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Recent Court Decision on (i) Scope of Medicinal Use Invention and (ii) Patent Linkage

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1. Introduction

In the field of pharmaceutical patents, a system known as "patent linkage" is introduced in numerous countries, and Japan is no exception. In general, the patent linkage system, in which regulatory authorities consider potential infringement of patents covering brand-name drugs during the approval process of their follow-on drugs (i.e., generics or biosimilars), helps prevent patent infringement disputes from occurring after the sale of follow-on drugs. Therefore, it is considered reasonable from the perspective of patent holders, as it efficiently protects their patent rights, and from the perspective of follow-on drug manufacturers, medical institutions and patients, as it ensures a stable supply of follow-on drugs.

However, the specific design and actual implementation of the system vary depending on the country. A key feature of the Japanese system is that it is not governed by law, and thus there is no expectation of obtaining a court judgement during the approval process. Instead, it is practically operated in accordance with an administrative notice (the "**Two Directors' Notice**")[1] issued by directors of Ministry of Health, Labour and Welfare (the "**MHLW**"). The MHLW reviews the relevant patents covering the brand-name drug based on the information provided by the brand-name drug manufacturers or patentees in a "drug patent information report sheet," which is not generally made public. If the MHLW believes that the follow-on drug would infringe the patents, it does not issue marketing authorization for the follow-on drugs.

The Tokyo District Court issued a decision on October 28, 2024 in a case involving a biosimilar manufacturer seeking a preliminary injunction against a patent holder (Samsung Bioepis Co. Ltd. v Bayer HealthCare LLC. (Case Number: 2024 (Yo) 30029, hereinafter referred to as the "**Subject Case**"). This decision addresses (i) the scope of protection for a medicinal use invention specified by its use for a specific group of patients, and (ii) whether a statement made by the patent holder to the MHLW regarding potential infringement during the patent linkage process may constitute "unfair competition" as defined in the Unfair Competition Prevention Act (the "**UCPA**"). In this newsletter, we provide an overview of the court's ruling.

2. Outline of the Subject Case

Bayer HealthCare LLC. (hereinafter referred to as "**Respondent**") owns the Japanese Patent No. 7320919 titled "Treatment of age-related macular degeneration with a small active choroidal neovascularization lesion" (hereinafter referred to as the "**Patent**"), which was registered on July 27, 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 (hereinafter referred to as the "**Certain Patients Group**"). Bayer Yakuhin, Ltd, an affiliate of the Respondent, started selling "EYLEA® solution for IVT inj. 40mg/mL"

1 The Two Directors' Notice states that the MHLW considers not only substance patents but also use patents (i.e., patents for use inventions), and that if there is a patent covering a part of the "indications and usage" and "dosage and administration" of a brand-name drug, and it is possible to manufacture a follow-on drug with "indications and usage" or "dosage and administration" not covered by the patent, the follow-on drug can be approved, except for the "indications and usage" or "dosage and administration" covered by the patent (a practice known as "skinny labeling").

(hereinafter referred to as the "**Respondent's Product**") in November 2012.

On the other hand, Global Regulatory Partners GK (hereinafter referred to as the "**GRP**") filed a marketing authorization application for a biosimilar correspondent to the Respondent's Product (hereinafter referred to as the "**Claimant's Product**") on May 31, 2023. The Claimant's Product was to be produced by Samsung Bioepis Co. Ltd. (hereinafter referred to as the "**Claimant**"). 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", which falls under wAMD, is included in the "indications and usage" of the Claimant's Product.

While GRP excluded wAMD from the "indications and usage" of the Claimant's Product based on MHLW's comments on November 9, 2023, there had been a meeting prior to that regarding GRP's application, involving the Claimant, GRP and the MHLW.

As the MHLW referred to the Respondent's opinion in the meeting, the Claimant asked the MHLW for details of the opinion. The MHLW responded by email, stating that the Respondent had provided a general opinion that if a marketing authorization for a biosimilar correspondent to Eylea is issued and the biosimilar is marketed, it would constitute an infringement of the Patent, in response to the MHLW's inquiry (The series of information-providing activities by the Respondent to the MHLW and the Pharmaceuticals and Medical Devices Agency (PMDA)[2] are referred to as the "**Statements**.").

The Claimant filed an application for a preliminary injunction with the Tokyo District Court, seeking to enjoin the Respondent from notifying the MHLW or the PMDA that the Claimant's Product infringes the Patent. The Claimant argued that the Statements constitute unfair competition as set forth in Article 2(1)(xxi) of the UCPA, and that the Claimant's business interests have been harmed by such unfair competition.

Article 2(1)(xxi) of the UCPA stipulates that an act of making or disseminating false statement that harms the business credibility of a business competitor constitutes unfair competition. In practice, if a statement is made to a third party claiming that a competitor infringes a patent, and a court later rules that the patent is not infringed, such a statement is considered a "false statement." The third party to whom the statement is made is typically a customer of the competitor, but in recent years, there have been cases where the reporting of infringement of intellectual property rights to an operator of a digital platform, such as an e-commerce site or SNS, has been disputed as a false statement.

3. Decision of the Court

The court rendered a decision dismissing the application for preliminary injunction on 28 October 2024 based in the following judgement.

3-1. Whether a statement made by the patent holder to the MHLW during the patent linkage process may constitute "unfair competition" under the UCPA

The court in charge of the Subject Case (hereinafter referred to as the "**Court**") acknowledged that a "drug patent information report sheet" is submitted voluntarily by the patent holder or the manufacturer of the brand-name drug as internal documentation for the MHLW and the PMDA, and that there are no particular restrictions on the content of the report, so stating their own opinion on whether or not the generic drug infringes the patent covering the brand-name drug is not prevented. The Court further acknowledged that, if a statement made by the patent holder to the MHLW regarding potential infringement during the patent linkage process is considered unfair competition in a case where a court later rules that the patent is not infringed, the patent holder would not be able to sufficiently state its opinion in the "drug patent information report sheet." Additionally, the Court pointed out that it is clear that patent linkage does not allow the patent holder of the brand-name drug to provide arbitrary information nor grant them broad exemption, since the purpose of patent linkage is to ensure a stable supply of follow-on drugs by considering whether the follow-on drug infringes the patent covering the brand-name drug during the approval process.

Based on this balance of interests, the Court indicated that the provision of false information constitutes unfair

2 The PMDA is an agency that conducts the scientific review of marketing authorization applications.

competition when it is made in order to place the applicant for marketing authorization of the follow-on drug in an unfavorable position and put the provider in a competitively advantageous position. In other words, while it is not immediately illegal to provide an opinion that the follow-on drug infringes the patent covering the brand-name drug, even if such opinion is later denied in a court decision, the provision of such an opinion can be regarded as unfair competition under the UCPA in cases where there are "special circumstances" that are recognized as being significantly lacking in reasonableness in light of the purpose of the patent linkage system.

The Court then proceeded to determine whether the Statements made by the Respondent were false.

3-2. Scope of protection for a medicinal use invention specified by its use for a specific group of patients

As mentioned in section 2 above, claim 1 of the Patent covers a pharmaceutical composition for use in the treatment of a specific group of patients. Some recent medicinal use inventions are defined not only by a disease but also by a specific group of patients having the disease, specified by conditions such as specific symptoms.

A "use invention" is understood as an invention characterized by the discovery of unknown properties in a known substance and the creation of a new application with remarkable effects based on those properties. It is generally understood that a patent covering a use invention is infringed only when the known substance is produced, used, sold, etc., for use in the new application. To determine whether the known substance is produced, etc., for use in the new application, courts examine whether there is a circumstance where it is objectively recognizable that the product is intended for the new, patented application, such as by attaching a label to the product indicating the application.

In the case of a medicinal use invention, whether the known substance is produced, etc., for use in the new application is generally determined by the information provided by the drug manufacturer, such as the contents of the package insert or the "interview form[3]."

In the Subject Case, the Court clarified that the patented invention is characterized by the discovery of unknown properties, specifically that the known VEGF inhibitor exhibits a better therapeutic effect in a specific group of wAMD patients (i.e., the Certain Patients Group) than in other wAMD patients, even though it had been known to be effective in the latter group. The Court then stated that the Patent is infringed when the VEGF inhibitor is produced, used, sold, etc., exclusively for administration to the Certain Patients Group.

The Court proceeded to apply the criterion to the Subject Case. The Court found that the draft package insert of the Claimant's Product does not mention the Certain Patients Group in either the "indications and usage" or "dosage and administration" sections, nor does it mention that the drug exhibits a remarkable effect when administered to the Certain Patients Group. Based on the above, the Court found that the application for marketing authorization for the Claimant's Product was not made for administration to the Certain Patients Group as recited in the claim, and that there were no special circumstances indicating the probability of the Claimant's Product being sold for a use other than those described in the application for marketing authorization.

The Court additionally stated that, since the Respondent's Products had been sold and administered to the Certain Patients Group prior to the priority date, the patented invention was publicly used prior to the priority date, and therefore, the Patent should be invalidated.

Therefore, the Court concluded that the Claimant's Product does not infringe the Patent and that the Statements stating that the Claimant's Product would infringe the Patent were false.

3-3. Whether there were any special circumstances that were recognized as being significantly lacking in reasonableness in light of the purpose of the patent linkage system

Since the Court concluded that the Statements were false, the Court proceeded to determine whether there were "special circumstances" that were recognized as being significantly lacking in reasonableness in light of the purpose of the patent linkage system.

3 An interview form is a document containing detailed information about a drug, prepared by the company that obtained marketing authorization for the drug, to supplement the package insert.

In determining whether there were such "special circumstances," the Court pointed out the following factors:

- The Respondent's view that the Claimant's Product infringes the Patent on the grounds that the patients to whom the Claimant's Product is administered include the Certain Patients Group is not apparently contrary to existing Supreme Court precedents.

- The Respondent argues that, while the marketing of the Respondent's Products prior to the priority date does not constitute public use, the marketing of the Claimant's Product constitutes infringement of the Patent due to changes in common general knowledge after the priority date. It could not be said that such an argument was immediately unreasonable because the determination of such common general knowledge would be a core issue in determining whether the Patent is infringed, and a full trial is necessary to determine such common general knowledge.

- There were no judicial precedents addressing whether the provision of information by the brand-name drug manufacturer or patent holder during the patent linkage process constitutes unfair competition under the UCPA.

- Parallel infringement lawsuits have been filed in various countries, and the Subject Case is a part of the global dispute, so it was unavoidable for the Respondent to respond that the Patent would be infringed when inquired by the MHLW and the PMDA.

Based on these factors, the Court held that there were no "special circumstances" that were recognized as being significantly lacking in reasonableness in light of the purpose of the patent linkage system, and concluded that the Statements does not constitute unfair competition.

4. Comments

This decision is the first court ruling to address either of the two issues: (i) the scope of protection for a medicinal use invention specified by its use for a specific group of patients, and (ii) whether a statement made by the patent holder to the MHLW regarding potential infringement during the patent linkage process may constitute "unfair competition" as defined in the UCPA. Therefore, this decision is significant. On the other hand, this is a decision by a court of first instance made in a preliminary injunction proceeding, and a later court may apply a different legal standard. We will provide an update if there is any material progress.

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