NEWSLETTER

Recent Tokyo District Court Decision: Does Patent Information Disclosure under Japan's Patent Linkage System Violate the Unfair Competition Prevention Act?

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Japan's current patent linkage process for generics/biosimilars allows innovator-patent holders for innovative drugs to provide relevant patent information about active pharmaceutical ingredients to the regulatory authorities on a voluntary basis. This case involved an argument by Samsung Bioepis Co., Ltd. ("Samsung"), a generic/biosimilar company, that the provision by Bayer HealthCare LLC ("Bayer"), the patent holder and manufacturer of the innovative pharmaceutical product aflibercept, of information to the Ministry of Health, Labour and Welfare (MHLW) claiming that a Samsung biosimilar product infringed a Bayer patent (Japanese Patent No. 7320919) ("919 Patent") constituted unfair competition under Article 2, Paragraph 1, Item 21 of the Unfair Competition Prevention Act (UCPA). Samsung sought a preliminary injunction to stop Bayer from providing information to the MHLW.

On October 28, 2024, the Tokyo District Court held that while Bayer's provision of inaccurate information was considered a false statement, it was not deemed significantly unreasonable when viewed in light of the purpose of the patent linkage system. Therefore, the court rejected Samsung's request (Case No. 2024 (*Yo*) 30029).

It has been pointed out that Japan's patent linkage system does not have a legal basis and lacks transparency and fairness. This Tokyo District Court decision clarified for the first time that in the course of approval review of a generic drug/biosimilar, a generic/biosimilar manufacturer can request that the court rule on alleged infringement of a patent for an innovative drug and the validity of the relevant patent by asserting "unfair competition" under the UCPA with respect to information on substance and use patents that the innovator-patent holder voluntarily provides to the MHLW.

I Background

In Japan, since November 2012, Bayer Yakuhin, Ltd. (a Bayer subsidiary) has been marketing the pharmaceutical product "EYLEA® Solution for Intravitreal Injection 40mg/mL," which contains aflibercept (a recombinant fusion protein that combines the Fc domain of human IgG1 with the extracellular domain of the human VEGF receptor) as its active pharmaceutical ingredient, as an innovative drug. The current indications for this product include the treatment of (i) age-related macular degeneration associated with subfoveal choroidal neovascularization (AMD), (ii) macular edema associated with retinal vein occlusion, (iii) choroidal neovascularization in pathologic myopia, (iv) angiogenic glaucoma, and (v) retinopathy of prematurity.

Samsung filed a marketing authorization application for aflibercept as a biosimilar to Bayer's EYLEA®, which was approved on June 24, 2024. The approval was granted for the limited indications of (i) macular edema associated with retinal vein occlusion, (ii) choroidal neovascularization in pathologic myopia, and (iii) angiogenic

glaucoma, and the indication of AMD was withdrawn considering Bayer's use patent provided to the MHLW during the course of the patent linkage process.

Under Japan's patent linkage system, the "Drug Patent Information Report" submitted to the MHLW by innovator companies is used to assess whether there is patent infringement between original drugs and generics/biosimilars and to determine whether to approve generics/biosimilars. Innovator companies are not precluded from providing their views on patent matters to the MHLW when submitting this report.

In this court case, Samsung sought a preliminary injunction to stop Bayer from providing patent information to the MHLW. Samsung argued that Bayer's actions, which involved submitting to the MHLW during the patent linkage process information on the potential infringement of a Bayer patent by the biosimilar product EYLEA®, constituted unfair competition under Article 2(1)(xxi) of the UCPA.

II Court Decision

After establishing the criteria for determining whether a patentee of an original drug making a false statement about infringement of a patent on innovative drugs by generic drugs under the patent linkage system constitutes unfair competition, the court ruled that Bayer's provision of inaccurate patent information to the MHLW in this case involved a false statement. However, considering the facts and circumstances of the case, the court found that Bayer's actions could not be deemed "significantly unreasonable" in light of the purpose of the patent linkage system. The court concluded that Bayer's provision of patent information did not fall within the category of unfair competition, as defined in Article 2(1)(xxi) of the UCPA. As a result, the court found Samsung's argument to be baseless and denied its request for a preliminary injunction.

In particular, the Tokyo District Court held that:

● Criteria – Whether Information Provision under the Patent Linkage System Constitutes Unfair Competition under the UCPA

"In Japan, patent linkage refers to the process by which the MHLW collects information on substance patents or use patents related to the active pharmaceutical ingredients of approved drugs to ensure a stable supply of generic drugs, based on MHLW notices. From the perspective of ensuring a stable supply of generic drugs, the MHLW gathers this information and assesses whether generic drugs infringe the patents on the original drugs during approval reviews under the Pharmaceuticals and Medical Devices Act (PMD Act).

According to the aforementioned MHLW notice, the patentee of a substance or use patent, or a party that has obtained approval for a pharmaceutical product containing the active pharmaceutical ingredient covered by such a patent, is required to fill out and voluntarily submit a Drug Patent Information Report form. The notice also specifies that a generic drug will not be approved in the approval review process under the PMD Act if the manufacture of the active pharmaceutical ingredient of the original drug is not possible due to the existence of a patent on the active ingredient, or if a patent exists on certain indications of the original drug and it is not possible to manufacture a drug that claims other indications. However, if a patent exists for specific indications of the original drug but it is possible to manufacture a drug for other indications, the generic drug may still be approved.

As described above, the Drug Patent Information Report form is voluntarily submitted by the patentee of an original drug as an internal document for the MHLW to assess whether a stable supply of generic drugs can be ensured when an application for marketing authorization for a generic drug is made. There are no specific restrictions on what is to be stated in the form, and its submission does not prevent the patentee from expressing its own opinion on whether or not a generic drug infringes the patent on the relevant innovative drug.

On the other hand, it is clear that when a person in a competitive relationship states or disseminates a false fact that harms a competitor's business reputation, it puts the competitor at a disadvantage and could be considered an attempt to gain an unfair advantage, thereby impeding fair competition. From the perspective of preventing such outcomes and ensuring fair competition, Article 2(1)(xxi) of the UCPA defines these actions as a form of unfair competition. Since there is a competitive relationship in the drug market between the patentee of an original drug and a party applying for approval to manufacture and sell a generic drug, if, under patent linkage, the patentee were to assert that a generic drug infringes the patent on the relevant innovative drug—contrary to a subsequent court decision—the patentee could be liable for a fine up to the amount of the generic drug's price. If the act of claiming that a generic drug infringes the patent on an innovative drug were immediately deemed illegal as a notification of a false fact, the patentee would be unable to express its views on the existence of patent infringement in full in the Drug Patent Information Report form. As a result, the MHLW would not be able to determine appropriately whether a stable supply of generic drugs can be ensured, which could undermine the purpose of the patent linkage system.

However, since the purpose of patent linkage is to check for patent infringement between the patents on original drugs and generic drugs during approval examinations of generic drugs, with the aim of ensuring a stable supply of generic drugs, it does not permit arbitrary provision of information by patentees of original drugs, nor does it grant broad immunity to patentees. Therefore, it is clear that the approval review process is not intended to allow arbitrary information provision by patentees of original drugs or to grant patentees broad immunity.

Thus, if the patentee of an original drug falsely claims that a generic drug infringes the patent on the innovative drug in an attempt to disadvantage the applicant for marketing authorization of the generic drug and gain a competitive advantage, while outwardly appearing to provide information under patent linkage, such an act is considered an obstacle to fair competition and a violation of Article 2(1)(xxi) of the UCPA. It is reasonable to conclude that these actions constitute a form of unfair competition in light of the purpose and intent of Article 2(1)(xxi) of the UCPA, as its hinders fair competition among business operators.

In light of the foregoing, if the patentee of an innovative drug, in the context of patent linkage, provides a false statement claiming that a generic drug infringes the patent on the relevant innovative drug, and there are special circumstances in which such a false statement is deemed significantly unreasonable in light of the purpose of patent linkage, that act is considered to constitute unfair competition under Article 2(1)(xxi) of the UCPA as it involves providing false information that harms the business reputation of a competitor applying for approval to market a generic drug."

● Does Patent Information Provision Constitute Unfair Competition?

"Samsung's product is essentially a biosimilar to Bayer's product, and the draft package insert for Samsung's

product that was submitted with the marketing approval application mentions only “age-related macular degeneration with subfoveal choroidal neovascularization” (AMD) as an indication. There are no descriptions related to the specific patient group in the [Indications and Effects] or [Dosage and Administration] sections, and there are no indications suggesting that the product has a significant effect when administered to the specific patient group in question.

Based on the facts above, it cannot be said that an application has been filed for marketing approval for Samsung’s product to be administered to the patient group defined by the requirements A2, B, and C of this invention.

In this case, even from all of the prima facie evidence, there is not enough evidence to clearly recognize the existence of special circumstances making it probable that Samsung will market the product for a use different from that for which the application for marketing approval was filed.

Under these circumstances, Samsung’s marketing of its biosimilar product cannot be regarded as an act of producing, using, or distributing an anti-VEGF agent exclusively for administration to the specific patient group in question. Therefore, it is insufficient to conclude that it infringes the 919 Patent.

Even if Bayer’s view is that the marketing of Samsung’s product infringes the 919 Patent on the grounds that Samsung’s product may be administered to a certain percentage of the specified patients, Samsung’s product, based on the aforementioned facts, is a biosimilar to Bayer’s product and is equivalent to and homogeneous with Bayer’s product. It is clear that the marketing for Bayer’s product makes it a publicly worked invention, as defined in Article 29(1)(ii) of the Patent Act, and therefore, the 919 Patent should be invalidated.

Therefore, Bayer’s provision of inaccurate information to the MHLW, claiming that Samsung’s product infringes the 919 Patent, is considered a false statement.”

● Existence of Special Circumstances Significantly Contrary to Japan’s Patent Linkage System?

“As explained above, the Drug Patent Information Report in the context of patent linkage is considered an internal document provided to the MHLW for it to assess whether a stable supply of generic drugs can be ensured. Providing a response contrary to the court’s decision on the existence of patent infringement before that decision is finalized is not immediately illegal.

Based on the aforementioned premise and the specifications, both the original biologic (Bayer’s product) and the follow-on biologic (Samsung’s product) are intended for the same indication (wet-AMD). The target patient groups for both products necessarily include the target patient group of the invention (the specific patient group). Therefore, it is acknowledged that at least part of Samsung’s product is used for the specified patient group.

Based on Bayer’s view of the sufficiency of the constituent features of the use patent invention (though it is unique argument), it still constitutes a valid claim of patent infringement. Given that no Supreme Court ruling has explicitly excluded this view, it cannot be asserted that Bayer’s perspective immediately is an invalid allegation.

From this Bayer's perspective, as to the sufficiency of the constituent features of the use patent invention, Bayer would argue that the marketing of its product prior to the priority date does not constitute open working of the 919 Patent, but that subsequent changes in technical common knowledge have resulted in the marketing of generic products that satisfy the constituent features of the 919 Patent. In this case, the changes in technical common knowledge becomes the central issue. It is essential to make a decision based on the expert knowledge of a person skilled in the art. Therefore, it cannot be said immediately that Bayer's argument is invalid, especially at a stage in which full trial proceedings have not yet been conducted, including exhaustive arguments on the merits and the appointment of expert committee members to assess its expert knowledge. Moreover, there have been no court decisions on whether the provision of information by patentees in the patent linkage process constitutes a false notification under the UCPA, nor has a judicial standard been established for similar cases. Additionally, given that similar patent infringement lawsuits have been filed globally regarding the relationship between the 919 Patent and biosimilar products, this case is part of those global disputes. Therefore, it can be argued that Bayer's submission of this patent report to the MHLW, reflecting its own viewpoint, was unavoidable.

Considering the various circumstances in this case, while Bayer's act of submitting this patent report may be criticized as thoughtless, it cannot be deemed significantly unreasonable in light of the purpose of patent linkage, unless the report is repeated in the future. Accordingly, the special circumstances mentioned earlier cannot be established.

Therefore, Bayer's act of issuing this notice does not constitute unfair competition under Article 2(1)(xxi) of the UCPA."

III Comments

Patent linkage is generally understood to be a system that takes into account the valid patent rights of an original drug when the pharmaceutical regulatory authorities grant marketing approval for a generic drug/biosimilar product. In Japan, there is no explicit legislation for patent linkage; however, the MHLW provides and operates a certain patent linkage system on the basis of the MHLW notice dated 5 June 2009 by setting the following requirements for reviewing marketing approval applications for generic drugs:

- the active pharmaceutical ingredient of the original drug is not protected by a valid patent (substance patent); and
- the indications, dosage, and administration of the original drug are not protected by a valid patent (use patent).

This Japanese patent linkage system has been said to have many issues, particularly in terms of transparency and fairness. Under this system, it has been considered that, before the MHLW determines whether a generic drug/biosimilar product should be approved, there is no opportunity for a generic drug/biosimilar company to claim non-infringement of the patent for the innovative drug or to challenge the validity of the patent before a court. A generic drug company filed a lawsuit against the patent holder of an original drug to confirm that the patent holder did not have the right to demand an injunction and that there was no infringement of patent rights, but the Tokyo District Court, on August 30, 2022 (Case No. 2021 (*Wa*) 13905), and its appeal court, the Intellectual Property High Court, on May 10, 2023 (Case No. 2022 (*Ne*) 10093), denied the standing of the

generic company and dismissed the case without prejudice; as a result, there is no avenue for generic manufacturers to obtain a court decision on patent infringement before obtaining marketing approval by the MHLW.

This Tokyo District Court decision is important and novel in that the court found that in the course of approval review of a generic drug/biosimilar, a generic/biosimilar manufacturer can request that the court rule on alleged infringement of a patent for an innovative drug and on the validity of the patent by asserting “unfair competition” under the UCPA with respect to information on substance and use patents that the innovator-patent holder voluntarily provides to the MHLW. Consequently, for generic/biosimilar manufacturers, if they are informed of the patent information provided by patent holders to the MHLW in the Drug Patent Information Report, they can consider claiming non-infringement or challenging the validity of the patents listed in the report before a court, and for innovators/patent holders of original drugs, they need to carefully consider the relevant patent rights to be listed in the report.

Currently, the MHLW is considering incorporating into the patent linkage system a mechanism for consulting experts in patent law to obtain their opinions. It is necessary to carefully monitor future developments with regard to the MHLW’s operation of the current patent linkage system.

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