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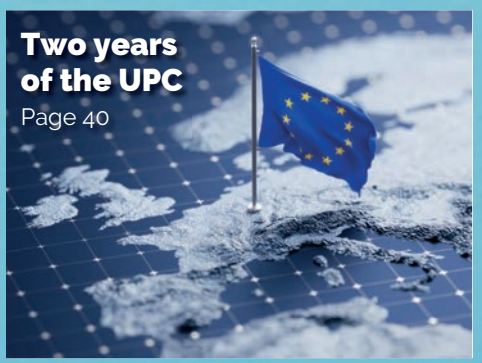
Improvement to the patent term extension system for drug patents in China

ASIA PACIFIC Law firm RANKINGS

Eddie Zheng and Dawn Chen of Corner Stone & Partners examine the dual impact of China's patent term extension system on pharmaceutical R&D and innovation and offer policy recommendations for its improvement.

An interview with Ceres Power
Page 22

Dr Thaler's AI legal battle
Page 26



Two years of the UPC
Page 40

CTC Legal Media

The gray area between patent rights and physician practice

Osamu Yamamoto of Yuasa and Hara examines the recent Intellectual Property High Court decision on a patent infringement case involving a "composition for breast augmentation," emphasizing the importance of balancing healthcare practices with robust patent protection.

Impact of recent IPHC decision

In Japan, an invention of a therapeutic method is deemed not to meet the requirements of industrial applicability and thus is not patentable. As a result, it is common practice to claim an invention of a product, for example, a use-limited pharmaceutical composition. Thus, regardless of whether an invention is essentially directed to a method, it is necessary to draft a claim for an invention of a "product."

The decision of the Intellectual Property High Court (IPHC) issued on March 19, 2025, Case No. 2023 (Ne) 10040, relates to a patent infringement case involving an "invention of a composition for breast augmentation." Aside from the fundamental issue of whether a cosmetic medical procedure carried out by a physician infringes a patent right of a use-limited composition, the decision will have a significant impact on patent practice in the fields of medicine and cosmetics in the future; namely, with respect to fulfillment of patentability requirements of "industrial applicability" and the interpretation of "limitations of patent right against dispensing practices."

Osamu Yamamoto

A high level of interest in this case is apparent. First, the IPHC designated the case as a Grand Panel case, a system in which a panel of five judges hears cases involving particularly important intellectual property rights. Second, the IPHC applied the third-party opinion solicitation system, which is the Japanese version of the Amicus Brief System.

Summary of the case

The patentee, Kabushiki Kaisha Tokai Ika, has a patent right (Patent No. 5186050) titled: "Composition for promoting increase of subcutaneous tissue and subcutaneous fatty tissue." The patent relates to "a composition for breast augmentation" that contains autologous plasma, b-FGF (Basic Fibroblast Growth Factor), and a lipid emulsion. Namely, the composition of the patent comprises three ingredients.

The patent at issue is the invention of Claim 4, which is dependent on Claim 1 and reads as follows:

"A composition for promoting increase in subcutaneous tissue that is used for breast augmentation characterized in that it comprises autologous plasma, a basic fibroblast growth factor (b-FGF), and a lipid emulsion."

In this connection, physician Y, the alleged infringer, had performed a cosmetic breast augmentation treatment. The patentee filed a lawsuit before the Tokyo District Court (TDC), claiming compensation for damages against Y under Article 709 of the Civil Code and Article 102 (2) (3) of the Patent Act on the grounds that the

Résumé

Osamu Yamamoto is a patent attorney and a partner of Yuasa and Hara, Japan. He is the acting Chief of the Life Science and Chemistry group of the Patent Division. Osamu has approximately 25 years of experience in intellectual property, with a focus on patents, including drafting patent applications, providing expert opinions, and defending or challenging patent rights. He has represented a variety of companies in the fields of biotechnology, pharmaceuticals, diagnostics, and food and beverages. Osamu often gives lectures on patents. Before specializing in IP, he gained 10 years' experience working in pharmaceutical and biotechnology research and development for a chemical company.

composition for breast augmentation manufactured by Y falls within the technical scope of the patented invention.

The Plaintiff asserted that the Defendant (Y) manufactured a composition comprising all three components and then administered the composition to a person to be treated for breast augmentation treatment. In response, Y asserted that Y manufactured two different pharmaceutical compositions, each comprising only a part of these three components, and administered them separately to patients; thus, Y did not manufacture the composition falling within the technical scope of the invention.

The TDC denied the infringement of the patent on the grounds that Y could not be found to have administered the three components simultaneously. The patentee then brought the case to the IPHC.

IPHC Grand Panel decision and its significance

Infringement

The IPHC (the court of appeal) overturned the TDC ruling and found that the act of physician Y constituted an infringement of the patent right, ordering Y to pay approximately JPY 15 million as an 8% royalty rate compensation for the infringement.

The IPHC confirmed that Y formulated and administered a composition containing three components simultaneously to patients, taking into account the description of the drug notebook prepared at the clinic, statements from nurses, and Y's testimony at trial. Consequently, the IPHC judged that Y was found to have produced a composition within the technical scope of the invention.

Validity of a patent

Y asserted that although the claim is described as a product invention, it is essentially a "method invention for breast augmentation surgery," and therefore does not satisfy the patentability requirements of industrial applicability (Principal clause of Article 29(1) of the Patent Act). The rationale is that the invention comprises a series of acts for breast augmentation surgery: blood collection by a physician, manufacture of the composition, and administration of the manufactured composition by the physician under the recipient's skin.

The IPHC judged that the fact that the composition is for administration to a human body does not mean that the invention should be regarded as a method invention for medical application. In addition, the IPHC emphasized that the act of manufacturing pharmaceuticals, etc., using materials collected from the human body as raw materials is not necessarily carried out by physicians, and that there is a need for patent protection to promote technological progress in the field.

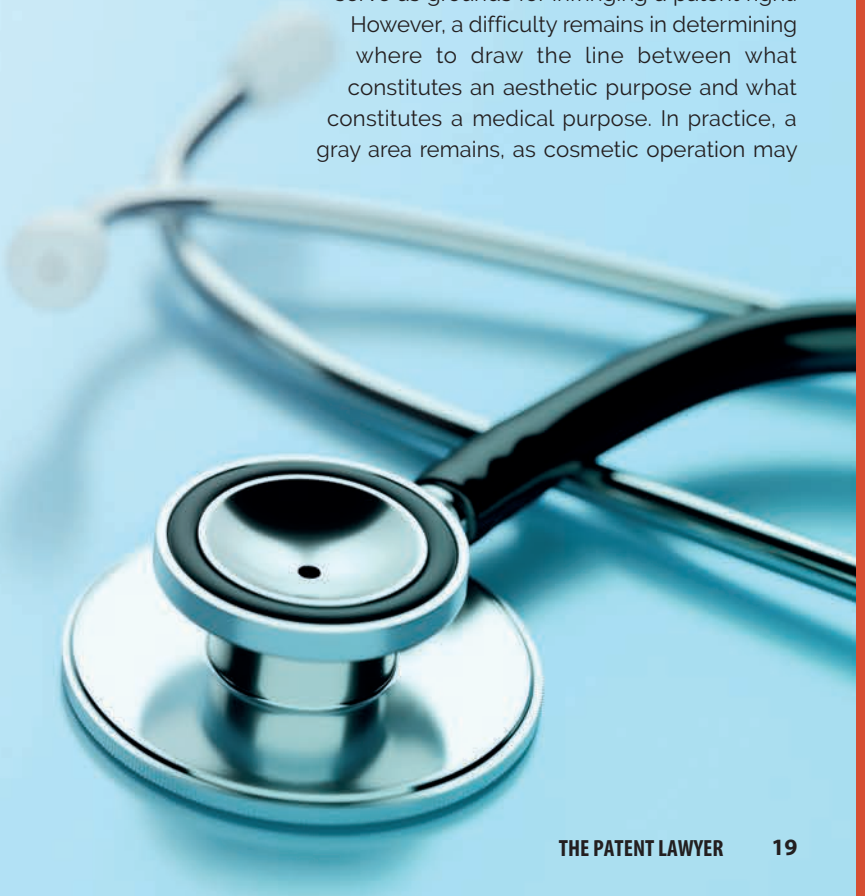
> **"The patentee filed a lawsuit before the Tokyo District Court (TDC), claiming compensation for damages against Y under Article 709 of the Civil Code, etc."**

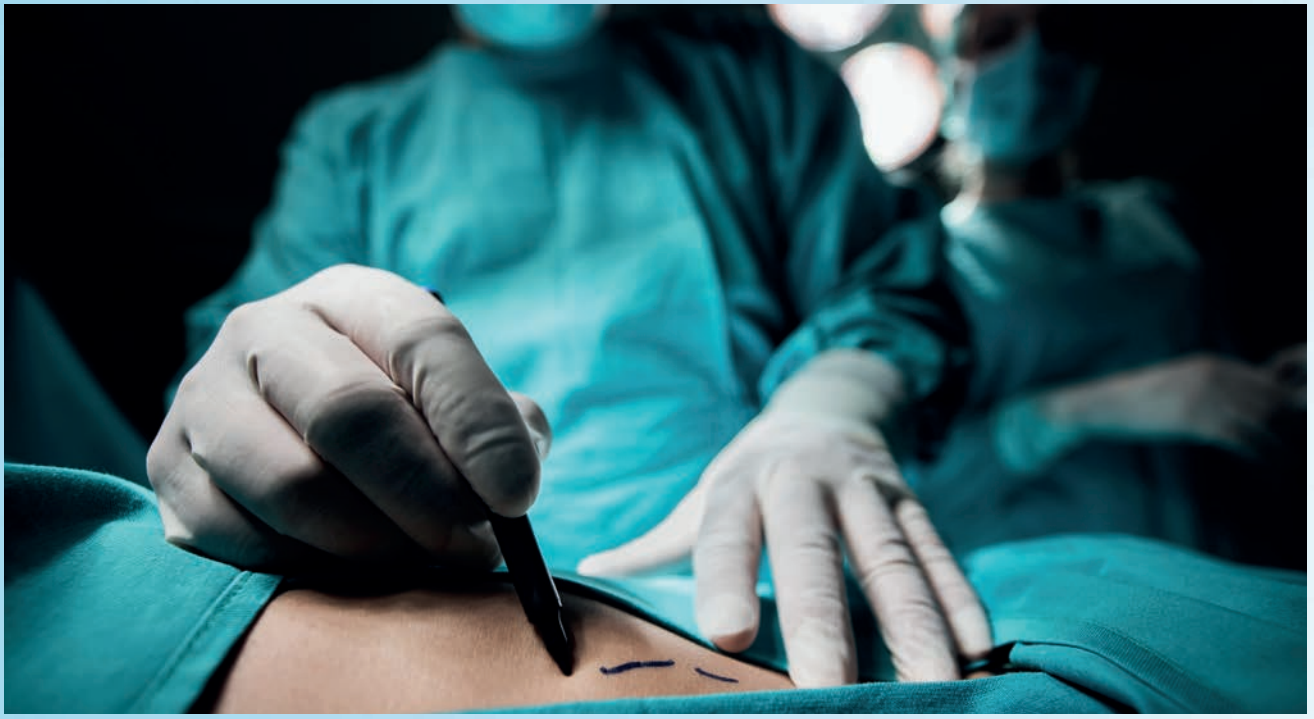
This decision is significant in that it aligns with the concepts outlined in the Examination Guidelines, which indicate that a variety of inventions in the medical field, including regenerative medicine and personalized therapy, can be protected as a "product invention" to the extent reasonably possible. In particular, a precedent is set for the handling of technology using patient-derived substances. As a result of the precedent, there is a possibility that patent filing and patent enforcement in the fields of cosmetics, regenerative medicine, and personalized medicine will increase in the future.

Provisions on limitation of patent rights

Article 69 (3) of the Patent Act stipulates that the effect of a patent right does not extend to a medicine to be manufactured by mixing two or more drugs. Herein, "medicine" means "a product used in the diagnosis, therapy, treatment, or prevention of human diseases." A question arose as to whether the preparation of a composition for cosmetic surgery by a physician would be exempt under Article 69(3).

Based on recognition that the intended use of breast augmentation preparation is limited to "aesthetics," the IPHC determined that the manufacture by Y is not subject to the provisions of the article concerning medicines. This is an important precedent in the field of cosmetics, as it demonstrates that physician's action can serve as grounds for infringing a patent right. However, a difficulty remains in determining where to draw the line between what constitutes an aesthetic purpose and what constitutes a medical purpose. In practice, a gray area remains, as cosmetic operation may





> **Consequently, the IPHC judged that Y was found to have produced a composition within the technical scope of the invention.**

also involve the treatment or prevention of disease. Accordingly, the need for patent risk management in related technical fields is increasing, and strengthening cooperation among physicians, medical institutions, and legal practitioners will become a significant practical issue.

Amicus request

The procedure of calling for third-party opinions was introduced on April 1, 2022, in patent and utility model infringement suits. Regarding the second case, the IPHC issued a request for opinions during the proceedings, with a deadline of September 6, 2024.

The IPHC issued a request for opinions on the following issues:

1) Should an invalidation trial invalidate the patent in question as being "an industrially inapplicable invention" under Article 29(1) of the Patent Act?

2) Does the invention in question constitute "an invention of a medicine to be produced by mixing two or more medicines" under Article 69(3) of the Patent Act?

3) In certain hypothetical situations,

   - Does the act of the appellant in instructing a nurse or assistant nurse at a clinic to make a surgical composition that is a mixture of the claimed ingredients, without issuing a prescription, fall under the "act of dispensing a drug by prescription of a physician or dentist" under Article 69 (3) of the Patent Act?

   - Since the appellant's act of making the composition in question closely relates to medical practice, does any reason exist why the effect of the patent right does not cover the act?

   - In a case that the appellant, a physician, uses the drug containing "A" and "B" and the drug containing "C" separately for surgery at the clinic, and "A" to "C" are mixed in the body of the subject, does the surgery by the appellant constitute "production" of the "composition" of the patented invention?

According to an article published in *Nikkei Asia* on October 5, 2024, the IPHC received 19 responses. However, the article also stated that

about 80% of responses received presented arguments from both sides and adopted a neutral stance. When submitting opinions as a group or organization rather than as an individual, a stance is taken such that an opinion is generally not presented from one side only, and opinions are included from both sides. However, this is a regrettable stance, as it does not align with the intended purpose for which the system was introduced.

Final remarks

The contents of the judgments on the respective issues have generated a considerable number of suggestions regarding future patent practice in the medical and cosmetic fields. However, in the present case, it has not been judged whether the claimed composition should be regarded as produced when each component of the patented composition is separately administered and mixed in a human body to produce the patented composition.

Legal and institutional arrangements for balancing healthcare practices that provide the best therapy for individuals, as well as a need to protect patents to ensure adequate incentives for healthcare techniques, will remain significant challenges in the future. One desirable option would be a shift to downstream regulation, whereby therapy, diagnostic, and surgical methods are patentable, and physicians' medical practices are exempt from patent infringement. From a viewpoint of predictability, it is necessary to clarify the scope of medical practice, either by moving to downstream regulation or by maintaining upstream regulation that restricts current patent right acquisition.

> **"There is a need for patent protection to promote technological progress in the field."**

In light of the development and diversification of medical-related technologies and related businesses, it is strongly expected that the Patent Act will be amended to address these issues by expanding the scope of patentable subject matter and clarifying the exemption for physicians' practice.

Contact

Yuasa and Hara
Section 206, Shin-Ohtemachi Building,
2-1, Ohtemachi 2-chome,
Chiyoda-ku, Tokyo 100-0004, Japan
Tel: +81 3 3270 6641
yamamoto-ch@yuasa-hara.co.jp
www.yuasa-hara.co.jp