Decisions on Combination Drug Patent Infringement

August 18, 2025
Michiko UEHARA (Partner, Patent Attorney)
Seiwa Patent & Law (Tokyo, Japan)

Abstract

In March 2025, the IP High Court handed down a decision on a patent infringement lawsuit. The patent owner, holding rights to a combination drug containing multiple ingredients, sued a surgeon who had used several drugs containing constituent ingredients of the patented combination drug in breast augmentation surgery. The Court found that the surgeon had mixed all the ingredients prior to administration, which constituted the "production" of the patented combination drug. It further held that the surgeon was not exempt from patent enforcement because the surgery was performed for cosmetic, rather than therapeutic purpose. This ruling reversed the Tokyo District Court's decision, which had found no infringement. This article outlines both decisions and discusses issues relating to combination drugs and cosmetic/medical procedures.

****

CONTENTS

****

I. The first instance (Reiwa 4 (Wa) 5905, Tokyo District Court)

Tokai Medical Co., a Japanese company (hereinafter "Plaintiff/Appellant"), is the owner of Japanese Patent No. 5,186,050, which relates to a composition comprising plasma, a growth factor, and a fat emulsion. A surgeon (hereinafter "Defendant/Appellee") performed a breast augmentation surgery by administering a mixture of plasma, a growth factor, and other components (hereinafter "Agent A") together with a drug containing an emulsifier and other components (hereinafter "Agent B"). The Plaintiff filed a lawsuit against the surgeon in the Tokyo District Court, seeking damages on the grounds that the Defendant's acts infringed on the patent. The Plaintiff argued that the Defendant's conduct constituted the "production" of the inventions according to Claims 1 and 4 of Patent No. 5,186,050.

1. A composition for promoting subcutaneous tissue growth, comprising autologous plasma, basic fibroblast growth factor (b-FGF), and a fat emulsion.
4. A composition consisting of the composition for promoting subcutaneous tissue growth according to any one of claims 1 to 3, for promoting the growth of subcutaneous tissue.

The Defendant argued that: (i) Agents A and B were administered separately to the patient in order to avoid coagulation and increased viscosity that would result from mixing the agents in advance, accompanied by the submission of an experimental report; (ii) the Defendant's act constituted a medical procedure, which should be exempt from patent enforcement under Article 69, Paragraph 3 of the Patent Act[i] (exemption provision for dispensing medicines, hereinafter "Article 69(3)"); and (iii) the patent should be invalidated for lack of industrial applicability under Article 29, Paragraph 1, the main paragraph of the Patent Act[ii] (provision on patent eligibility, hereinafter "Article 29(1) main para").

The court found that Agents A and B had been administered separately, and dismissed the plaintiff's claim on that basis of point (i), without making any decision on points (ii) and (iii).

Dissatisfied with the decision, the Plaintiff then appealed to the IP High Court.

II. The second instance (Reiwa 5 (Ne) 10040, IP High Court)

1. Main points

Point 1: Whether the preparation of drugs by the surgeon (hereinafter "Appellee") for use in surgery constituted the "production" of the patented invention.
Point 2: Whether there were grounds for invalidation of the patent, such as lack of industrial applicability under Article 29(1) main para.
Point 3: Whether the Appellee's acts should be exempt from patent enforcement under Article 69(3).
Point 4: How damages should be calculated in the event that infringement is found.

2. Appellant's arguments

Point 1: The experimental report submitted by the Appellee could not be relied upon to establish that mixing Agents A and B would cause problems such as coagulation, given inconsistencies in the instructions and explanations provided to nurses and patients at the time of administration. Furthermore, even assuming that Agents A and B had been administered separately, the Agents would mix inside the body to form a composition falling within the scope of the patented invention, and thus the Appellee's act should be deemed to constitute the production of the patented composition.
Point 2: Even if the composition contains a biological substance such as plasma collected from a human body, the collected blood is merely used as a material to produce the composition, and the act of collecting the blood is not part of the production of the patented composition.
Point 3: The term "medicine" in Article 69(3) is defined as a substance to be used for diagnosis, therapy, treatment, or prevention of diseases of diseases. Since the patient undergoing the breast augmentation surgery was a healthy individual, the present invention does not fall within the "medicine" as defined in Article 69(3).
Point 4: Article 102, paragraph 2 of the Patent Act[iii] (provision on presumption of lost profits; hereinafter "Article 102(2)") should be applied in calculating the amount of damages.

3. Appellee's arguments

Point 1: Agents A and B had to be administered separately, as mixing them in advance would cause coagulation and other issues. Even if Agents A and B were to mix within the body, enforcing the patent right against such surgical procedures would be extremely unfair.

Point 2: It is inevitable, in producing the patented composition, to collect blood for obtaining autologous plasma. Moreover, the composition is intended for subcutaneous administration. Therefore, the patented invention is essentially directed to a series of medical procedures, namely, blood collection, preparation of the composition, and administration, which constitutes a ground for invalidation under Article 29(1) main para.

Point 3: Even assuming that Drugs were deemed to have been mixed prior to administration, the patented invention relates to a cosmetic medicine, which contributes to mental and physical health through restoration of physical features. Accordingly, the Appellee's act should be exempt from the enforcement of the patent right under Article 69(3).

Point 4: Article 102(2) should not apply, on the grounds that the Appellant did not conduct the patented invention, and therefore suffered no lost profits as defined in Article 102(2).

4. Court decisions

Point 1: The court overturned the prior appeal decision, finding the experimental results lacked credibility in light of other evidence, such as the instructions given to nurses, and held that Agents A and B had been mixed before administration, thereby constituting the production of the patented composition.

Point 2: The court determined that a product invention cannot be interpreted as an invention of a medical method, and that the acts of blood collection, preparation of the composition, and administration are not inseparable. In addition, the court noted the necessity of patent protection for regenerative medicines.

Point 3: The court held that the composition within the scope of the patented invention was used not for diagnosis, therapy, treatment, or prevention of diseases, but for breast augmentation for cosmetic purposes. Accordingly, the court concluded that Article 69(3) was not applicable, and that the Appellee could not be exempt from the enforcement of the patent right.

Point 4: The court found that there was no evidence to establish that the Appellant held an exclusive ordinary license, and therefore declined to apply Article 102(2). Instead, the court applied Article 102(3)[iv](provision on reasonable royalty) and ordered the Appellee to pay approximately 15 million yen, calculated based on 8% of sales, together with attorney's fees and other related costs.

III. Solicitation of third party opinions (Japanese Amicus Brief) and issues of this case

The IP High Court, utilizing the system for soliciting third party opinions, sought public comments. This solicitation attracted attention as it was the second solicitation, following Dwango v. FC2 (IP High Court, Case No. 2022 (Ne) 10046). Opinions were submitted by a broad range of entities and individuals, from the Japan Federation of Bar Associations to

individual medical professionals. The present case highlights issues in relation to combination drug, dispensing medicines, and cosmetic/medical procedures.

1. Issues about Combination Drug

A question was raised as to whether it constitutes the production of a combination drug if the constituents thereof are administered separately but mixed inside the body.

Two opposing views emerged. One view was that such a case falls within the production of the patented invention and that the patent right should therefore be enforceable. The other view was that the patent right should not be enforced, since a combination drug produced within the body cannot be sold and is therefore difficult to exploit commercially.

No judgment has been made on this point in the IP High Court. However, if claims are drafted to cover either Agent A or Agent B, for example as follows, the patent right could be enforceable with respect to each individual drug. Care must therefore be taken when drafting claims of a combination drug.

1. A composition comprising Agent A, wherein said composition is used in combination with Agent B.
2. A composition comprising Agent B, wherein said composition is used in combination with Agent A.

2. Issues about Patentability of Invention of Medical Method

Under the Examination Guidelines, “methods for surgery, treatment, or diagnosis of human body” are regarded as an industrially inapplicable invention set forth in Article 29(1), serving as an upstream regulation that renders an invention directed to a medical method unpatentable.

Most of the submitted opinions addressed the need for downstream regulation, for example, the introduction of an exemption provision should be adopted so as not to discourage healthcare professionals from performing such procedures in clinical practice. However, the court did not discuss legislative measures as a downstream regulation.

3. Issues about Invention of Medicines

Although medical methods are unpatentable, product inventions such as medicines, drugs, and compositions are patentable. However, the act of dispensing medicines may be exempt from the enforcement of such patents under Article 69(3), which constitutes a downstream regulation. The purpose of this regulation is to protect human health.

In this regard, a question was raised as to whether Article 69(3) should be applied to acts of dispensing medicines for cosmetic purpose.

Regarding this issue, there were differing opinions. Some argued that the enforcement of the patent right should be denied, as it would be unreasonable to expect doctors to consider patent enforcement during medical procedures, while others were in favor of enforcing the

patent right.

However, it is difficult to draw a clear line between cosmetic and health-related purposes. Although the purpose of the breast augmentation surgery in this case was determined to be cosmetic, it remains unclear how to assess cases such as breast reconstruction surgery following breast cancer resection or breast augmentation performed as a treatment for dysmorphophobia.

4. Issues about Regenerative Medicines

The Appellee also argued that the patented invention is not industrially applicable, as the patented composition uses plasma that inevitably requires a medical procedure to collect blood from the human body.

In this regard, most opinions were that the scope of patentable inventions should not be restricted for such regenerative medicines, so as to promote industrial development in the medical field. The court also clearly indicated the necessity of patent protection for regenerative medicines, implying its intention to ensure their protection as products.

IV. Comments

Notably, the case established that even a physician's act cannot be exempt from liability for infringement of a product patent if the purpose of the act is deemed unrelated to health. While this is advantageous for the patent holder, the difficulty lies in the fact that the boundary between medical and cosmetic purposes remains unclear, and no decision was rendered on the issue of whether a combination drug is "produced" when its constituents are administered separately but mixed inside the body. However, the issue regarding combination drugs could have been avoided if the claims had been drafted to cover each constituent individually.

END

---

[i] Article 69, Paragraph 3 provides an exemption from the effects of a patent right for acts of preparing a medicine by dispensing multiple medicines for diagnosis, therapy, treatment, or prevention of diseases performed by a physician or dentist or a person acting under their direction. This provision is intended to allow medical professionals to prepare medicines in the course of providing medical care without infringing a patent.

[ii] Article 29(1) main para sets forth the requirement for patent eligibility that an invention must be "industrially applicable". In the context of medical acts, the Examination Guidelines state that methods for medical activities performed on the human body for the purpose of diagnosis, treatment, or surgery are not considered "industrially applicable" under Article 29(1) main para.

[iii] Article 102(2) provides a legal presumption for calculating damages in patent infringement cases. If the patent owner could have earned profits but for the infringement, those profits are presumed to represent the amount of damages.

[iv] Article 102(3) provides that, when calculating damages for patent infringement, if the provisions of Article 102(1) or (2) do not apply, the patentee may claim an amount equivalent to a reasonable royalty as damages.