

Second case “calling for third-party opinions”

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The procedure of calling for third-party opinions, which could be called the Japanese version of *amicus curiae*, was introduced on April 1, 2022, in patent and utility model infringement suits. As the second case under the proceeding, relating to cosmetic medical technology, the Intellectual Property High Court (IPHC) issued a request for opinions, with a deadline of September 6, 2024.

1. Outline of the proceeding for calling third-party opinions

Under the proceeding, if the Tokyo District Court (TDC), the Osaka District Court, or the IPHC considers it necessary, they can invite opinions from the public for use as evidence in proceedings.

Either party involved in litigation can make a request to the court for applying the proceeding for calling for third-party opinions. The court will decide whether to solicit third-party opinions contemplating the opinions from both parties.

The scope of issues where opinions are gathered is broad, not limited to legal issues and rules of thumb, but extends to such matters as the court considers necessary depending on the case. An example of an issue for gathering opinions includes "how to calculate royalties in each industry for a particular IoT technology."

The timing and deadline for submitting opinions will be determined at the discretion of the courts. Overseas companies and organizations etc. need to be careful because there may be only a short period of time to make submissions. There is no limitation on who can submit opinions. Individuals including experts such as researchers, individual companies, industry associations, administrative organs, etc. can submit opinions from their respective viewpoints that will contribute to the judgment of the court.

In the proceeding, both parties inspect and copy the opinions submitted to the court by third parties. Then, each party selects opinions favorable to the party and submits them to the court as documentary evidence. This means that opinions not selected by either party will not be submitted to the court as evidence. This is a significant difference compared to the U.S. system.

2. Second Case

As for the second case, the patent relates to an invention of a composition relating to cosmetic medical technology, and the defendant is a doctor who runs a plastic surgery clinic. Currently, an invention for treating a human is not a patentable subject matter, and therefore it is obligatory to try to obtain patent rights for an invention of a “product” as far as possible, even if it is essentially a method invention. With the recent development of advanced medical technology, many problems and issues have arisen in the above practice.

(1) Patent

The plaintiff is the patentee of JP No. 5186050. Claim 1 of the patent is shown below:

A composition for promoting subcutaneous tissue increase, characterized in that the composition comprises autologous plasma, basic fibroblast growth factor (b-FGF) and fat emulsion.

(2) Case

The plaintiff claimed that the hematopoietic breast augmentation surgery performed by the defendant at the clinic constitutes infringement of the patent and demanded compensation for damages. One of the disputed issues at the TDC was whether the defendant had produced the “composition” for promoting subcutaneous tissue increase, as recited in Claim 1, that contains autologous plasma. The TDC dismissed the plaintiff's claim without deciding the other disputed issues, stating that the evidence was insufficient to find that the defendant had prepared and manufactured the claimed “composition” that simultaneously contained the ingredients recited in the claim.

The plaintiff appealed to the IPHC.

(3) Opinion gathering

The IPHC issued a request for opinions, with a deadline of September 6, 2024. The following issues are the subject of the opinion gathering.

- (i) Should the patent in question be invalidated by an invalidation trial as being “an industrially inapplicable invention” under Article 29(1) of the Patent Act?
- (ii) 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?
- (iii) In certain hypothetical situations,

(3-a) Does the act of the appellant instructing a nurse or assistant nurse at the 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?

(3-b) Since the appellant's act of making the composition in question closely relates to medical practice, can it be said that for some reason the effect of the patent right does not cover it?

(3-c) In case the appellant, a physician, uses the drug containing (1) and (2) and the drug containing (3) separately for surgery at the clinic, and (1) to (3) are mixed in the body of the subject, does the surgery by the appellant constitute “production” of the “composition” of the patented invention?

We expect that a decision by the IPHC will be issued next year.

3. Patentability of Medical-Related Inventions

Although there is no explicit provision in the Patent Act, it has been interpreted that an invention of a “method for treating a disease, or diagnosing a human” does not fall under the category of “industrially applicable invention” as stipulated in Article 29, Pillar 1 of the Patent Act. 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 the issues by expanding the scope of patentable subject matter and clarifying the exemption for physicians' acts.

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