1446, 1458 (Fed Cir 1988)). On the other hand, courts may also consider whether an ANDA filer's launch will irreparably harm the market otherwise dominated by a brand product (Abbott Lab'ys v Sandoz, 544 F.3d 1341, 1361-62 (Fed Cir 2008)). Factors such as the impact on patient populations and changes in patentees' market shares are considered even if the subject matter of the cases differs (eg, cases involving pharmaceutical products or medical devices). See, for example, Abbott, 544 F.3d at 1361-62 and Hologic, Inc v Senorx, Inc, 2008 WL 1860035 at *19 (ND Cal 25 April 2008).

Courts may issue preliminary injunctions (PIs) only after notice has been provided under FRCP 65. Alleged infringers can file evidence to oppose motions for PIs. The average timing from filing to a decision for a PI varies across districts – for instance, based on data in the past four years,

decisions take on average four months in the District of Delaware, 2.7 months in the Northern District of California, and 3.7 months in the Eastern District of Texas.

When an injunction is requested also depends on the type of action. Given that the "irreparable harm" factor considers the immediacy of the harm, PIs in ANDA actions are often filed after the expiration of the 30-month stay and approval of the accused product if there is evidence of potential imminent launch by the generic challenger.

aBLA applicants must provide notice to the sponsor 180 days before commercial marketing begins, but this notice may be provided after filing an aBLA — even before the applicant receives FDA approval to license its biosimilar (Sandoz Inc v Amgen Inc, 137 S Ct 1664, 1677 (2017)). However, this notice alone may not be sufficient to establish "immediacy" in harm. See Genentech, Inc v Amgen Inc, 2019 WL 3290167 at *2–3 (D Del 18 July 2019).

Unlike Hatch-Waxman actions, BPCIA actions involve different phases. The first phase ensues if the biosimilar applicant initiates the "patent dance" – ie, a statutory system established to facilitate information exchange between the applicant and patent owner before an action starts (42 USC Section 262(l)(2)). During the patent dance, parties identify which patents will be litigated as part of the first phase and which patents will be subject to dispute in the second phase in accordance with 42 USC Section 262(l)(3). The second phase starts after the reference product sponsor (RPS) receives the 180-day notice; at this point, the RPS can seek a PI to prohibit the manufacture or sale of the biosimilar (42 USC Section 262(l)(8)(B)). The RPS may assert any patents identified in the patent dance. However, if a PI is not granted at this time, the biosimilar can launch during litigation.

Protective letters are not filed in the US.

1.4 Structure of Main Proceedings on Infringement/Validity

In the US, infringement and validity proceedings are generally not bifurcated, and they tend to be handled together. Sometimes, the issue of damages may be handled separately – either upon application or by sua sponte order of a court.

It is possible to file patent actions while the Patent Office is conducting IPR. It is also possible to file for an IPR during the pendency of district court proceedings on patents. The cancellation of patents by IPR will render moot the parallel district court action (Dragon Intell Prop, LLC v Dish Network LLC, 956 F.3d 1358, 1361 (Fed Cir 2020)). As a result, district court cases are often – although not always – stayed if there is a parallel IPR proceeding.

1.5 Timing for Main Proceedings on Infringement/Validity

In 2017, the Supreme Court made it more difficult to maintain a laches defence in patent infringement cases (SCA Hygiene Prods Aktiebolag v First Quality Baby Prods, LLC, 137 S Ct 954 (2017)). However, pursuant to 35 USC Section 286, a patentee may generally only reach back six years prior to the filing of the complaint for infringement damages.

Parties in patent proceedings are notified of the action by service. Service is governed by Federal Rules of Civil Procedure (FRCP) 4 and 5, as well as local rules of the district in which the case is filed.

Under FRCP 4(m), a defendant must be served within 90 days after the complaint is filed. Service can be delayed if service cannot be effected, and the remainder of the deadlines in the case do not run until service is effected. A party can waive formal service in return for an automatic extension on the deadline to answer the complaint (FRCP 4(d)).

The usual time to a final decision varies greatly by district. In the District of Delaware, for instance, termination by judgment takes an average of 36.1 months based on data in the past four years; however, it takes 24.1 months in the Eastern District of Texas.

1.6 Requirements to Bring Infringement Action

A patent can only be asserted in an infringement action after it is granted.

The type of patent asserted varies by type of action. In Hatch-Waxman actions, process patents are not permitted to be listed in the Orange Book and are therefore typically not litigated. However, process patents (eg, process claims for manufacturing biosimilars) can be – and often are – litigated in BPCIA actions. Generally, in order to maintain an action for infringement of a process patent, the process must occur in the USA.

Regardless of patent type, the burden of proving infringement remains with the entity asserting the patent.

1.7 Pre-Action Discovery/Disclosure

Pre-action discovery is generally not available. The closest alternative is asking for an order to depose someone to perpetuate their testimony under FRCP 27. This is a means to preserve evidence that may not be available later. Under FRCP 27(a)(4), a deposition to perpetuate testimony may be used under FRCP 32(a) in district court actions involving the same subject matter if the deposition is admissible. Such depositions are exceedingly rare.

However, there are pre-action exchanges in Hatch-Waxman and BPCIA cases.

In Hatch-Waxman actions, an ANDA holder challenging an Orange Book-listed patent is required to send a notice letter along with an offer of confidential access. This offer of confidential access defines the terms under which the ANDA holder is willing to provide access to their ANDA so the brand company can determine whether a lawsuit may be brought.

In BPCIA actions, aBLA holders can – but are not required to – participate in the aforementioned patent dance governed by 42 USC Section 262 (Sandoz Inc v Amgen Inc, 137 S Ct 1664, 1675–76 (2017)). aBLA filers who do participate in the patent dance must provide their application and manufacturing information within 20 days of the FDA accepting their application for review (42 USC Section 262(l)(2)). The RPS then provides a list of patents they believe are infringed within 60 days of receipt of the applicant's information under 42 USC Section 262(l)(3). The parties go on to exchange contentions on those patents to then settle on a final set of patents to litigate in BPCIA actions (42 USC Section 262(l)).

1.8 Search and Seizure Orders

Search and seizure orders are not available in US patent litigation. Even in discovery, parties are not permitted to search for or remove materials in the same way that search and seizure orders are conducted in other contexts. Instead, parties must use discovery requests – such as

interrogatories or requests for production – to obtain information.

However, it is possible to use pre-action discovery materials obtained in other jurisdictions – provided there is no restriction from the originator court on such use.

1.9 Declaratory Relief

Declaratory relief is available both to life sciences patentees and patent challengers. Exemplary types of declaratory relief available in life sciences patent proceedings are:

- declarations of non-infringement;
- declarations of invalidity; and
- declarations regarding damages issues, such as a finding that a case is exceptional pursuant to 35 USC Section 285.

In BPCIA actions, however, if an aBLA holder does not participate in the patent dance or fails to follow the patent dance disclosure requirements, they may not bring a declaratory judgment action against the RPS (42 USC Section 262(l)(9)).

1.10 Doctrine of Equivalents

If an accused infringer does not literally infringe, they may still infringe under the Doctrine of Equivalents (DoE), which is typically analysed as follows:

- function–way–result ("whether the accused product performs substantially the same function in substantially the same way to obtain the same result"); and
- insubstantial differences ("whether the accused product or process is substantially different from what is patented") (Mylan Institutional LLC v Aurobindo Pharma Ltd, 857 F.3d 858, 866-67 (Fed Cir 2017)).

"The doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." (Warner-Jenkinson Co, Inc v Hilton Davis Chem Co, 520 US 17, 29 (1997).)

Other considerations for DoE include the following.

- Ensnarement – this bars a patentee from asserting an infringement claim that would ensnare the prior art (Jang v Boston Sci Corp, 872 F.3d 1275 (Fed Cir 2017)).
- Claim vitiation – this prevents the application of DoE if it would eliminate a claim element (Edgewell Pers Care Brands, LLC v Munchkin, Inc, 998 F.3d 917, 923 (Fed Cir 2021)).
- Prosecution history estoppel – this prevents a patentee from recapturing equivalents surrendered during prosecution to procure issuance of the patent (Festo Corp v Shoketsu Kinzoku Kogyokabushiki Co, 535 US 722, 723 (2002)).

1.11 Clearing the Way

There is no obligation, per se, to "clear the way" ahead of a new product launch. However, FTO analyses are often conducted before launches in the form of formal opinions from counsel, which are used by business persons to weigh whether to launch a product. Such formal opinions may be used later in litigation to defend against allegations of wilful infringement – although such use will also result in waiver of attorney–client privilege.

1.12 Experts

It is common for courts to use expert evidence to determine infringement and validity issues, as well as occasionally during claim construction. The use of expert evidence may even be required in some contexts – for example, expert evidence is usually required for means-plus-

function claims (Elcommerce.com, Inc v SAP AG, 745 F.3d 490, 506 (Fed Cir 2014)).

In the US, parties retain their own experts. Courts do not typically appoint experts. It is typical for each party to retain multiple experts across several disciplines in life sciences cases to address infringement and validity issues.

FRCP 26(a)(2) governs the disclosure requirements for expert testimony in advance of trial, including requirements for written reports. Opposing counsel may take an expert's deposition and conduct oral cross-examination at trial. Expert testimony can be significant in decision-making, especially in Hatch-Waxman cases where a judge – rather than a jury – decides the case. As such, experts are expected to be impartial and may be disqualified for having conflicts of interest.

1.13 Use of Experiments

In the US, experimental results from testing conducted by experts may be used to assess infringement and validity issues. Experts can conduct experiments to test whether the accused products embody the patented compositions or whether design-arounds are possible to avoid infringement. It is also fairly common for experts from each side to engage in a battle of experimental protocols.

Experts who conduct such experiments and wish to present the results as evidence must provide a written report that contains:

- a complete statement of all opinions the witness will express and the basis and reasons for the opinions;
- the facts or data considered by the witness in forming these opinions;
- any exhibits that will be used;
- the witness' qualifications;
- a list of all other cases in which the witness testified as an expert in the previous four years; and
- a statement of the compensation to be paid for the study and testimony (FRCP 26(a)(2)(B)).

1.14 Discovery/Disclosure

In the US, the scope of discovery is generally wide. Parties may obtain discovery for any non-privileged matter that is relevant to any party's claim or defence and is proportional to the needs of the case, taking into consideration:

- the importance of the issues at stake;
- the amount in controversy;
- the parties' access to relevant information;
- the parties' resources;
- the importance of the discovery in resolving the issues; and
- whether the burden or expense of the proposed discovery outweighs its likely benefits (FRCP 26(b)(1)).

There are several discovery tools that may be used – for example, requests for production of documents under FRCP 34 can be used to obtain documents or electronically stored information such as lab notebooks, emails, or data compilations. Document discovery is not limited by the type of document, but by the level of responsiveness to the discovery demand as supported by FRCP 26.

Parties may rely on interrogatories (FRCP 33) and requests for admission (FRCP 36), as well as individual and corporate fact witness depositions, in order to obtain discovery. Opposing parties may also take a testifying expert's deposition pursuant to FRCP 26(b)(4)(A).

Certain districts have local rules that provide for exchange of contentions in which parties explain their theories of infringement and invalidity. Particular procedures for discovery tools (such as restrictions on the type or scope of discovery) may further vary depending on the district or judge.

1.15 Defences and Exceptions to Patent Infringement

There are several defences available in infringement actions.

Patent invalidity can be proven through multiple statutory avenues, such as:

- failing to provide a sufficient written description or failing to enable a person skilled in the art (35 USC Section 112) – the more a party claims, the broader the monopoly it demands, the more it must enable (Amgen Inc v Sanofi, 598 US 594, 613 (2023));
- anticipation by a single prior art reference (35 USC Section 102);
- obviousness in light of one or more prior art references (35 USC Section 103); and
- claiming patent ineligible subject matter (35 USC Section 101).

Other doctrines that are judicially created, such as obviousness-type double patenting (where patent claims at issue are obvious variants of claims from a commonly owned reference patent), may also be raised. For a patent that has received patent-term extension (PTE), obviousness-type double patenting analysis is based on the expiration date of the patent before the addition of PTE (Novartis AG v Ezra Ventures LLC, 909 F.3d 1367, 1373–74 (Fed Cir 2018)). By contrast, for a patent that has received patent-term adjustment (PTA) for delay by the PTO during prosecution, obviousness-type double patenting analysis must be based on the expiration date of the patent after the addition of the PTA (In re: Cellect, LLC, 81 F.4th 1216, 1226 (Fed Cir 2023)). In 2024, the Federal Circuit again addressed this issue, noting that a first-filed, first-issued parent patent having duly received PTA cannot be invalidated by a later-filed, later-issued child patent with less, if any, PTA (Allergan USA, Inc. v MSN Lab'ys Priv. Ltd., 111 F.4th 1358, 1370 (Fed Cir 2024)). Equitable doctrines may also render patents unenforceable as follows.

- "Unclean hands" – a defence that can be asserted to prevent a patent owner from being granted an equitable remedy because the patent owner acted unethically concerning the action at issue.
- Inequitable conduct – found when the patent owner materially deceived the US Patent and Trademark Office (USPTO) during patent prosecution. If inequitable conduct is found, all related patent claims may be rendered unenforceable.
- Equitable estoppel – proven by an accused infringer through three elements:
  (a) the patentee's misleading conduct led the alleged infringer to reasonably infer that the patentee did not intend to enforce its patent against the alleged infringer;
  (b) alleged infringer relied on that conduct; and
  (c) owing to this reliance, the alleged infringer would be materially prejudiced if the patentee is allowed to proceed with its claim (AC Aukerman Co v RL Chaides Constr Co, 960 F.2d 1020, 1028 (Fed Cir 1992)).

Another defence to accusations of patent infringement is prior use by the accused infringer, governed by 35 USC Section 273. It applies to subject matter that consists of a process,

machine, manufacture, or composition of matter in which:

- the commercial use of the subject matter in the US was in good faith; and
- the commercial use occurred at least one year before the earlier of either the effective filing date of the patent at issue or the date on which the claimed invention was disclosed to the public in a manner that qualified for the prior art exceptions under 35 USC Section 102(b).

However, establishing prior use under Section 273(g) is insufficient in itself to establish anticipation or obviousness.

1.16 Stays and Relevance of Parallel Proceedings

Patent proceedings can be stayed pending the outcomes of other proceedings before the US Patent Trial and Appeal Board (PTAB), including interferences, post-grant review, IPRs, and ex parte re-examination. Courts can grant motions to stay pending conclusion of a USPTO re-examination (Ethicon, Inc v Quigg, 849 F.2d 1422, 1426–27 (Fed Cir 1998)).

District courts typically balance three factors in making stay determinations:

- the stage of the proceedings;
- the potential to simplify issues; and
- the undue prejudice to the non-movant or a clear advantage for the movant resulting from a stay (Murata Mach USA v Daifuku Co, Ltd, 830 F.3d 1357, 1359–60 (Fed Cir 2016)).

Courts consider the outcomes of parallel proceedings for decisions to stay infringement and validity proceedings. Stays are justified when the outcomes of re-examinations would assist the court in determining patent issues (In re: Cygnus Telecomms Tech, LLC, Pat Litig, 385 F Supp 2d 1022, 1023 (ND Cal 2005)).

Pursuant to 28 USC Section 1659, district courts must stay district court litigation at the request of any respondent to an International Trade Commission (ITC) proceeding until a final decision, so long as the request is made within 30 days of the district court action's filing or after a party is named as a respondent in the ITC proceeding.

When IPR proceedings result in a final written decision, 35 USC Section 315(e)(2) precludes petitioners from raising invalidity grounds in a parallel district court litigation that they raised or reasonably could have raised during that inter partes review (California Inst of Tech v Broadcom Ltd, 25 F.4th 976, 989 (Fed Cir 2022)). ITC decisions have no preclusive effect on district courts but may have persuasive value (Texas Instruments Inc v Cypress Semiconductor Corp, 90 F.3d 1558, 1569 (Fed Cir 1996)).

1.17 Patent Amendment

Patents can be amended during litigation. Certificates of correction arising from the USPTO's mistake are governed by 35 USC Section 254. For more substantive changes to patent claims, one can file a request for reexamination (37 CFR Section 1.510) or reissuance (35 USC Section 251) of an application.

An application for reissuance of a patent that enlarges the scope of the claims of the original patent must be filed within two years of the original patent being granted (35 USC Section 251(d)). Otherwise, new matter cannot be introduced, and claims can only be narrowed (35 USC Section 251). Patents may also be amended during IPR proceedings upon motion by the patentee.

Requests for re-examination can be filed at any time (35 USC Section 302). However, if a patent is involved in an ex parte or inter partes re-examination or becomes involved in litigation, the director of the USPTO can decide whether to suspend the ex parte (37 CFR Section 1.565) or inter partes re-examination proceeding (37 CFR Section 1.987).

Patentees may also seek certificates of correction, for instance, to correct mistakes. However, the Federal Circuit has held in one case, which involved a certificate of correction from the USPTO over an issued claim that was missing a limitation, that a "certificate of correction is only effective for causes of action arising after it was issued". (H-W Tech, LC v Overstock.com, Inc, 758 F.3d 1329, 1334 (Fed Cir 2014).)

1.18 Court Arbiter

In the US, recent court decisions have made forum shopping substantially more difficult. As in any US case, courts must have personal jurisdiction over defendants. Patent litigation has the same common-law principles and procedural rules as other types of civil litigation (SCA Hygiene Products Aktiebolag v First Quality Baby Products, LLC, 137 S Ct 954, 964 (2017)). Defendants must have minimum contacts with a forum state for personal jurisdiction to apply (Int'l Shoe Co v Washington, 326 US 310, 316 (1945)). Courts also analyse whether application of personal jurisdiction comports with due process by deciding whether:

- the defendant purposefully directed activities at residents of the forum state;
- the litigation results from those activities; and
- assertion of personal jurisdiction is reasonable and fair (New World Int'l, Inc v Ford Glob Techs, LLC, 859 F.3d 1032, 1037 (Fed Cir 2017)).

In addition to establishing personal jurisdiction, patentees must also satisfy the venue requirement. For the purposes of identifying a proper venue, patent infringement actions may be brought where the defendant either:

- resides or is incorporated; or
- has committed acts of infringement and has a principal place of business (TC Heartland LLC v Kraft Foods Grp Brands LLC, 137 S Ct 1514, 1518–19 (2017)).

Hatch-Waxman cases are typically tried before Federal District court judges. However, Hatch-Waxman cases may be tried before a jury if the accused product has been approved and has been launched at risk, thereby having harmed patentee(s). BPCIA litigation may proceed before a jury on request.

2. Generic Market Entry

2.1 Infringing Acts

The FD&C Act holds that it "shall be an act of infringement to submit" an ANDA under Section 505(j) or a "paper" NDA as described in Section 505(b)(2) for a drug (or its use), which is claimed in a patent, if the purpose of the submission "is to obtain approval... to engage in the commercial manufacture, use, or sale of a drug... claimed in a patent or the use of which is claimed in a patent" before the patent's expiration (35 USC Section 271(e)(2)). Some courts have thus held that submission of the application is itself an act of technical infringement sufficient to establish jurisdiction for initiating an action.

Under the Hatch-Waxman framework, suits can be brought before the accused product has been approved or marketed. Given that an actual accused product may not exist at the time of

suit, infringement inquiry under Section 271(e)(2) considers "whether the probable ANDA product would infringe once it is made, used or sold" (Par Pharm, Inc v Eagle Pharms, Inc, 44 F.4th 1379, 1383 (Fed Cir 2022)).

If the FDA specification of the generic challenger defines the accused product in a manner that clearly resolves the question of infringement, then the specification controls the inquiry. If a specification does not full resolve the question of infringement "clearly and directly", courts may consider "other relevant evidence, such as data or samples the ANDA filer has submitted to the FDA".

A drug applicant may exclude a patented use from its label by submitting its proposed label to the FDA and "carving out" those methods of use which are claimed in patents (GlaxoSmith-Kline LLC v Teva Pharms USA, Inc, 7 F.4th 1320, 1327 (Fed Cir 2021); see 21 USC Section 355(j)(2)(A)(viii)).

An applicant may also be liable for induced or contributory infringement under 35 USC Section 271(b) and (c). To show induced infringement, a plaintiff must demonstrate that "the alleged infringer's actions induced infringing acts and that [they] knew or should have known [their] actions would induce actual infringements" (GlaxoSmithKline LLC v Teva Pharms USA, Inc, 7 F.4th 1320, 1327 (Fed Cir 2021)). Where allegations of inducement are based on an ANDA applicant's label as well as its public statements and/or marketing materials, the totality of the allegations must be considered (Amarin Pharma, Inc. v Hikma Pharms. USA Inc., 104 F.4th 1370, 1377 (Fed Cir 2024)).

An ANDA applicant may be liable for contributory infringement if it sells or offers to sell a material or apparatus for use in a patented combination or process where the ANDA product is a material part of the patented invention and has no substantial non-infringing uses. (See BTG Int'l Ltd v Amneal Pharms LLC, 352 F Supp 3d 352, 399 (D NJ 2018).)

An ANDA applicant's launch prior to conclusion of Hatch-Waxman litigation is sometimes referred to as an "at-risk" launch. In such cases, the applicant may be liable under 35 USC Section 271(a).

2.2 Regulatory Data and Market Exclusivity

The FD&C Act and the Code of Federal Regulations set out the following categories of exclusivities available to pharmaceutical product applicants, with varying lengths and protections.

- New drug product exclusivity grants limited exclusivity for drug products with new chemical entities or approved active moieties that were subject to new and essential clinical investigations. This exclusivity bars the FDA from reviewing any NDA or ANDA for any drug containing the same active moiety for four years from the date of approval of the first-approved drug application if the NDA or ANDA contains a paragraph IV certification or for five years if it does not (21 CFR Section 314.108(a)–(b)).
- New clinical investigation exclusivity confers three years from the date of approval of an NDA that includes investigations in humans with results that were not previously relied upon by the FDA to demonstrate substantial evidence of effectiveness for a previously approved drug product.
- Orphan drug exclusivity confers seven years of exclusivity to drugs designated and approved to treat rare diseases – ie, those

affecting under 200,000 people in the US – or drugs that have no reasonable expectation of recouping the costs of developing and making the drug available (21 USC Section 360bb(a)(2); 21 USC Section 360cc).
- Paediatric exclusivity confers six months of exclusivity to drugs from the end of other exclusivity protection or patent protection when, in response to a written request from the FDA, a sponsor has submitted paediatric studies on the active moiety in their drug product (21 USC Section 355a).
- 180-day exclusivity is conferred to the first ANDA applicant(s) seeking approval. The exclusivity generally begins after the first commercial marketing of the drug or after a court decision holding the patent invalid, unenforceable, or not infringed (21 USC Section 355).

2.3 Acceptable Pre-Launch Preparations

The Hatch-Waxman Act contains a safe harbour provision providing that it "shall not be an act of infringement to make, use, offer to sell, or sell... a patented invention... solely for uses reasonably related to the development and submission of information under a federal law [that] regulates the manufacture, use, or sale of drugs" (35 USC Section 271(e)(1)). Such protection extends to not only drug products but also to medical devices and food or colour additives (Eli Lilly & Co v Medtronic, Inc, 496 US 661 (1990)).

However, only allegedly infringing activities subject to FDA pre-market approval that are "reasonably related" to submission of information qualify (Proveris Sci Corp v Innovasystems, Inc, 536 F.3d 1256, 1265–66 (Fed Cir 2008)). Such use includes not only preclinical studies but may also extend to scenarios where no data is actually submitted to the FDA (Merck KGaA v Integra Lifesciences I, Ltd, 545 US 193, 205–08 (2005)).

2.4 Publicly Available Drug and Patent Information

In the US, The Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) provides a list of all approved prescription drug products with therapeutic equivalence evaluations, as well as patents identified by the drug sponsors as covering those products. It is updated with an Annual Edition and monthly Cumulative Supplement.

When seeking approval of a drug product, an ANDA applicant must certify to the FDA – for each patent listed in the Orange Book for that drug – a statement that:

- the patent information has not been filed;
- the patent has expired;
- the date on which the patent will expire; or
- the patent is invalid or not infringed by the manufacturer, use, or sale of the ANDA drug product (21 USC Section 355(j)(2)(A)(vii)).

If the applicant certifies that the patent will not be infringed or is invalid, the applicant must also give notice of such paragraph IV certification to the patent owner and the holder of an approved application under 21 USC Section 355(b) for a drug that is claimed by the patent (21 USC Section 355(j)(2)(B)). However, an ANDA applicant need not provide certifications for method-of-use patents claiming a use that the ANDA application does not seek approval to use (AstraZeneca Pharms LP v Apotex Corp, 669 F.3d 1370, 1374 (Fed Cir 2012)).

2.5 Reimbursement and Pricing/Linkage Markets

In the US, grant of marketing authorisation for pharmaceutical products is linked with patent status but only with regard to those patents listed in the Orange Book that:

- claim the drug substance (active ingredient) or drug product (formulation or composition); or
- claim a method of using the drug that has been sought or granted in the application.

Applicants may "carve out" certain methods of use from approval, thereby potentially avoiding method-of-use patents. As discussed further earlier, 505(b)(2) and 505(j) applicants must file certain certifications as to these patents. One such paragraph IV certification serves as notice to any patent owners – and holders of approved applications of drugs claimed by the patent – that the NDA filer alleges the related patents will not be infringed or are invalid.

The recipient of the paragraph IV certification has 45 days after receiving notice to file an action "for infringement of the patent that is the subject of the certification" (21 USC Sections 355(c)(3) and 355(j)(5)(B)). If such action is brought, approval of the NDA will become effective only after expiration of a 30-month period or upon a judicial decision that the patent is invalid or not infringed (21 USC Section 355(c)(3) and 355(j)(5)(B)).

3. Biosimilar Market Entry

3.1 Infringing Acts

Biologic applicants operate under a different framework from ANDA applicants, with the former governed by the BPCIA. The BPCIA amended the Patent Act to provide that it "shall be an act of infringement to submit... an application seeking approval of a biological product" with regard to patents that are or could be identified pursuant to Section 351(l)(3) of the Public Health Service Act (21 USC Section 271(e)(2)(C)).

If the applicant engages in the patent dance, the parties will negotiate a list of patents that are subject to immediate litigation. Only listed patents at this stage are subject to a declaratory action of infringement, validity or enforceability until the applicant provides notice to the patent owner that it will begin commercial marketing of the biosimilar in not less than 180 days (42 USC Section 262(l)(9)(A)). Although an aBLA applicant cannot be forced to engage in the patent dance (Amgen Inc v Sandoz Inc, 137 S Ct 1664 (2017)), failure to do so bars the applicant from initiating a declaratory judgment action – whereas the patent owner may immediately bring a declaratory judgment action for any patent claiming the biosimilar (42 USC Section 262(l)(9)(C)).

3.2 Data and Regulatory Exclusivity

The BPCIA provides the following exclusivities for applicants.

- Reference product exclusivity grants to new biologics approved under a BLA a four-year exclusivity period, during which no aBLA may be filed on the product, and a 12-year period during which the FDA may not approve any biosimilar products (42 USC Section 262(k)).
- Paediatric exclusivity confers an additional six months of exclusivity if the reference product conducted paediatric studies pursuant to the FD&C Act Section 505A (42 USC Section 262(m)).
- Biosimilar applicant exclusivity grants a one-year period of exclusivity to the first biosimilar of a licensed biologic that is approved under the BPCIA, thereby preventing the FDA from approving any other biosimilars to the same reference biologic (42 USC Section 262(k)(6)(A)).

3.3 Acceptable Pre-Launch Preparations

The safe harbour provision of 35 USC Section 271(e)(1) also shelters activities of biosimilar applicants conducted solely for the purpose of developing and submitting information under federal law.

3.4 Publicly Available Drug and Patent Information

The FDA maintains the Purple Book, or List of Licensed Biological Products, which contains biological products regulated by the Center for Drug Evaluation and Research. This includes not only reference products but also licensed biosimilars. The Purple Book includes the date of licensing for the product, the date of expiration for exclusivity periods, and certain patent information.

However, the Purple Book differs from the Orange Book in that BLA holders are only required to submit to the FDA the patent lists that they serve on biosimilar applicants during the patent dance (within 30 days of providing the biosimilar applicant with the list). The FDA updates the Purple Book every 30 days (42 USC Section 262(k)(9)(A)).

As noted earlier, biosimilar applicants can choose whether to participate in the patent dance. If they choose to participate, biosimilar applicants must provide the patent owner a copy of their aBLA within 20 days of the FDA accepting the application. Thereafter, the patent owner and applicant negotiate what patents can be immediately asserted and which, if any, the RPS would be willing to license (42 USC Section 262(l)). This includes exchanging statements detailing – on a claim-by-claim basis – each party's positions regarding invalidity, enforceability and infringement for each patent.

3.5 Reimbursement and Pricing/Linkage Markets

Unlike the Hatch-Waxman Act, the BPCIA:

- outlines an information-exchanging mechanism (ie, the patent dance);
- requires aBLA applicants to provide notice of commercial launch before launching;
- does not have the automatic 30-month stay; and
- has different exclusivities.

4. Patent Term Extensions for Pharmaceutical Products

4.1 Supplementary Protection Certificates

Under the Hatch-Waxman framework, patent term extension (PTE) is available for patents claiming drug products – and methods of use or manufacture of drug products – that are subject to regulatory review before commercial marketing or use (35 USC Section 156(a)). In order to obtain PTE, the holder must submit an application for extension within 60 days of receiving permission from the FDA to market the product.

The PTE determination is made by the FDA and USPTO together. The FDA is responsible for initially calculating the length of the regulatory review for the product, which is published in the Federal Register (35 USC Section 156(d)(2)(A)(ii)). After a chance for comment by interested parties, the USPTO calculates the final PTE length, which is capped at five years (35 USC Section 156(g)(6)(A)). Only one patent on a product can be extended for the same regulatory review period (35 USC Section 156(c)(4)).

Although biologics are also eligible for PTE, the rules applicable for granting PTE are less settled.

This is due at least to the fact that biologics can present a difficult question of what is the relevant "active ingredient".

4.2 Paediatric Extensions

Paediatric exclusivity extensions exist for both small molecule drugs under the Hatch-Waxman framework and biologics under the BPCIA. Paediatric exclusivity under either is granted where a sponsor has submitted paediatric studies on the active moiety in their drug product – in response to a written request from the FDA – and confers on the applicant an additional six months of exclusivity for drug products containing the moiety (21 USC Section 355a and 42 USC Section 262(m)).

4.3 Paediatric-Use Marketing Authorisations

In the US, the sponsor who conducts pediatric studies as requested by the Secretary of Health and Human Services can obtain a six-month pediatric exclusivity extension for any listed patent that satisfies 21 USC Section 355a(b)(1)(B). If no patent or exclusivity is in place, the six-month pediatric exclusivity does not create a new independent exclusivity period.

4.4 Orphan Medicines Extensions

The Orphan Drug Act provides seven years of market exclusivity upon FDA approval of a designated orphan drug. This exclusivity prevents approval of the same drug for the same orphan indication. Different orphan indications for the same drug may each earn their own seven-year exclusivity periods once approved. Because orphan drug exclusivity is indication-specific, a generic applicant may "carve out" the protected orphan indication from its label in order to enter the market.

5. Relief Available for Patent Infringement

5.1 Preliminary Injunctive Relief

In the US, a PI may be granted before or during trial – or even pending appeal.

FRCP 65 dictates that a court may issue a PI only if the movant provides a bond sufficient to pay the costs and damages sustained by any party found to have been wrongfully enjoined as determined by the court.

A court may issue a PI only on actual notice to the adverse party – by personal service or otherwise – of the injunction, such that the patent owner gives the defendant sufficient advance notice in order to allow the accused infringer to prepare and present its defence.

If a court issues an injunction, enforcement is administered via its contempt authority. A party could move for contempt to sanction the party who fails to comply with the court order. Typical contempt sanctions include a monetary fine or fee-shifting.

5.2 Final Injunctive Relief

A permanent injunction is a court order requiring a person to do or cease doing a specific action that is issued as a final judgment in a case. Unlike PIs, permanent injunctions generally do not require bonds. In ANDA actions, upon a finding of infringement, courts are required to order a permanent injunction such that the effective date of approval is not earlier than the patent expiration date (35 USC Section 271(e)(4)). Likewise, upon a finding of infringement by an aBLA applicant, a court must order a permanent injunction prohibiting any further infringement of the patent until expiration of the infringed patent.

If an ANDA is approved and the drug is already on the market, an injunction could be obtained under a four-factor test showing:

- the patent owner has suffered an irreparable injury;
- remedies, such as monetary damages, are inadequate;
- the balance of hardships favours the patent owner; and
- the permanent injunction would not hurt public interest (Weinberger v Romero-Barcelo, 456 US 305, 312 (1982)).

A permanent injunction is ordinarily effective upon issue and, if not stayed, also effective pending appeal. When a party decides to appeal an issued injunction, a court also have the power to grant a stay.

5.3 Discretion to Award Injunctive Relief (Final or Preliminary)

In the US, monetary damages and injunctions are not mutually exclusive – for example, a court may award monetary damages for past infringing acts, while issuing injunctions to prevent future infringement. However, in ANDA actions, monetary damages may be awarded only after the infringer launches at risk.

For certain pharmaceutical products, the public interest factor for injunctive relief could be especially important. A patent owner may argue for an injunction based on safety concerns, for example. An accused infringer, on the other hand, may argue that the court should not issue an injunction that takes life-saving drugs off the market if they cannot be substituted by another product.

5.4 Damages

Under 35 USC Section 284, courts shall award the patent owner damages adequate to compensate for the infringement but in no event less than a reasonable royalty, together with interest and costs fixed by the court.

Two main types of damage awards are reasonable royalties and lost profits. A reasonable royalty is an estimation of the royalty that a licensee would pay for the rights to the claimed invention in a hypothetical negotiation. Lost profits are profits that a patent owner would have made if an infringer had not infringed. Damage awards may encompass both lost profits and a reasonable royalty.

To obtain lost profits, a patent owner must show that there is a reasonable probability that but, for the infringement, the patent owner would have made the infringer's sales. One useful, but non-exclusive, method to establish the entitlement to lost profits is the Panduit test, which requires a patent owner to establish (Rite-Hite Corp v Kelley Co, 56 F.3d 1538, 1545 (Fed Cir 1995) (en banc)):

- demand for the patented product;
- absence of acceptable non-infringing alternatives;
- manufacturing and marketing capability to exploit the demand; and
- the amount of profit it would have made.

Determination of reasonable royalties could be based on established royalty rates, a hypothetical negotiation, or an analytical approach. Established royalty rates must come from pre-infringement licence agreements on comparable technology. In the absence of established royalty rates, a court may consider a hypothetical negotiation between a willing licensor and licensee

to fix a royalty rate. A determination of the royalty stemming from a hypothetical negotiation is often made by assessing certain factors set forth in Georgia-Pacific Corp v US Plywood Corp, 318 F Supp 1116, 1120 (SD NY 1970). A district court may also use an analytical approach – obtaining the reasonable royalty by subtracting the industry standard profit margin from infringer's actual profit margin.

35 USC Section 284 gives district courts discretion to award enhanced damages against infringers in egregious cases. This can include an award of treble damages for wilful infringement. Courts may also award pre-judgment interest on the compensatory portion of the damages award under this section, and post-judgment interest of the entire award under FRCP 37.

35 USCA Section 286 limits the recovery of damages for past infringement to six years from the filing of the claim of infringement. Generally, there is no infringement liability for activities before a patent issues. However, provisional damages may begin after the publication date of the patent application if (35 USCA Section 154(d)):

- the infringer had notice of the publication; and
- the asserted claims are substantially identical to the claims in the publication.

In jury trials, a district court has discretion to try damage-related issues together with – or separate from – other issues. As to the execution of judgment on damages, proceedings to enforce it are stayed for 30 days after its entry, unless the court orders otherwise (FRCP 62(a)).

If an accused infringer is wrongfully enjoined, the relief to the injured party is typically limited to the terms of the bond.

A party does not need to be the patent owner to claim damages in a patent litigation – for example, a party with all substantial rights to a patent may also claim damages against an infringer.

In the pharmaceutical industry, no monetary damage would result from filing an ANDA paragraph IV certification before commercial marketing. And the BPCIA limits a patent owner's damages to a reasonable royalty if an infringement suit is untimely filed. Patent owners can only seek PIs after receiving notice of commercial marketing. In both ANDA and BPCIA litigations, a company may decide to launch at risk, thereby making monetary damages possible if it is later found to have infringed a patent.

5.5 Legal Costs

Under the American Rule, each party in a litigation pays its own attorney's fees, unless the case is considered "exceptional" (35 USC Section 285). District courts have discretion to award reasonable attorney fees to the prevailing party in exceptional cases. An exceptional case is one that stands out from others with regard to:

- the substantive strength of a party's litigation position; or
- the unreasonable manner in which the case was litigated (Octane Fitness, LLC v ICON Health & Fitness, Inc, 572 US 545, 554 (2014)).

Not all legal costs can be shifted in a patent case. Even where attorney fees are shifted, for example, experts' fees generally still may not be shifted (Finjan, Inc v Juniper Networks, Inc, 2021 WL 3140716, at *5 (ND Cal 26 July 2021)).

5.6 Relevance of Claimant/Plaintiff Conduct to Relief

In the US, there are equitable doctrines that sanction patent owners' conduct in bad faith as follows:

- inequitable conduct could render a patent (and possibly a patent family) unenforceable (GS Cleantech Corp v Adkins Energy LLC, 951 F.3d 1310, 1325 (Fed Cir 2020));
- unclean hands could "close the doors of a court of equity to one tainted with inequitableness or bad faith" (Precision Instrument Mfg Co v Automotive Maintenance Machinery Co, 324 US 806, 814 (US 1945)); and
- asserting weak litigation positions may result in shifting the attorney's fees to the patent owners (Octane Fitness, LLC v ICON Health & Fitness, Inc, 572 US 545, 554 (2014)).

6. Other IP Rights

6.1 Trade Marks

In the US, trade marks are protected by both statutory and common law. Trade mark disputes are not commonly adjudicated in the same action as patent disputes. In addition to exclusiveness, trade marks also provide other benefits to life sciences and pharmaceutical products by:

- helping consumers find their desired products;
- reducing medication errors; and
- incentivising investment in new medications.

Non-traditional trade marks, such as the colour of the drug, may provide additional protection. Since these non-traditional marks are not inherently distinctive, secondary meanings are usually required. Another concern regarding these non-traditional trade marks is that they may be deemed functional, which renders the marks not fit for trade mark protection.

6.2 Copyright

Copyright issues are uncommon in life sciences and pharmaceutical cases. In a lawsuit where copyright was at issue, for example, the Second Circuit held that the ANDA filer could not be liable for copyright infringement for copying verbatim the text used in the SmithKline users' guide because the labelling requirement under the Hatch-Waxman Act trumped the copyright concern (SmithKline Beecham Consumer Healthcare, LP v Watson Pharm, Inc, 211 F.3d 21, 29 (2d Cir 2000)).

6.3 Trade Secrets

A trade secret typically consists of (at least minimally) novel and commercially valuable information that is valuable because of its secrecy. Trade secrets disputes are not commonly adjudicated in the same action as patent disputes in the life sciences and pharma sector, but may occasionally be adjudicated in the ITC.

7. Appeal

7.1 Timeframe to Appeal Decision

Parties to patent actions have a right to appeal, although the timing of such appeal varies as follows.

- A party appealing district court decisions must file its notice within 30 days following the judgment or order appealed against (28 USC Section 2107).
- A party adversely affected by an ITC final determination must file its appeal notice within 60 days of the ITC decision becoming final (19 USC Section 1337).

- A party seeking to appeal from a PTAB and the US Trademark Trial and Appeal Board (TTAB) proceedings must file such notice within 63 days of the date of the final Board decision (37 CFR Section 90.3).

Under 28 USC Section 1292, interlocutory appeals may be filed before the final decision.

7.2 Appeal Court(s) Arbiter

The Federal Circuit has nationwide and exclusive jurisdiction in a variety of subject areas, including patents, trade marks, and international trade. This means that the Federal Circuit handles all federal district court appeals regarding patent cases. The Federal Circuit also reviews certain administrative agency decisions, including those from the PTAB, TTAB and ITC.

The Federal Circuit's work begins after the Clerk's Office dockets a new appeal or petition and assigns a docket number. The parties to the cases prepare and file written briefs to present their arguments. The appeal is then randomly assigned to a panel comprising three randomly selected judges. There may be oral arguments, in which each side is typically allotted 15 minutes for argument. Parties may seek review of a Federal Circuit decision in the US Supreme Court.

7.3 Special Provisions

Generally, US district courts have broad discretion to streamline cases before them. Many district courts have local rules and, more specifically, patent rules. Such rules may govern claim construction proceedings, exchange of infringement and invalidity contentions, and procedures for pre-trial and trial exchanges.

8. Other Relevant Forums/ Procedures

8.1 The UPC or Other Forums

US forums other than district courts (eg, the PTAB, TTAB and ITC) are also relevant to the pharmaceutical industry.

The PTAB generally conducts hearings such as IPR proceedings, hears appeals from adverse examiner decisions in patent applications and re-examination proceedings, and renders decisions in interferences.

The TTAB handles appeals involving applications to register marks, appeals from expungement or re-examination proceedings involving registrations, and trial cases of various types involving applications or registrations.

The ITC investigates and makes determinations in proceedings involving imports claimed to injure a domestic industry or violate US IP rights.

9. Alternative Dispute Resolution

9.1 ADR Options

Although court actions are more popular in the US compared with many other jurisdictions, there are other mechanisms for resolving disagreements between parties. Such ADR proceedings may result in faster and less expensive resolutions.

In mediations, for example, a neutral mediator may be used to discuss potential settlements. The mediator generally helps parties assess their legal positions. Even if parties do not reach an agreement, the mediation process facilitates exchange of information.

Although a mediation is normally not binding, an arbitration usually resolves the case on the merits. In an arbitration, parties present evidence and argue their positions before a neutral arbitrator. The procedural and evidentiary rules are usually set according to an arbitration agreement. If an arbitration is binding, for example, a party may not be able to reject the arbitration decision.

10. Settlement/Antitrust

10.1 Considerations and Scrutiny

The Federal Trade Commission pays particular attention to settlements in life sciences litigation, and certain state laws may furthermore restrict the scope and content of settlements between such parties. NDA applicants are not permitted to "pay for delay" of generic drug entry, for example (FTC v Actavis, Inc, 570 US 136, 140 (2013)). Avoiding uncertainties and litigation costs, however, is permissible. Antitrust liabilities may also attach to patent misuse, inequitable conduct, and product hopping.

11. Collective Redress

11.1 Group Claims

Group claims in US life sciences litigation often proceed as class actions under Federal Rule of Civil Procedure 23. To certify a class, plaintiffs must show numerosity, commonality, typicality and adequate representation. The court must also be satisfied that common legal or factual issues predominate and that the class action format is superior to other methods of adjudication.

In the pharmaceutical and medical device arena, class actions frequently arise in product liability, false advertising, antitrust, and securities fraud cases. However, class actions are rare in Hatch-Waxman litigations. Instead of class actions, some cases are consolidated for pre-trial proceedings through multidistrict litigation (MDL) under 28 USC Section 1407. See, eg, In Re: Aflibercept Patent Litigation, MDL No 1-24-md-03103 (NDWV). MDLs streamline discovery and other pre-trial matters while allowing individual cases to retain their separate identities.

Trends and Developments

Contributed by:
Ed Haug, Andrew Wasson and Wan Chieh (Jenny) Lee
Haug Partners LLP

Haug Partners LLP has an extensive team of attorneys, many of whom have advanced science or engineering degrees, as well as industry experience. The firm's grasp of legal and scientific intricacies provides critical insight when evaluating or litigating complex and challenging intellectual property or commercial disputes, and is key to effectively representing clients dealing with innovative life science and technology matters. Haug Partners routinely litigates and tries cases before federal district courts throughout the US, the Patent Trial and Appeal Board, and the International Trade Commission. The firm's experience ranges across all areas of intellectual property, including patents, trade marks, copyrights, trade secrets, business torts, and contract disputes. With this expertise, Haug's attorneys are adept at explaining the legal and technical nuances that are unique to intellectual property cases to judges, juries and clients.

Authors

Ed Haug is an original founder of Haug Partners LLP and currently serves as chairperson and head of the firm's litigation practice. He has over 40 years' experience as a first-chair litigator in numerous high courts around the world. His strong technical background enables him to litigate complex "bet the company" technology and life science cases. He holds prominent memberships in esteemed organisations such as the Lawyers of Distinction, Federal Circuit Bar Association (past president), American Bar Association, and International Patent and Trademark Association.

Andrew Wasson is a partner at Haug Partners LLP and serves as chair of the firm's FDA practice. He specialises in intellectual property and regulatory law within the pharmaceuticals sector. He is actively involved in various professional organisations, including the Food and Drug Law Institute and the New York Intellectual Property Law Association. In addition, Mr Wasson serves on the editorial board of the Food and Drug Law Review and has served as an Adjunct Lecturer of Entrepreneurship & Innovation at Iona University.

Contributed by: Ed Haug, Andrew Wasson and Wan Chieh (Jenny) Lee, **Haug Partners LLP**

Wan Chieh (Jenny) Lee is a partner at Haug Partners LLP and brings over 19 years of patent expertise to the firm's patent prosecution group. Her practice focuses on strategic counselling, procurement of worldwide patent rights, due diligence, freedom to operate, and intellectual property transactions. She routinely advises clients in the pharmaceutical, biotechnology and medical device industries regarding patentability, validity, freedom-to-operate, and regulatory exclusivity. She actively contributes to the legal community through her leadership roles with the New York Intellectual Property Law Association, New York Intellectual Property Law Educational Foundation, and American Intellectual Property Law Association.

Haug Partners LLP

745 Fifth Avenue, 10th Floor
New York
NY 10151
USA

Tel: +1 212 588 0800
Fax: +1 202 588 0500
Email: firm@haugpartners.com
Web: www.haugpartners.com

Patent Litigation Trends in the Life Sciences in the US

While there have been a number of trends in patent litigation in the life sciences recently, in this chapter the authors focus on two particularly pressing and notable trends. First, the authors address the growing clamour around the proper "listability" requirements for Orange Book patents and comment on likely behaviour of generic applicants going forward. Second, now that some time has passed, the authors discuss the ramifications of the Amgen v Sanofi Supreme Court case on the use of invalidity for lack of enablement under Section 112 as a defence in life sciences litigation.

Orange Book listability will likely remain a pressing topic in Hatch-Waxman litigation

While always an important issue, the determination of whether a patent meets the requirements for listing in the Orange Book has recently taken on increased significance. The debate about the correct standard for "listability" and whether specific patents have been correctly listed in the Orange Book continues to play out in multiple fora. In the context of Hatch-Waxman innovator-versus-generic patent litigation, high-profile attempts to oust (or "delist") a patent from the Orange Book have already begun. The authors expect that such attempts will continue, with generic companies becoming even more aggressive with the types of patents that they target for delisting.

The "Orange Book" is an FDA publication with the official title, "Approved Drug Products with Therapeutic Equivalence Evaluations" and is a central component to Hatch-Waxman's patent resolution mechanisms. The Orange Book contains a list of patents that claim an innovator drug or a method of using it. Generic applicants seeking to market a drug referencing the innovator drug are obligated to address each and every patent listed in the Orange Book for the innovator drug that the generic seeks to reference. When a generic applicant chooses to challenge a patent listed in the Orange Book, the generic applicant generally must certify that the generic product will not infringe the patent, or that the patent is invalid or unenforceable (ie, a "paragraph iv" certification). The generic applicant is obligated to send notice of its certification to the NDA holder and patent assignee as well as a detailed statement describing the basis for its position. Critically, if a patent infringement suit is brought, the FDA is barred from approving the generic application for 30 months (the 30-month stay). The FTC periodically raises the concern that improper listing of patents in the Orange Book could give rise to unjustified stays of generic approval with alleged anti-competitive effects.

Consequently, ensuring that patents are properly listed in the Orange Book is of tantamount importance. The general requirements for listing a patent in the Orange Book are specified in the Hatch-Waxman statute itself. The Act directs that applicants must submit patent information for listing a patent that: "(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent" or "(II) claims a method of using such drug for which approval is sought or has been granted in the application" (21 USC Section 355(j)(2)(A)(iv)). In addition, the Act requires submitting patent information only for patents where "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug...". Within the broad category of "drug", the FDA has long-stated that drug substance (ingredient) patents and drug

product (formulation and composition) patents are properly listable, while methods of manufacture and process patents are not properly listable. Then, after prompting from the FTC in 2002, the FDA further determined that polymorph and product-by-process patents are properly listable, but patents claiming packaging, metabolites and intermediates are not.

While the FDA was able to describe several baskets of properly listable patents, it soon found that the line between "packaging" and some types of complex pharmaceutical products was harder to draw. For example, industry urged the FDA to clarify whether patents claiming device components of drug–device combination products like pre-filled syringes and metred dose inhalers were properly listable. Proponents of listability of device patents for these complex products contended that devices were not packaging – rather they were integral to the approved dosage form. Responding to these comments in 2003, the FDA declined to categorically exclude patents covering devices. Rather, pointing to the Orange Book appendix that lists approved dosage forms, such as metred aerosols and prefilled drug delivery systems, the FDA found that the key factor was whether the patent claims the finished dosage form.

But the FDA's 2003 comments were largely its last words on the issue. Seeking additional clarity, a number of innovators asked the FDA to provide advisory opinions about whether certain categories of device patents were listable. In particular, among other related issues, innovators asked the FDA to clarify whether it was necessary for a patent to specifically claim or mention the active ingredient in the drug product. The FDA has not responded, however, and has not otherwise provided guidance to industry on this issue.

While the Agency has remained silent, the issue of whether patents are properly listed in the Orange Book more recently has started falling in the lap of courts. In 2020, the issue of whether a patent claiming "a drive mechanism in a drug delivery device" was properly listed for Sanofi's Lanus (insulin glargine) SoloSTAR product was determined by the First Circuit in the context of an antitrust litigation (In re Lantus Direct Purchaser Antitrust Litig., 950 F.3d 1 (1st Cir 2020)). In the Lantus case, antitrust plaintiffs contended that the alleged improper listing of the drive mechanism patent was anticompetitive conduct. The district court dismissed the complaint, but the First Circuit reversed the dismissal, finding that the patent-at-issue did not meet the listing criteria. The First Circuit commented that the patent did not claim, let alone mention, Lantus SoloSTAR or insulin glargine. Consistent with the FDA's 2003 comments, the First Circuit distinguished between a component in a device (like a drive mechanism) and the finished product itself (for example, the injector pen).

Notwithstanding the FDA's silence, the Federal Trade Commission has again turned up the heat on innovators, starting with its September 2023 policy statement. In the FTC's policy statement, it announced that it would scrutinise improper Orange Book listings and warned that improper listing could give rise to civil and criminal liability. But critically, the FTC did not articulate the standards for proper listing in its policy statement. Soon thereafter, the FTC issued two sets of challenges (November 2023 and April 2024) identifying specific innovators, products and patents that the FTC alleged were improperly listed. Simultaneously with these challenges, the FTC also initiated the FDA's patent information dispute pathway for the patents. In response to the FTC's challenges, some innovators voluntarily delisted the challenged patents.

Just weeks after the FTC issued its policy statement, Teva sued Amneal in the District of New Jersey for patent infringement of six patents listed in the Orange Book for ProAir® HFA (albuterol sulfate) inhalation aerosol. The patents generally were directed to the dose counter component of an inhaler – all patents that were challenged by the FDA just a few weeks later as improperly listed. In response, Amneal availed itself of Hatch-Waxman's counterclaim delisting provisions to seek an order requiring Teva to delete the patent information on the ground that the patents do not claim the drug for which the application was approved (see 21 USC Section 355(j)(5)(c)(ii)(II)). Teva moved to dismiss Amneal's delisting counterclaims and Amneal cross-moved for judgment on the pleadings.

At the district court level, Judge Chesler denied Teva's motion to dismiss and granted Amneal's cross motion, finding that the Orange Book patents were not listable. Judge Chesler found that the case turned on whether the patent claimed the drug for which the applicant submitted the application, as required by the Hatch-Waxman statute. Judge Chesler found that the drug for which Teva submitted its application was albuterol sulfate inhalation aerosol. Thus, according to Judge Chesler, patents claiming a dose counter component of an inhaler did not claim the drug for which Teva submitted the application – rather, it only claimed a component.

On appeal, Teva warned of far-reaching consequences if the Federal Circuit allowed Judge Chesler's opinion to stand. For example, Teva contended that Judge Chesler's logic would result in the delisting of many patents that are commonly accepted as properly listable, including patents claiming chemical genera, novel inactive ingredients or dosage forms, or patents claiming one of multiple active ingredients. To the extent that the Federal Circuit does not reach the listability of these types of patents, we may see that generic applicants become increasingly aggressive in asserting delisting counterclaims. Thus, the authors expect to see generic applicants seek to delist not only the types of patents that the FTC has challenged recently (eg, device patents) but also for any patent that does not expressly recite the active ingredient, such as for chemical genera and formulation platform patents.

In December 2024, the Federal Circuit affirmed the district court order delisting the challenged Orange Book patents (Teva Branded Pharm. Prods. R&D v Amneal Pharms. of NY, LLC, 124 F.4th 898 (Fed Cir 2024)). A unanimous panel rejected Teva's principal arguments. The Federal Circuit rejected Teva's argument that the statutory term "claims" was effective coterminous with an infringement analysis as well as Teva's argument that the definition of "drug" in the Federal Food Drug and Cosmetic Act contemplated that components of a drug were individually considered "drugs" under the statute. As of the time of submission, Teva has petitioned the Federal Circuit for en banc review of the panel's determination.

Innovators should anticipate challenges to Orange Book listing and prepare in advance. Such preparation should include a critical evaluation of the basis for listing all patents in the Orange Book. For many patents, the justification for listing is likely relatively straightforward. Special care should be taken to justify patents that are listed relating to device components of drug–device combination products. In addition, innovators should confirm the basis of listability for any patent that does not expressly claim the active ingredient, even if that patent is a type that has been commonly accepted as listable, such

as chemical genus patents, or formulation platform patents. Innovators should also consider having a strategic plan ahead of time should a generic applicant challenge an Orange Book patent, either through a delisting counterclaim during litigation or otherwise through the FDA's dispute mechanism.

Wands factors remain as a key test for enablement post-Amgen

The specification of a patent is required to provide "a written description of the invention, and of the manner and process of making and using it... as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same..." (35 USC Section 112(a)). This requirement is commonly referred to as the enablement requirement. Although the Supreme Court does not often hear patent cases, it revisited the enablement requirement last year in Amgen v Sanofi in the context of patent claims that broadly covered all antibodies that functionally meet certain binding requirements (antibodies that (i) bind to specific amino acid residues on PCSK9, and (ii) block PCSK9 from binding to LDL receptors) (Amgen Inc. v Sanofi, 598 US 594, 143 S. Ct. 1243 (2023)). The Supreme Court unanimously affirmed invalidity of these broad functional antibody claims for failure to meet the enablement requirement for the full scope of the claim.

The Court in Amgen reiterated that "[i]f a patent claims an entire class of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the entire class", or simply, "[t]he more one claims, the more one must enable." The claims in dispute in Amgen potentially encompass a vast number (at least millions) of antibodies. The specification described 26 antibodies and provided a step-by-step "roadmap" for how to identify additional antibodies within the scope of the claim. The Court analogised disclosure of the "roadmap" to a combination lock with 100 tumblers, each of which can be set to 20 different positions, and require significant amounts of trial-and-error to discover the successful combinations. The Supreme Court considered this type of disclosure to be no more than "a hunting license" for "random trial-and-error discovery", which is not enablement.

The Supreme Court's holding in Amgen suggests that broad functional claims are more susceptible to invalidity challenges for lacking enablement. Since the Amgen decision, the Court of Appeals for the Federal Circuit has invalidated broad genus claims in four out of five decisions applying the enablement standard under Amgen. In these post-Amgen decisions, the Federal Circuit extended the analysis of Amgen beyond antibody technologies and reinforced use of the Wands factors for evaluating the enablement requirement.

The first decision from the Court of Appeals for the Federal Circuit that applied the enablement standard post-Amgen is In re Starett, which is a non-precedential decision arising from the Patent Trial and Appeal Board ("the Board") affirming rejections by an examiner of pending claims before the United States Patent and Trademark Office (USPTO) (In re Starett, 2023 US App LEXIS 14231 (Fed Cir 2023)). The claims at issue in Starett are related to methods and machines for maintaining augmented telepathic data that includes data structures representing categories of biological signals in a body such as "Nervous System" and "Sensory System". The specification disclosed a broad and abstract organisational structure used to accomplish the maintenance of augmented telepathic data, but

provides little guidance as to what type of devices are encompassed by the claims and how the devices would function. Citing to Amgen, the Federal Circuit concluded that "[h]ere, much is claimed and little is enabled" and affirmed the rejections of the claims as lacking enablement. Although this first post-Amgen decision from the Federal Circuit is non-precedential, it provides a first glimpse that the ramifications of the Supreme Court's holding in Amgen may extend beyond antibody technologies.

Shortly after Starett, the Court of Appeals for the Federal Circuit, in a precedential decision, extended the Supreme Court's analysis from Amgen beyond antibodies technologies to invalidate a method of treatment claim that functionally claimed clinical results (Medytox, Inc. v Galderma S.A., 71 F.4th 990 (Fed Cir 2023)). In Medytox, Inc. v Galderma S.A., the claims at issue are directed to a method for treating glabellar lines using an animal-protein-free botulinum toxin composition that "requires a responder rate at 16 weeks after the first treatment of 50% or greater." The specification provided three examples of responder rates above 50% at 16 weeks: 52%, 61% and 62%. During proceedings before the Board, the patent challenger provided expert testimony indicating that achieving the claimed 16-week responder rates is unpredictable, and that one skilled in the art would not have been able to achieve responder rates significantly higher than the exemplified 62% responder rate using the claimed animal-protein-free botulinum toxin formulations without undue experimentation (Galderma S.A. v Medy-Tox, Inc., 2021 Pat. App. LEXIS 4717 (PTAB 2021)). Relying on Amgen's explanation that "[t]he more one claims, the more one must enable", the Federal Circuit affirmed the Board's finding that "the arguments and evidence were insufficient to demonstrate enablement to a skilled artisan because said artisan "would not have been able to achieve" responder rates higher than the limited examples provided in the specification" (Medytox, Inc., 71 F.4th at 999).

It was not a long wait to see the impact of Amgen in a subsequent antibody decision. In Baxalta Inc. v Genentech, Inc., the Federal Circuit affirmed the district court's summary judgment of invalidity of claims reciting an isolated antibody that binds Factor IX or Factor IXa and increases the procoagulant activity of Factor IXa for lacking enablement (Baxalta Inc. v Genentech, Inc., 81 F.4th 1362 (Fed Cir 2023)). The specification in Baxalta describes eleven antibodies with the two claimed functions and a hybridoma-and-screening process for identifying additional antibodies that meet the claimed functions. In rejecting the hybridoma-and-screening process as enabling disclosure, the Federal Circuit noted that "Amgen makes clear that such an instruction, without more, is not enough to enable the broad functional genus claims at issue here." Here, the court was looking for additional guidance from the specification, such as common delineating features or explanation of why the disclosed antibodies worked, to identify which antibodies would perform the claimed functions, but did not find such guidance in the specification.

In view of the lack of any additional guidance in the specification, the court concluded that "[t]he facts of this case are materially indistinguishable from those in Amgen." The Federal Circuit stated that the trial and error testing necessitated by the specification "leaves the public no better equipped to make and use the claimed antibodies than the inventors were" when they set out to discover them. While the court in Baxalta relied on Amgen as the basis for its holding of invalidity, the Federal Circuit clarified that Amgen did

not disrupt prior enablement case law, including the longstanding Wands factors.

In another non-precedential opinion, In re Pen, the Federal Circuit provided a further glimpse at the potential expanded applicability of Amgen to broad claims beyond antibody technologies (In re Pen, 2024 US App LEXIS 14235 (Fed Cir 2024)). The claims at issue in Pen were directed to a chemical composition, a polycylic metallole heteroatom rich conductive long chain polymer, having a particular chemical structure containing n number of repeating units, each unit containing a number of R groups where "R is any substituent, and x is the number of R substituents." In rejecting the claims at issue, the USPTO examiner applied the Wands factors and discussed reasons why a skilled artisan would not be able to make and use the claimed invention without undue experimentation. This rejection was upheld by the Board and affirmed by the Federal Circuit. The Federal Circuit relied on Amgen to explain that "[i]n short, the more you claim, the more you must explain", and affirmed the Board's rejection of the pending claims for lack of enablement.

Most recently, the Federal Circuit affirmed the district court's determination of enablement for claims to a pharmaceutical composition comprising a combination of valsartan and sacubitril or sacubitrilat (Novartis Pharms. Corp. v Torrent Pharma Inc, 2025 US App. LEXIS 486 (Fed Cir 2015)). Some recent district court decisions also shed some light on distinctions from Amgen that support a finding of enablement. For example, in Regeneron Pharma v Mylan Pharma, the district court held that claims for an ophthalmic formulation of a vascular endothelial growth factor (VEGF) antagonist was sufficiently enabled by the description provided in the patent specification (Regeneron Pharm., Inc. v Mylan Pharm. Inc., 714 F.Supp.3d 652 (N.D.W.Va. 2023)). The district court distinguished the facts of this case from Amgen because "[h]ere, in contrast, the claims are directed to formulations of a specific protein at a specific concentration – not "an entire kingdom" of proteins." The claims recite specific structures, and the specification provides examples and lists of excipients and amounts to use. The district court relied on expert testimony and applied the Wands factors to reach the conclusion that "the Defendants have failed to demonstrate by clear and convincing evidence that the asserted claims of the Product Patent are invalid for lack of enablement."

More recently, in Supernus Pharma v Torrent Pharma, the district court applied the Wands factors and held that claims directed to sustained release formulations of topiramate "which is released immediately and continuously upon administration from the formulation" and where the extended release component "exhibits a maximum plasma concentration of topiramate in vivo at 16 or more hours after a single initial dose" met the enablement requirement (Supernus Pharms., Inc. v Torrent Pharms. Ltd., 2024 US Dist LEXIS 49856 (DNJ 2024)). In upholding validity of the claims, the district court distinguished this case from Amgen in two meaningful ways: (i) the claims do not encompass an entire genus of release-controlled coatings regardless of physical characteristics or chemical properties; and (ii) expert testimony indicating that it would have been routine to adjust the coating precisely to achieve a desired release rate once a first in-vitro dissolution test has been conducted.

In view of the developing post-Amgen case law, patentees should anticipate invalidity challenges alleging lack of enablement and prepare litigation strategy in advance. Such preparation

should include a review of the claims asserted and the scope of species encompassed by the claims. In particular, consider whether the claims asserted recite structural elements in addition to functional limitations. The patentee should also conduct a thorough review of the specification to identify any guidance for identifying which species would fall within the scope of the claims and which species would not. As demonstrated in the district court cases discussed above, expert testimony can be probative in an enablement analysis. Therefore, patentees should also prepare ahead of time to present expert testimony and other evidence for each of the Wands factors in support of enablement.

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