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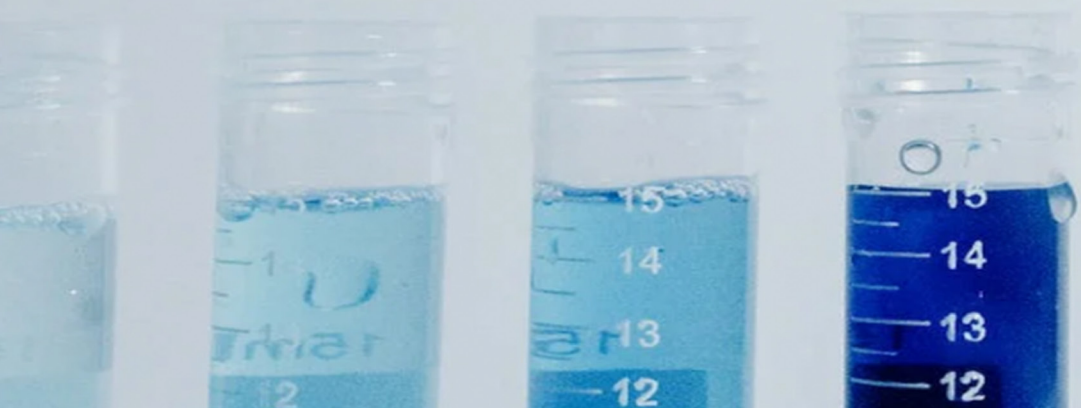
Japan: Trends and Developments

Kenji Tosaki and Takahiro Hatori
Nagashima Ohno & Tsunematsu



Trends and Developments

Contributed by:
Kenji Tosaki and Takahiro Hatori
Nagashima Ohno & Tsunematsu

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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/

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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.

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