Patent Right	Date	March 19, 2025	Court	Intellectual Property High Court, Special Division
	Case number	2023 (Ne) 10040		

- A case in which the court determined that a doctor's act of manufacturing a mixed pharmaceutical agent for breast augmentation operation using blood collected from the person to be treated as an ingredient constitutes working of a patented invention relating to a composition for breast augmentation.
- A case in which the court held that it cannot be said that a patent relating to an invention that is a product which uses an ingredient collected from a human and which is intended to be finally returned inside the body of that human was granted in violation of the requirement of "an invention with industrial applicability" referred to in the main sentence of Article 29, paragraph (1) of the Patent Act.
- A case in which the court determined that a patented invention of a composition for breast augmentation does not constitute "a medical invention (medicine meaning a product used in the diagnosis, therapy, treatment, or prevention of human diseases; hereinafter the same applies in this paragraph) that is to be manufactured by two or more medicines being mixed together" referred to in Article 69, paragraph (3) of the Patent Act.

Case type: Compensation

Result: Reversal of prior instance judgment, claim partially upheld

References: The main sentence of Article 29, paragraph (1), Article 36, paragraph (6), items (i) and (ii), Article 69, paragraphs (1) and (3), Article 70, paragraphs (1) and (2), and Article 102, paragraphs (2) and (3) of the Patent Act, and Article 709 of the Civil Code

Related rights, etc.: Patent No. 5186050

Judges: HONDA Tomonari (presiding judge), MIYASAKA Masatoshi, SHIMIZU Hibiku, NAKADAIRA Ken, and AMANO Kenji

Judgment of the prior instance: Tokyo District Court, 2022 (Wa) 5905, rendered on March 24, 2023

Summary of the Judgment

No. 1 Main text of the judgment

1. The judgment in prior instance shall be revoked.

2. The Appellee shall pay to the Appellant 15,032,196 yen and amounts accrued thereon at the rate of 3% per annum for the periods from the dates stated in the "Initial date for

the calculation of delay damages" column of Attachment 1 "List of Acceptable Amounts" for the amounts respectively stated in the "Acceptable amount" column of that list until the completion of the payment.
3. The Appellant's other additional claims shall be dismissed.
4. The court costs throughout the first and second instances are divided into eight parts, of which, seven parts shall be borne by the Appellant and the rest shall be borne by the Appellee.
5. This judgment may be provisionally executed only with regard to paragraph 2.

No. 2 Background
1. Summary of the claims and the judgment in prior instance

The Appellant (first-instance Plaintiff) is the patentee of Patent No. 5186050. The patented invention subject to the present case is an invention of a "composition for breast augmentation" comprising the following three components: [i] autologous plasma; [ii] a basic fibroblast growth factor (b-FGF); and [iii] a lipid emulsion.

The Appellant seeks payment of damages (100 million yen and delay damages) against the Appellee, alleging that the Appellant's abovementioned patent right was infringed by the act of the Appellee (first-instance Defendant), who is a doctor, to manufacture a pharmaceutical agent to be used in "blood breast augmentation mammoplasty" provided at a cosmetic clinic managed by the Appellee.

In the judgment in prior instance, the court denied patent right infringement and dismissed the Appellant's claim, holding that the Appellee is not found to have prepared a pharmaceutical agent that simultaneously contains the abovementioned components [i] through [iii] and administered it to the person to be treated.
2. Main issues
(1) There is a fact-finding issue of whether the Appellee had prepared a pharmaceutical agent that simultaneously contains the abovementioned components [i] through [iii] and administered it to the person to be treated (Issue 1-2 in the judgment).
(2) Next, the "composition" of the patented invention in the present case ("the Patented Invention") requires collection of blood from inside the body of the person to be treated for its manufacturing, and the manufactured composition is intended to be administered under the skin of the person to be treated.

Due to the above, first there is a question of whether the Patented Invention has ground for invalidation, that is, the violation of the industrial applicability requirement for patentability (the main sentence of Article 29, paragraph (1) of the Patent Act) due to being patented as an "invention that is a product," i.e., a composition, but

substantively being patented as an invention of "medical practice" (Issue 2-1 in the judgment).

Second, there is a question of whether the Appellee's act of manufacturing a composition for breast augmentation by collecting blood from the person to be treated will be exempted from liability for patent right infringement pursuant to the provisions of Article 69, paragraph (3) of the Patent Act, which excludes an act of preparation of a medicine by a doctor's prescription from the effect of a patent right (Issue 3-2 in the judgment).

No. 3 Judgment of this court (summary of determinations on main issues)

1. Regarding the fact-finding issue (Issue 1-2 in the judgment)

According to the statements in a notebook prepared by the Appellee upon a breast augmentation operation, the statements of a document delivered to each person to be treated, the statements of advertisements, etc., the Appellee is found to have prepared a pharmaceutical agent that simultaneously contains the abovementioned components [i] through [iii] and administered it to the person to be treated.

2. Regarding industrial applicability (Issue 2-1 in the judgment)

Given that the 1975 amendment of the Patent Act clarified that even an invention of a medicine can be patented, it is difficult to construe that the "invention that is a product" is substantively an "invention that is a process" targeting medical practice, and that it does not constitute an "invention with industrial applicability," only based on the fact that it is intended to be administered to the human body.

In addition, an act of manufacturing a medicinal product, etc. by using an ingredient collected from a human is not necessarily conducted by a doctor, and development of such technologies greatly owes to not only doctors, but also research and development in the pharmaceutical industry and other industries, and such technologies can be used for maintaining or recovering humans' lives or health; therefore, it is necessary to allow protection of such technologies by patents in order to promote their development. Thus, with regard to an invention that is a product which uses an ingredient collected from a human and which is intended to be finally returned inside the body of that human, it cannot be said that this invention, due to such intended use thereof, substantively constitutes an "invention that is a process," or that it does not constitute an "invention with industrial applicability" because it is medical practice if regarded as a series of acts.

Accordingly, it cannot be said that the Patented Invention does not constitute an "invention with industrial applicability," and that the patent was granted in violation of

the provisions of the main sentence of Article 29, paragraph (1) of the Patent Act.

3. Regarding the provisions on exemption from liability regarding the act of preparation of a medicine (Issue 3-2 in the judgment)

In light of the statements in the description, etc., the composition relating to the Patented Invention is to be used for breast augmentation, and the purpose of the breast augmentation is primarily regarded to be aesthetic. In addition, even if the current social norm is taken into account, the composition relating to the Patented Invention is not found to be a "product used for any of the purposes of the diagnosis, therapy, treatment, or prevention of human diseases."

Accordingly, the Patented Invention does not constitute "a medical invention that is to be manufactured by two or more medicines being mixed together," and therefore, without having to examine whether the Appellee's act constitutes "an act of preparation of a medicine by prescription," the Appellee's defense to the effect that the Patent Right is not effective against the act pursuant to the provisions of Article 69, paragraph (3) of the Patent Act is groundless.

4. Regarding the value of damage (Issue 4-2 in the judgment)

From May 27, 2020 to May 27, 2020, the Appellee, by ordering a nurse, etc., collected blood from the person to be treated, manufactured a composition that fell within the technical scope of the Patented Invention, and performed breast augmentation operation by administering it to the person to be treated at the clinic the Appellee manages, and acquired the sales of at least about 170 million yen throughout this period.

When taking into consideration various circumstances, it is reasonable to find that the value of damage to be calculated pursuant to Article 102, paragraph (3) of the Act is 8% of the abovementioned sales amount.

○ Reference provisions

[Main sentence of Article 29, paragraph (1) of the Patent Act]

A person that invents an invention with industrial applicability may obtain a patent for that invention, unless the invention is as follows:

[Article 69, paragraph (3) of the Patent Act]

A patent right for a medical invention (medicine meaning a product used in the diagnosis, therapy, treatment, or prevention of human diseases; hereinafter the same applies in this paragraph) that is to be manufactured by two or more medicines being mixed together or for an invention of a process by which a medicine is manufactured by two or more medicines being mixed together has no effect against the act of

preparation of a medicine as per a physician's or dentist's prescription or against a medicine prepared as per a physician's or a dentist's prescription.

Judgment rendered on March 19, 2025
2023 (Ne) 10040 Appeal case of seeking compensation for damage
(Court of prior instance: Tokyo District Court, 2022 (Wa) 5905)
Date of conclusion of oral argument: January 27, 2025

Judgment

Appellant: Kabushiki Kaisha Tokai Ika

Appellee: Y

Main text

1. The judgment in prior instance shall be revoked.
2. The Appellee shall pay to the Appellant 15,032,196 yen and amounts accrued thereon at the rate of 3% per annum for the periods from the dates stated in the "Initial date for the calculation of delay damages" column of Attachment 1 "List of Acceptable Amounts" for the amounts respectively stated in the "Acceptable amount" column of that list until the completion of the payment.
3. The Appellant's other additional claims shall be dismissed.
4. The court costs throughout the first and second instances are divided into eight parts, of which, seven parts shall be borne by the Appellant and the rest shall be borne by the Appellee.
5. This judgment may be provisionally executed only with regard to paragraph 2.

Facts and reasons

No. 1 Judicial decisions sought by the parties

1. Object of the appeal

(1) The judgment in prior instance shall be revoked.
(2) The Appellee shall pay to the Appellant 100 million yen and amounts accrued thereon at the rate of 3% per annum for the periods from the dates stated in the "Initial date for the calculation of delay damages" column of Attachment 2 "List of the Amounts Claimed" for the amounts respectively stated in the "Amount claimed for each month" column of that list until the completion of the payment (in the present instance, the Appellant expanded the claim in prior instance for payment of the principal of 10,000,000 yen and the amount accrued thereon in this manner).

2. Answer to the object of the appeal

(1) The present appeal shall be dismissed.

(2) The Appellant's expanded claim in the present instance shall be dismissed.

No. 2 Background

The definitions of the abbreviations used in the text of the present judgment are as specified in Attachment 3 "List of Abbreviations," unless otherwise specified in the text. In addition, the Patent Act is referred to as the "Act" in the present judgment.

1. Summary of the claims

The Appellant is the patentee of the Patent for an invention titled "Composition for promoting increase in subcutaneous tissue and subcutaneous adipose tissue." The Appellee is a doctor who had provided aesthetic medical services, such as breast augmentation operations, at the Clinic from around 2019 to around 2022.

This is a case in which, in prior instance, the Appellant alleged that the Appellee's act of making a single pharmaceutical agent by mixing multiple pharmaceutical agents to use it for blood breast augmentation operations during the period from 2019 to March 10, 2022 (the date of filing the action) constitutes an act that infringes the Patent Right, and, under Article 709 of the Civil Code, demanded that the Appellee pay damages of 10,000,000 yen and delay damages accrued thereon at the rate of 3% per annum as prescribed in the Civil Code for the period from April 9, 2022 (the day following the date of service of the complaint) until the completion of the payment.

2. Judgment of the court of prior instance

The court of prior instance dismissed the Appellant's claim, holding that the Appellee is not found to have manufactured a pharmaceutical agent that falls within the technical scope of the Invention by mixing multiple pharmaceutical agents.

3. Filing of an appeal and expansion of claim

Dissatisfied with the judgment in prior instance, the Appellant filed an appeal, and in the present instance, the Appellant additionally claimed that, not only the Appellee's act of making a single pharmaceutical agent by mixing multiple pharmaceutical agents, but also the Appellee's act of injecting multiple pharmaceutical agents separately into the person to be treated and mixing these pharmaceutical agents inside the body constitutes an act that infringes the Patent Right (or the monopolistic non-exclusive license). Furthermore, in the present instance, the Appellant specified the period subject to the claim to be from January 1, 2019 to May 24, 2024, expanded their claim to a claim for payment of 100 million yen as damages (the specific claim, however, is a claim for a part of 222,697,768 yen alleged to be the value of damage at least incurred during the period from May 2020 to July 2021) and delay damages accrued thereon at the rate of 3% per annum as prescribed in the Civil Code for, with regard to the amount of those damages allocated to each month according to the value of damage incurred in

that month, the period from the day following the last day of that month (the first day of the following month) until the completion of the payment (No. 1, 1. (2)), and asserted the application of Article 102, paragraph (2) or (3) of the Act.

No. 3 Basic facts

1. The Patent Right, etc.

(1) The Patent and the Invention (Exhibit Ko 2)

The Patent is one for which an application was filed by Doctor A as its inventor on February 24, 2012, and of which the establishment was registered on January 25, 2013.

The Invention (of the invention stated in Claim 4 of the claims, the one citing the invention stated in Claim 1) is as described below.

"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."

(2) Attribution of the Patent Right, etc. (Exhibits Ko 1 and 16 and Exhibit Otsu 10)

The Appellant is a stock company for the purpose of selling, leasing, and otherwise handling medical devices.

The Patent Right was assigned by Doctor A to the Appellant and the transfer was registered on November 12, 2014.

Cancellation of the Patent Right was registered on July 13, 2022 due to non-payment of the patent fee for the ninth year of which the due date was January 25, 2021. However, restoration of the Patent Right was registered on January 10, 2023 due to discovery of a mistake. Therefore, pursuant to the provisions of Article 112-3, paragraph (2), item (i) of the Act, the Patent Right has no effect against acts of working the Invention performed during the period from July 26, 2021 to January 9, 2023.

2. Appellee's acts, etc. (Exhibits Ko 3, 4, and 9 and Exhibits Otsu 31, 40, and 41)

The Appellee, who is a doctor, opened the Clinic on June 10, 2019, and was providing the Operation called "3 WAY blood breast augmentation" using a "cell-free plasma gel" at the Clinic during a certain period before around October 2022. Of the components of the pharmaceutical agent which the Appellee was using in the Operation, "Trafermin (brand name: Fiblast)" corresponds to the "basic fibroblast growth factor (b-FGF)" of the Invention and "Intralipos" corresponds to the "lipid emulsion" of the Invention.

3. Notice of assignment of claims (Exhibit Ko 30 (hereinafter the branch numbers of documentary evidence are omitted unless otherwise specified) and the entire import of oral arguments)

On May 22, 2024, Doctor A's attorney notified the Appellee, while indicating that

the notice was given on behalf of Doctor A, that all of Doctor A's right to claim compensation for damage and right to claim the restitution for unjust enrichment as well as right to claim interest on these claims based on the Appellee's infringement of the Patent Right were assigned to the Appellant.

No. 4 Issues

1. Issues concerning fulfillment of constituent features

In the present case, one of the major issues is whether the Appellee's act of manufacturing a pharmaceutical agent to be used in the Operation constitutes "production" as an act of working the Invention.

Thus, first, there is a question as to [i] whether the "cell-free plasma gel," which is one component of the pharmaceutical agent used by the Appellee, corresponds to the "autologous plasma" of the Invention (Issue 1-1).

Next, there is a dispute over the mode of the Operation performed by the Appellee, as an issue in the finding of facts, and there is a question as to [ii] whether the Appellee manufactured a single pharmaceutical agent (composition) that had mixed three components, which are plasma, Trafermin, and Intralipos, before administering it to the person to be treated, as a pharmaceutical agent to be used in the Operation (Issue 1-2).

The Appellee argues that "Agent A" that contains plasma and Trafermin and "Agent B" that contains Intralipos were separately administered to the person to be treated, as the mode of the Operation, but even if the Operation is found to have been performed in this mode, "Agent A" and "Agent B" will be mixed inside the body of the person to be treated, so there is a question as to [iii] whether the Appellee's act of administering "Agent A" and "Agent B" separately to the person to be treated constitutes "production" of the composition relating to the Invention (Issue 1-3).

2. Issues concerning patent validity

The Appellee submitted a defense of patent invalidation (Article 104-3 of the Act).

The Invention has been patented as an "invention that is a product" which is a "composition for breast augmentation." However, the Appellee argues that, because there is a need to collect blood from inside the body of the person to be treated (human body) for manufacturing the composition and the composition is premised to be directly administered under the skin of the person to be treated (human body), the Invention, while taking the form of an "invention that is a product," is substantively an "invention that is a process for a breast augmentation operation," and in fact, the Operation, which is medical practice performed by the Appellee, is substantively the target for exercise of the patent right.

Thus, there is a question as to [i] whether the patent relating to the Invention has a

ground for invalidation, that is, the violation of the industrial applicability requirement (the main sentence of Article 29, paragraph (1) of the Act) (Issue 2-1).

Further, the Appellee also alleges [ii] violation of the support requirement (Issue 2-2) and [iii] violation of the clarity requirement (Issue 2-3) as grounds for invalidation of the Patent.

3. Issues concerning limitations of patent right

The Appellee argues that the Patent Right is not effective against the Appellee's acts.

Specifically, the Appellee asserts [i] application of the provisions on exemption from liability regarding the working of the patented invention for experimental or research purposes (Article 69, paragraph (1) of the Act) (Issue 3-1), [ii] application of the provisions on exemption from liability regarding the act of preparation of a medicine (paragraph (3) of that Article) (Issue 3-2), and [iii] abuse of right, etc. (Issue 3-3), and there is a question as to whether these assertions are appropriate.お o

4. Issues concerning damage

If the Appellee is found to have infringed the Patent Right (or the monopolistic non-exclusive license), the value of damage for which the Appellee should compensate becomes a question. As the Appellant first asserts calculation of the value of damage under Article 102, paragraph (2) of the Act, there is a question as to whether that paragraph is applicable to the present case (Issue 4-1). Also, as the Appellant selectively asserts the value of damage calculated under Article 102, paragraph (3) of the Act in addition to the value of damage calculated under paragraph (2) of that Article, the value of damage based on these calculations (Issue 4-2) becomes a question.

No.6 Judgment of this court

1. Regarding Issue 1-1 (whether the "cell-free plasma gel" corresponds to the "autologous plasma" of the Invention)

(1) Outline of the Invention

According to the statements of the Description, etc. (Exhibit Ko 2: the patent gazette), the outline of the Invention is found to be as follows ([ ] indicates the paragraph number in the Description, etc.).

A. Technical field

The Invention relates to a composition for promoting an increase in subcutaneous tissue that aims at accumulating and increasing subcutaneous tissue or adipose tissue under the skin of a breast and the like by generating and increasing the subcutaneous tissue or the adipose tissue, for example, around a mammary gland. ([0001])

B. Background art

In order to maintain a breast which is mainly composed of a mammary gland and adipose tissue, it is desirable to promote fat synthesis in the adipocytes thereof and promote increase and accumulation of the adipose tissue thereof and additionally, to increase the subcutaneous tissue thereof. ([0002])

Of conventional breast augmentation mammoplasty, methods such as a breast implant, fat grafting, and the injection of hyaluronic acid or collagen, etc. respectively had safety issues and had problems such as not demonstrating sufficient effects. ([0003] to [0008])

On the other hand, a method for ameliorating a skin problem by promoting an increase in cell tissue through the steps of combining autologous leucocyte-containing plate rich plasma (PRP) and a growth factor (GF) and injecting the mixture has been proposed. This method is believed to be applicable to augmentation mammoplasty. However, plasma separated as PRP is about one tenth to one twentieth of the collected blood volume. Therefore, it is not practical for breast augmentation in which as much as several tens of milliliters to several hundred milliliters of PRP is required. ([0009])

C. The Invention

Under such circumstances, the present inventor focused on plasma among autologous blood components, wherein the plasma is a liquid component making up half of the blood components. The present inventor confirmed that it was possible to aim at accumulating and increasing subcutaneous tissue under the skin of a breast by combining the plasma and a basic fibroblast growth factor (b-FGF) among other growth factors and injecting the combination into the subcutaneous tissue of the breast. The present inventor also confirmed that it was possible to aim at accumulating and increasing adipose tissue under the skin of a breast very effectively and obtain breast augmentation effect by supplementing an artificial lipid (fat), when the lipid in the plasma was insufficient. In this way, the present invention was accomplished. ([0010])

The problem to be solved by the Invention is to provide a composition for breast augmentation that is a composition for promoting an increase in subcutaneous tissue, which enables recovery of autologous tissue and recovery of appearance by a safe and natural process that accumulates and increases subcutaneous cell tissue and/or subcutaneous adipose tissue under the skin of a breast, while avoiding problems that had occurred in conventional breast augmentation mammoplasty. Specifically, the Invention is a composition for promoting an increase in subcutaneous tissue that is used for breast augmentation which is characterized in that it contains autologous plasma, a basic fibroblast growth factor (b-FGF), and a lipid emulsion. ([0012], [0013], [0016], [Claim 1], and [Claim 4])

D. Modes for carrying out the invention

Autologous plasma in a gel form can be prepared as follows. Blood is collected from a human on whom breast augmentation is to be performed. The blood is centrifuged at preferably within 3,000 to 4,000 rpm to separate the plasma. Then, heparin or citric acid, which is an anticoagulant, is added to the plasma. As a basic fibroblast growth factor (b-FGF), a product that has the generic name "Trafermin" and is marketed with the trade name "Fiblast spray" can be used as it is. Fat in the form of a lipid emulsion is administered at the same time in order to generate and increase a greater amount of adipose tissue. As a lipid emulsion, "Intrapilid infusion" formulation provided as a lipid emulsion for intravenous injection can be used. ([0025] to [0032])

(2) The meaning of "autologous plasma" of the Invention will be examined.

A. While there is no statement in the claims in the Description, etc. that specifically defines the meaning of "plasma," representative dictionaries in the field of biochemistry state as follows: "the liquid obtained by removing erythrocytes and other cell components from blood is called blood plasma, or simply plasma"(Exhibit Ko 7-1: *Iwanami Rikagaku Jiten* (Iwanami Dictionary of Physics and Chemistry) (4th edition)); and "a component obtained by removing blood cells from blood" (Exhibit Ko 7-2: *Seikagaku Jiten* (Dictionary of Biochemistry) (4th edition)).

The detailed explanation of the invention in the Description, etc. has statements including the following: "autologous leucocyte-containing plate rich plasma (PRP) ... has been proposed ... plasma separated as PRP is about one tenth to one twentieth of the collected blood volume ... which is not practical for breast augmentation in which as much as several tens of milliliters to several hundred milliliters of PRP is required" ([0009]); and "under the above-described present circumstances, the present inventor focused on plasma among autologous blood components, wherein the plasma is a liquid component making up half of the blood components ... protein as well as a lipid, glucose, and a hormone included in the plasma, particularly the lipid, combined with the effect of the b-FGF ..." ([0010]). In addition, although it is a part relating to a mode for carrying out the invention, there is also a statement that "autologous plasma is plasma obtained by collecting one's own blood and centrifuging the blood by a conventional method and is the liquid component that makes up approximately 55% of blood" ([0025]).

According to the statements above and the outline of the Invention in (1) above, it is reasonable to construe that "autologous plasma" of the Invention has a meaning of "a liquid component obtained by removing erythrocytes and other cell components from blood collected from the person to be treated."

B. Against this argument, the Appellee argues that, in light of the prosecution history, etc. of the Patent, the "autologous plasma" of the Invention should be construed in a limited sense to mean "platelet poor plasma (PPP)," and that this does not include plasma that was obtained by centrifuging the blood collected from the person to be treated and completely removing cell components from it (NCP), which the Appellee was using in the Operation.

Regarding this point, the written request for a trial (Exhibit Otsu 4) submitted by the applicant against the examiner's decision of refusal of the application for the Patent states as follows: "The plasma used in the present invention is autologous plasma, which is a liquid component included in blood from which erythrocytes, leucocytes, and platelets, which are blood cell components, have been removed. In other words, it is the supernatant liquid fraction called platelet poor plasma (PPP) which is separated on the layer above the buffy coat as stated in paragraph number [0004] of Cited Document 1 (note of the judgment: Unexamined Patent Application Publication No. 2009-235004 Gazette; Exhibit Ko 8); in short, it is plasma that contains hardly any platelets."

However, this statement merely indicates that "autologous plasma," which contains hardly any platelets, can be distinguished from the PRP in Cited Document 1, which contains abundant platelets, against the finding in the grounds for refusal given by the examiner that "the plasma used in the present invention cannot be distinguished from the PRP stated in Cited Document 1." In addition, given that the statement reads "it is plasma that contains hardly any platelets," but does not mention any positive meaning about containing the platelets, it cannot immediately be found that the statement "plasma that contains hardly any platelets" is intended to exclude "plasma that contains no platelets." Although the relationship between "plasma from which cell components are completely removed (NCP)" and "platelet poor plasma (PPP)" as argued by the Appellee is not necessarily clear, at least it cannot be construed from the statement in the abovementioned written request for a trial that "autologous plasma" excludes "plasma that contains no platelets (plasma from which platelets are completely removed)," and no other grounds are found in the Description, etc. or the prosecution history either to adopt such an interpretation.

Accordingly, the Appellee's argument that the meaning of the "autologous plasma" of the Invention should be construed in a limited sense, based on the prosecution history, etc. of the Patent, cannot be accepted.

(3) Summary

The "cell-free plasma gel," which the Appellee was using in the Operation, is plasma obtained by completely removing cell components from the blood of the person to be

treated that was collected prior to the Operation (Exhibit Otsu 25 and the Appellee). Therefore, it can be said that it corresponds to the "autologous plasma" of the Invention which has the meaning of "a liquid component obtained by removing erythrocytes and other cell components from blood collected from the person to be treated" as mentioned in (2) A. above.

2. Regarding Issue 1-2 (whether the Appellee manufactured a composition that had mixed plasma, Trafermin, and Intralipos)

(1) Facts found

According to the indicated evidence and the entire import of oral arguments, the following facts are found.

A. Opening of the Clinic, etc.

The Appellee, who is a doctor, opened the Clinic with cosmetic surgery and cosmetic dermatology departments in Chuo City, Tokyo, on June 10, 2019. (Exhibit Otsu 31)

B. Preparations for providing the Operation

(A) The Appellee started to purchase the Fiblast spray and Intralipos from around January 2020. (Exhibits Otsu 35 and 36)

(B) Around that time, the Appellee conducted acts including collecting their own blood and centrifuging it, and inquiring to the person in charge at the Ministry of Health, Labour and Welfare about whether the provision of medical services using plasma that contains no cell components is subject to regulations under the Act on the Safety of Regenerative Medicine. (Exhibits Otsu 7 and 8)

(C) The Appellee requested a patent attorney to investigate whether the assumed treatment method infringes the Patent Right, and on February 27, 2020, the Appellee received a written opinion on the Patent from the patent attorney. The contents of the written opinion were as follows. (Exhibit Otsu 32)

a. The Patent was granted in violation of the industrial applicability requirement, inventive step requirement, and support requirement, and has grounds for invalidation.

b. Act A—"to produce 'plasma from which cell components are removed (NCP)' by collecting blood from a patient who seeks breast augmentation, and centrifuging the blood; produce a composition that has mixed the produced 'plasma from which cell components are removed (NCP),' the Fiblast spray, and Intrapilid infusion (Composition 1); and administer Composition 1 to the patient for the purpose of breast augmentation"—formally falls within the technical scope of the Invention, but as it is construed that a patent right is not effective against a mode of working that constitutes medical practice, it does not infringe the Patent Right.

c. Act B—"to produce 'plasma from which cell components are removed (NCP)' by collecting blood from a patient who seeks breast augmentation, and centrifuging the blood; produce a composition that has mixed the produced 'plasma from which cell components are removed (NCP)' and the Fiblast spray (Composition 2); and separately administer Composition 2 and Intrapilid infusion to the patient for the purpose of breast augmentation"—has room to construe that a product relating to the Invention was produced at the points of time when Composition 2 and Intrapilid infusion were respectively administered. However, given that various substances exist and interact with one another inside the human body, separate administration of Composition 2 and Intrapilid infusion does not necessarily produce the same effect as administration of a single composition relating to the Invention, so Act B does not infringe the Patent Right.

C. Provision of the Operation

The Appellee provided the Operation at the Clinic to those who applied for monitor recruitment during a monitoring period from May 27, 2020 to around the end of November 2020, and to those who applied for open recruitment after the monitoring period from December 2020, by receiving consideration in both periods. (Exhibits Otsu 45, 47, and 52 to 58)

The Operation performed by the Appellee used the method stated as a working example in the Description, etc., except that "plasma from which cell components are removed (NCP)" was used as "autologous plasma" and that hyaluronic acid and placenta, etc. were added.

D. Statements in the Pharmaceutical Agent Notebook

At the Clinic, at least from the Operation performed on January 27, 2021, the Appellee verbally instructed a nurse or assistance nurse on the respective amounts of components of the pharmaceutical agent to be administered to the person to be treated. In response, the nurse or assistance nurse entered statements in a Pharmaceutical Agent Notebook, which contains information including the breakdown of components of the pharmaceutical agents to be administered to the persons to be treated, and the nurse or assistance nurse manufactured the pharmaceutical agent to be used for the relevant person to be treated based on these statements. The Pharmaceutical Agent Notebook contains the date and information for specifying the person to be treated at the left end of each line, and for each line, columns are provided for "Blood," "Gana HA," "Fiblast," "AA PE," "Intra," "Mels," and "Anti" from the left in this order (however, there is no "Anti" column in the statements up to February 23, 2021), and numerical values, etc. are stated in each space. In addition, at the end of the second page of the Pharmaceutical Agent Notebook, there is a statement "★ Person for whom Gana HA Intra was crushed

and mixed," and a "★" mark is indicated on the right-hand side of the information for specifying the person to be treated in some places. (Exhibit Ko 29 and Exhibits Otsu 60 and 62)

E. Explanatory materials, etc. prepared by the Appellee

(A) The Clinic's website introduced the Operation as being "3 WAY blood breast augmentation" consisting of the following three procedures: "cell-free plasma gel," "cup suction and fixation," and "binding enhancement EMS." With regard to the "injected pharmaceutical agent," the website stated, "To avoid the risk of the breast getting thin after the treatment, we also combine a growth factor and an emulsifier, in addition to cell-free plasma gel." (Exhibits Ko 3, 4, and 9)

(B) The "written approval and application (written oath) for breast augmentation operation by injection method," which the Appellee had delivered to the person to be treated and had required them to sign contained statements including the following: "This is an operation for breast augmentation performed by taking 200 cc or 400 cc of the patient's own blood, eliminating blood cell components from it, making it into gel, and returning it to the breasts."; "A pharmaceutical agent comprising a growth factor, and partially a hyaluronic acid preparation, and nutrient, etc. is used as a filler."; "The amount that can be injected in this operation is 100 cc or 200 cc on one side, or 200 cc or 400 cc on both sides combined."; "Trafermin® is used in breast augmentation by breast reconstruction. There is an allergy induced by edetic acid contained in this pharmaceutical agent. In addition, Intralipos does not contain soy protein, but it contains lipids from egg yolk, so it is known to cause allergies. When breast augmentation by breast reconstruction is performed, the doctor asks about drug allergy and egg allergy, and the solution for breast augmentation by breast reconstruction is injected while monitoring oxygen partial pressure in the blood." (Exhibit Ko 6)

(2) According to the facts found in (1) above, the following are found: [i] the Pharmaceutical Agent Notebook, which is found to contain statements entered by a nurse or assistance nurse of the Clinic when they manufacture the pharmaceutical agent to be administered to the person to be treated in the Operation based on the Appellee's instruction, and based on whose statements the nurse or assistance nurse is found to have been actually manufacturing the pharmaceutical agent, states "Blood," "Gana HA" (a hyaluronic acid preparation), "Fiblast," "AAPE" (a preparation containing a growth factor), "Intra" (Intralipos), "Mels" (a placenta agent with the brand name "Melsmon"), "Anti"(Antibiotic), and the amounts of components administered to the person to be treated, but there is no distinction that corresponds to that between Agent A ("Fiblast," etc.) and Agent B ("Intralipos," etc.) as mentioned by the Appellee, and also, there is a

statement "★ Person for whom Gana HA Intra was crushed and mixed" at the end of the second page of the Pharmaceutical Agent Notebook, and such statement is considered to be based on a premise that "Gana HA" and "Intra" will be mixed together into the pharmaceutical agent; and [ii] the Clinic's website states "we also combine a growth factor and an emulsifier, in addition to cell-free plasma gel" with regard to the injected pharmaceutical agent, while the "written approval and application (written oath) for breast augmentation operation by injection method," which had been delivered to the person to be treated, also provided an explanation about the allergy risks of Trafermin and Intralipos along with statements such as "a pharmaceutical agent comprising a growth factor, and partially a hyaluronic acid preparation, and nutrient, etc. is used as a filler," but none of these statements suggest that the pharmaceutical agent is administered as separate multiple agents.

In addition to these points, there are no circumstances suggesting that the Appellee changed the contents or the administration method of the pharmaceutical agent administered to the persons to be treated in the Operation throughout the period in which the Operation was performed on those who applied for monitor recruitment and the period in which it was performed on those who applied for open recruitment. In light of these facts, it can reasonably be presumed that the Appellee had been manufacturing plasma from blood collected from each person to be treated, manufacturing a pharmaceutical agent by mixing all of the components stated in the Pharmaceutical Agent Notebook, including the Fiblast spray and Intralipos, with the plasma, and administering this to the person to be treated in the Operation throughout these periods.

(3) Against this, the Appellee argues that the pharmaceutical agents which the Appellee were manufacturing prior to the Operation were "Agent A" in which NCP and other pharmaceutical agents including a growth factor (Trafermin) were mixed and "Agent B" in which an emulsifier (Intralipos) and a nutrient, etc. were mixed, and that in the Operation, Agent A was administered first to a deep part of the breast, then Agent B was administered near the skin surface of the breast, and further Agent A and Agent B were administered alternately in a gradation in the area between the two.

However, in addition to the determination made as described in (2) above, the Appellee has not been able to provide a specific and reasonable explanation during the examination of the Appellee in the present instance about the following series of processes: deciding how much the respective components should be used in the person to be treated as the determination of the Appellee as a doctor; telling this information to a nurse or assistance nurse and having them manufacture Agent A and Agent B; and

managing and using these pharmaceutical agents in the Operation. In other words, the Appellee was unable to specifically identify the parts where the selection of components, which is to be determined as appropriate according to the attributes and constitution of each person to be treated, is reflected in the statements in the Pharmaceutical Agent Notebook. In addition, with regard to the fact that components contained in Agent A and components contained in Agent B are stated in the Pharmaceutical Agent Notebook in a mixed manner, the Appellee asserted that nurses somehow stated in such order without intention. Moreover, as for the names by which the pharmaceutical agents were called inside the Clinic, the names mentioned by the Appellee changed among "A, B," "plasma, white," "red, white," and others during the questioning, and regarding how the pharmaceutical agents were switched when Agent A and Agent B were to be administered flexibly in the third step of the treatment, the Appellee said at one time that the Appellee gives instructions to a nurse, etc., but at another time the Appellee said that the Appellee switches the pharmaceutical agents on their own, and the specific situation is unclear. In addition to such contents of the Appellee's statements and the attitude when making those statements, in the present case, there was no submission of objective evidence which suggests that the Appellee instructed a nurse or assistance nurse to manufacture separate pharmaceutical agents, Agent A and Agent B, at the time of an operation and managed and used those pharmaceutical agents, while such evidence is naturally considered to exist if these processes were actually taken. In light of these facts, the Appellee's statements cannot be accepted.

Furthermore, based on the Appellee's experimental results (Exhibits Otsu 12 and 13), the Appellee argues that they have never mixed plasma, Trafermin, and Intralipos outside the body of the person to be treated, because if these components are mixed outside the body of the person to be treated, the pharmaceutical agent will coagulate and cannot be administered by using the instruments used by the Appellee, and even if it could be administered, a lump would develop after the treatment.

However, the experiment performed by the Appellee was one in which collected blood was centrifuged, the upper fraction was put into a medical tray, and it was shaken together with added Intralipos and Fiblast for about one minute. The manufacturing method and the management conditions of the experiment differ from those stated in the working example of the Description, and they may not be the same as those at the time of the actual treatment. Therefore, it cannot immediately be found based on the Appellee's experiment results that the pharmaceutical agent will coagulate and its administration itself will become difficult if plasma, Trafermin, and Intralipos are all mixed outside the body of the person to be treated.

(4) As mentioned in (2) and (3) above, it can reasonably be presumed that the Appellee manufactured plasma from blood collected from the person to be treated, and manufactured a pharmaceutical agent by mixing all of the components stated in the Pharmaceutical Agent Notebook, including the Fiblast spray and Intralipos, with the plasma, and even if the Appellee's arguments, etc. are taken into consideration, they are not enough to overturn this presumption.

Accordingly, the Appellee is found to have manufactured a composition containing the abovementioned three components throughout the period in which the Operation was performed on those who applied for monitor recruitment and the period in which it was performed on those who applied for open recruitment, and as this composition was manufactured to be used in the Operation, which is a breast augmentation operation, the Appellee is found to have manufactured a composition that falls within the technical scope of the Invention.

3. Regarding Issue 2-1 (whether the patent relating to the Invention has a ground for invalidation, that is, the violation of the industrial applicability requirement (the main sentence of Article 29, paragraph (1) of the Act)

(1) The Appellee argues that, while the Invention relates to a "composition for breast augmentation," in order to manufacture the composition, a doctor needs to collect blood from the person to be treated and obtain "autologous plasma," and the manufactured composition is premised to be directly administered under the skin of the person to be treated by the doctor, and therefore that the Invention is substantively no different from a series of acts that are conducted in sequence, namely, collection of blood and manufacturing and administration of a composition, that is, no different from an invention that is a process for a breast augmentation operation. Based on this argument, the Appellee further argues that, because medical practice does not constitute an "invention with industrial applicability," the patent relating to the Invention should be invalidated.

(2) The main sentence of Article 29, paragraph (1) of the Act only states, "a person that invents an invention with industrial applicability may obtain a patent for that invention, unless the invention is as follows," and it does not explicitly provide that a product administered to the human body, including a composition that is used for breast augmentation, such as the Invention should be excluded from the subject matter of patent.

In addition, the Act prior to the amendment by Act No. 46 of 1975 had specified an "invention of a medicine (meaning a product used in the diagnosis, therapy, treatment, or prevention of human diseases; the same applies hereinafter) or of a process of

manufacturing a single medicine by mixing two or more medicines" as an unpatentable invention (Article 32, item (ii) of the Act prior to that amendment), but this provision was deleted by the amendment, which should be considered to have clarified that even an invention of a medicine that is intended to be administered to the human body can be patented.

Therefore, it is difficult to construe that the "invention that is a product" is substantively an "invention that is a process" targeting medical practice, and that it does not constitute an "invention with industrial applicability," only based on the fact that it is intended to be administered to the human body.

(3) Next, while the "autologous plasma" of the Invention is obtained by collecting blood from the person to be treated and is intended to be finally administered to that person, an act of manufacturing a medicinal product, etc. by using an ingredient collected from a human is not necessarily conducted by a doctor, and it cannot be said that collection of blood, manufacturing of a composition, and its administration to the person to be treated are inseparable acts that should always be regarded as a series of acts that are integrated into one. Rather, given the recent situation in which advanced medical technologies, such as regenerative medicine and gene therapy, have made remarkable progress, development of technologies, such as manufacturing of medicinal products by using an ingredient collected from a human, greatly owes to not only doctors, but also research and development in the pharmaceutical industry and other industries, and such technologies can be used for maintaining or recovering humans' lives or health; therefore, it is found to be necessary to allow protection of such technologies by patents in order to promote their development.

Thus, with regard to an invention that is a product which uses an ingredient collected from a human and which is intended to be finally returned inside the body of that human, it cannot be said that this invention, due to such intended use thereof, substantively constitutes an "invention that is a process," or that it does not constitute an "invention with industrial applicability" because it is medical practice if regarded as a series of acts.

(4) According to the above, the Appellee's argument that the Invention does not constitute an "invention with industrial applicability" cannot be accepted, and it cannot be said that the patent relating to the Invention was granted in violation of the provisions of the main sentence of Article 29, paragraph (1) of the Act. Therefore, the Appellee's defense to the effect that the Patent Right cannot be exercised because it has that ground for invalidation is groundless.

4. Regarding Issue 2-2 (whether the patent relating to the Invention has a ground for

invalidation, that is, the violation of the support requirement (Article 36, paragraph (6), item (i) of the Act))

(1) The Appellee argues that, although the "autologous plasma" of the Invention is described in a manner that literally includes all types of plasma, the applicant asserted that "autologous plasma" is "platelet poor plasma (PPP)," so the technical scope of the Invention cannot be expanded or generalized to compositions in general which comprise plasma other than "platelet poor plasma (PPP)," and therefore, the Invention is not an invention that is stated in the detailed explanation of the invention, and the patent relating to the Invention was granted in violation of the provisions on the support requirement (Article 36, paragraph (6), item (i) of the Act).

(2) However, while it is reasonable to construe that the "autologous plasma" of the Invention has a meaning of "a liquid component obtained by removing erythrocytes and other cell components from blood collected from the person to be treated" as mentioned in 1. (2) A. above, the detailed explanation of the invention in the Description, etc. has the following statements regarding "autologous plasma": "plasma among autologous blood components, wherein the plasma is a liquid component making up half of the blood components" ([0010]); and "autologous plasma is plasma obtained by collecting one's own blood and centrifuging the blood by a conventional method and is the liquid component that makes up approximately 55% of blood," as a mode for carrying out the invention ([0025]). It also states working examples for obtaining autologous plasma ([0037]). According to these, it can be said that the Invention is an invention that is stated in the detailed explanation of the invention.

The applicant's assertion in the examination process of the application as pointed out by the Appellee merely indicates that "autologous plasma," which contains hardly any platelets, can be distinguished from the PRP in Cited Document 1, which contains abundant platelets, against a ground for refusal given by the examiner, as mentioned in 1. (2) B. above, and it cannot be regarded to indicate that the invention disclosed in the detailed explanation of the invention differs from the invention stated in the claims. Meanwhile, a person ordinarily skilled in the art who has read the statements "plasma separated as PRP is about one tenth to one twentieth of the collected blood volume ... it is not practical for breast augmentation in which as much as several tens of milliliters to several hundred milliliters of PRP is required" ([0009]), and "under such circumstances, the present inventor focused on plasma among autologous blood components, wherein the plasma is a liquid component making up half of the blood components" ([0010]) in the Description, etc. would have easily understood that PRP is not included in the "autologous plasma" of the Invention.

(3) According to the above, the Invention is found to be an invention stated in the detailed explanation of the invention in the Description, etc., and therefore, it cannot be said that the patent relating to the Invention was granted in violation of the provisions of Article 36, paragraph (6), item (i) of the Act. Therefore, the Appellee's defense to the effect that the Patent Right cannot be exercised because it has that ground for invalidation is groundless.

5. Regarding Issue 2-3 (whether the patent relating to the Invention has a ground for invalidation, that is, the violation of the clarity requirement (Article 36, paragraph (6), item (ii) of the Act))

(1) The Appellee argues that the patent relating to the Invention was granted in violation of the provisions on the clarity requirement (Article 36, paragraph (6), item (ii) of the Act), because, while there is no clear description about the structure or characteristics of the "autologous plasma" of the Invention, at the time of manufacturing the autologous plasma, only the doctor knows who the person to be treated is, and the structure or characteristics of that product cannot be objectively determined.

(2) However, the Description, etc. has statements including the following regarding "autologous plasma": "Specifically, autologous plasma ... can be prepared as follows. Blood (autologous blood) is collected from a human on whom breast augmentation by using the composition for breast augmentation of the present invention is to be performed. The blood is centrifuged ... to separate the plasma" ([0026]). Therefore, a person ordinarily skilled in the art who has read the Description, etc. would have easily understood that "autologous plasma" is manufactured by using blood collected from the person to be treated on whom breast augmentation by using the composition for breast augmentation is to be performed, and it should be said that there is no risk of causing third parties unexpected detriments, such as depriving them of foreseeability as to the scope of the exclusive right.

(3) Accordingly, it cannot be said that the patent relating to the Invention was granted in violation of the provisions of Article 36, paragraph (6), item (ii) of the Act. Therefore, the Appellee's defense to the effect that the Patent Right cannot be exercised because it has that ground for invalidation is groundless.

6. Regarding Issue 3-1 (whether it can be said that the Patent Right is not effective against the Appellee's acts pursuant to the provisions on exemption from liability regarding the working of the patented invention for experimental or research purposes (Article 69, paragraph (1) of the Act))

(1) As per the facts found in 2. (1) above, the Appellee was conducting *in vitro* tests, such as tests in test tubes using blood collected from the Appellee themself, until around

May 2020, as research for performing blood breast augmentation mammoplasty, and there is no dispute between the parties regarding the fact that such act does not constitute an act that infringes the Patent Right pursuant to Article 69, paragraph (1) of the Act (the Appellant has not included the abovementioned act in the subject of the claim in the present case).

(2) The Appellee argues that the working of the Invention during the period from around May 2020 to around November of that year was working for experimental or research purposes, and that the Patent Right is not effective against it, giving such reasons as that the Appellee recruited monitors during that period in order to verify the effects of the Operation, requested monitors to receive the Operation at a discount price, to consent to publication of relevant information on the website, and to visit the Clinic multiple times, among other requests, and paid additional personnel costs at the Clinic for collecting and analyzing data.

(3) The gist of Article 69, paragraph (1) of the Act is construed to be to achieve harmony between the interests of the patentee and the general public from the industrial policy viewpoint, as working of a patented invention for experimental or research purposes normally does not harm the economic interests of the patentee, and extending the effects of a patent right to such experiments would rather result in impeding technological progress and impairing industrial development.

Here, while the patentee has an exclusive right to work the patented invention in the course of trade (the main sentence of Article 68 of the Act), an act of working the patented invention by receiving consideration will harm the economic interests of the patentee, and considering the gist of Article 69, paragraph (1) of the Act to achieve harmony between the interests of the patentee and the general public, it should be construed that such act of working the patented invention does not constitute "the working of the patented invention for experimental or research purposes" unless there are special circumstances, even if the act also has a research purpose.

When this is examined with regard to the present case, as found and explained in 2. above, the Appellee is found to have provided the Operation by receiving consideration from clients and have manufactured (produced) compositions that fall within the technical scope of the Invention to be used in the Operation at the Clinic since May 27, 2020.

In addition, according to evidence (Exhibits Otsu 45, 47, and 52 to 58), the amount of money which the Appellee received from clients as consideration for the Operation was often discounted, but the amount of discount was not uniform, and there were cases in which no discount was given even during the monitoring period (May to November

2020) alleged by the Appellee and cases in which a large amount of discount was given even after the monitoring period, and at least it cannot be said that the Operation was provided for a low price that practically cannot be regarded as consideration due to the reason that it was a monitoring period. Thus, the abovementioned special circumstances cannot be found, and it should be said that the working of the Invention by the Appellee does not constitute "working of the patented invention for experimental or research purposes."

(4) Accordingly, the Patent Right is not effective against the *in vitro* tests, etc. conducted by the Appellee until around May 2020 pursuant to Article 69, paragraph (1) of the Act. However, the Appellee's defense to the effect that the Patent Right is not effective against the acts conducted during the so-called monitoring period from May 27, 2020 to around November of that year pursuant to that paragraph is groundless.

7. Regarding Issue 3-2 (whether it can be said that the Patent Right is not effective against the Appellee's acts pursuant to the provisions on exemption from liability regarding the act of preparation of a medicine (Article 69, paragraph (3) of the Act))

(1) The Appellee argues that the Patent Right is not effective against the Appellee's acts pursuant to the provisions of Article 69, paragraph (3) of the Act.

(2) While Article 69, paragraph (3) of the Act targets "a medical invention (medicine meaning a product used in the diagnosis, therapy, treatment, or prevention of human diseases; hereinafter the same applies in this paragraph) that is to be manufactured by two or more medicines being mixed together," the composition relating to the Invention is one "that is used for breast augmentation," as is clear from the statements of the claims, and the purpose of the breast augmentation is primarily regarded to be aesthetic, as indicated in the statement "there is a high demand among women to maintain ample breasts for the purpose of achieving a beautiful appearance and various breast enlargement operations for this purpose have been performed for a long time" in paragraph [0003] of the Description, etc. When such statements of the Description, etc. as well as the current social norm are taken into account, the composition relating to the Invention is not found to be a product used for any of the purposes of the diagnosis, therapy, treatment, or prevention of human diseases.

(3) Against this, the Appellee argues that, while the Invention relates to aesthetic medical care, aesthetic medical care is a field that contributes to improving mental and physical health as well as self-esteem through reconstruction, restoration, or formation of physical features, and it affects therapy and the structure or function of the body, and therefore that the Invention constitutes "a medical invention (medicine meaning a product used in the diagnosis, therapy, treatment, or prevention of human diseases;

hereinafter the same applies in this paragraph) that is to be manufactured by two or more medicines being mixed together" referred to in Article 69, paragraph (3) of the Act.

However, "disease" is a term that generally means "a phenomenon in which an organism suffers an abnormality in the physiological state of the whole or a part of its body, an inability of the body to perform normal functions, and various types of pains"(Exhibit Ko 25: the dictionary *Kōjien* (7th edition)), and "a state in which a living organism experiences a disorder in its form or physiological or mental functions, accompanied by pain or discomfort, and cannot lead a healthy daily life" (Exhibit Ko 26: the dictionary *Daijisen* (1st, expanded, and new edition)). Thus, it is difficult to say that a state that requires a breast augmentation operation, which is primarily for an aesthetic purpose as mentioned above, is a "disease" in such a general sense, and it is also difficult to say that a composition for breast augmentation is "a product used in the ... therapy, treatment, or prevention of human diseases."

Meanwhile, Article 69, paragraph (3) of the Act is a provision that was introduced upon the law amendment by Act No. 46 of 1975, in line with deletion of the provision concerning an "invention of a medicine (meaning a product used in the diagnosis, therapy, treatment, or prevention of human diseases; the same applies hereinafter) or of a process of manufacturing a single medicine by mixing two or more medicines," which was specified as an unpatentable invention (Article 32, item (ii) of the Act prior to that amendment). The gist of the new provision is construed to be that preparation of such "medicine" is conducted by way of a doctor selecting a medicine that is expected to have the most appropriate efficacy for therapy, etc. of a human disease from among a large variety of medicines, and instructing a pharmacist, etc. via prescription, and it should be ensured that the selection by the doctor would not be obstructed by a patent right, from the viewpoint of realizing the public interest of smooth implementation of medical practice. However, at least with regard to the selection of the pharmaceutical agent to be used in the breast augmentation operation relating to the Invention, such public interest cannot immediately be found, and as mentioned above, it should be said that no practical reason can be found to deviate from the general meaning of the term "disease" and specially protect such act from exercise of the patent right.

(4) Accordingly, the Invention does not constitute "a medical invention that is to be manufactured by two or more medicines being mixed together," and therefore, without having to examine whether the Appellee's act constitutes "an act of preparation of a medicine by prescription," the Appellee's defense to the effect that the Patent Right is not effective against the act pursuant to the provisions of Article 69, paragraph (3) of

the Act is groundless.

8. Regarding Issue 3-3 (whether exercise of the Patent Right constitutes abuse of right, etc. and is impermissible)

The Appellee asserts that exercise of the Patent Right by the Appellant is nothing but exercise of a patent right against a series of medical practices performed by the Appellee, as a doctor, which is to manufacture NCP by collecting blood from the person to be treated and to administer a pharmaceutical agent manufactured by using the NCP to the person to be treated, and because there are also cases where people become mentally ill due to having physical complexes, a breast augmentation operation can be regarded as a medical practice, and treating a patent right to be not effective against the manufacturing of a mixed pharmaceutical agent to be used in such operation coincides with public interest and welfare. On such basis, the Appellee argues that exercise of the Patent Right by the Appellant is impermissible as abuse of right, or simply, that exercise of a patent right does not extend to a medical practice.

However, it cannot be said that collection of blood from the person to be treated, manufacturing of a composition for breast augmentation, and its administration to the person to be treated are inseparable acts that should always be regarded as a series of acts that are integrated into one, as mentioned in 3. above. In addition, it is difficult to say that a state that requires a breast augmentation operation, which is primarily for an aesthetic purpose, is a "disease," and the public interest of smooth implementation of medical practice cannot immediately be found at least with regard to selection of the pharmaceutical agent to be used in the breast augmentation operation relating to the Invention, as mentioned in 7. above.

Based on such premise, even if the act that is regarded to be an act of working the patented invention in the present case is the manufacturing of a composition for breast augmentation, and even if the Appellee is a doctor, it cannot be said that exercise of the Patent Right against such act constitutes abuse of right, and there are no other grounds to determine that the Patent Right is not effective against such act.

Accordingly, the Appellee's defense that asserts abuse of right, etc. is groundless.

9. Regarding Issue 4-1 (whether Article 102, paragraph (2) of the Act is applicable to calculation of the value of damage in the present case)

(1) Introduction

According to the facts found in 2. (1) above, the Appellee is regarded to have worked the Invention in the course of trade as a result of manufacturing a pharmaceutical agent to be used in the Operation, and at least negligence is found with regard to this aspect. Therefore, the Appellee's obligation to compensate for damage is

examined below.

(2) Regarding the argument that the right to claim compensation for damage was assigned by Doctor A to the Appellant

A. The Appellant argues that, while the Appellant had established a monopolistic non-exclusive license regarding the Patent Right for Doctor A, the right to claim compensation for damage against the Appellee due to infringement of the monopolistic non-exclusive license was assigned by Doctor A to the Appellant, and that Article 102, paragraph (2) of the Act should be applied in calculating the value of damage incurred by Doctor A.

However, there is no sufficient evidence to find that the Appellant had established a monopolistic non-exclusive license regarding the Patent Right for Doctor A. Rather, according to evidence (Exhibit Otsu 42), the Appellant is found to have solicited a non-exclusive licensee or an exclusive licensee on the Appellant's website, under the titled "Leasing of a patent on a mammary gland regeneration type breast augmentation injection," by clearly indicating the Patent Right, from February 2018 to December 2021. The Appellant's such position is incompatible with the establishment of a monopolistic non-exclusive license, which ensures that a license of the same contents will not be granted to a third party within the same scope of the patent.

B. Against this, the Appellant argues that, even if the patentee has established a monopolistic non-exclusive license, the patentee is able to further grant a license to a third party as long as there is the consent of the monopolistic non-exclusive licensee, and that the Appellant's solicitation for establishment of a non-exclusive license is not incompatible with the establishment of a monopolistic non-exclusive license regarding the Patent Right for Doctor A. However, as mentioned in A. above, the Appellant solicited not only a non-exclusive licensee, but also an exclusive licensee, so the Appellant's argument cannot be accepted.

C. Accordingly, Doctor A is not found to have held a monopolistic non-exclusive license regarding the Patent Right, and therefore, the Appellant's argument that the right to claim compensation for damage was assigned by Doctor A to the Appellant lacks a premise and cannot be accepted.

(3) Regarding the argument that the "Appellant group" was gaining profit

Next, the Appellant asserts that Article 102, paragraph (2) of the Act should be applied to calculation of the value of damage incurred by the Appellant due to infringement of the Patent Right. As the reason for this, the Appellant argues that, because it can be said that the Appellant and Doctor A are economically integrated and that the Appellant is gaining profit by working the Invention through Doctor A, there

are circumstances where the Appellant could have gained profit if the Appellee did not commit the act of patent right infringement.

However, there is no sufficient evidence to find such facts as that the Appellant is working the Invention or is providing competing products or competing services. While the Appellant and Doctor A respectively have a legal personality, there is also no sufficient evidence to find such facts as that there is a system in which the profit gained by Doctor A through business is inevitably distributed to the Appellant.

Accordingly, there are no circumstances where the Appellant could have gained profit if the Appellee did not commit the patent right infringement, and therefore, Article 102, paragraph (2) of the Act cannot be applied in calculating the value of damage incurred by the Appellant.

10. Regarding Issue 4-2 (the value of damage)

As mentioned in 9. above, Article 102, paragraph (2) of the Act cannot be applied in calculating the value of damage incurred by the Appellant. Therefore, the value of damage incurred by the Appellant will be calculated pursuant to paragraph (3) of that Article.

(1) Regarding the license fee rate

A. First, there is no sufficient evidence to find that the Appellant was actually licensing the Invention to a third party and was receiving a license fee.

Looking at the trends of general license fees, "Research Report on Ideal Use of Patents, etc. Based on Valuation of Intellectual Property" (Teikoku Databank; 2010) (Exhibit Ko 34) indicates a result of a questionnaire survey on royalty rates among domestic companies showing that the royalty rate in the "medical and biotechnology" field was 6.0%, while "Methodology for Calculating the Amount Equivalent to License Fees for Patent Rights, etc." (Japan Intellectual Property Arbitration Center, License Fee Determination Project Team; 2018) (Exhibit Otsu 44) states, "It cannot be denied that there is general recognition that the license fee rates presented in negotiations for patent licensing contracts in Japanese industry are usually around 3% for the general manufacturing industry and around 6% for medicinal products, with about 1 to 2% increased or decreased according to ranks referred to as "shōchikubai" (literally, pine, bamboo, and plum, respectively indicating high, medium, and low ranks) or the like." According to these statements, it can be said that 6% serves as a guideline for the general licensing fee rate in the medical and biotechnology field.

B. Next, the contents, etc. of the Invention will be examined.

While the Invention is an invention relating to a composition that is used for breast augmentation, in order to perform a breast augmentation operation by actually using

this composition and to obtain the desired effect, it is not enough to obtain the composition and simply administer it under the skin of the person to be treated, and it is obvious that the skill of the doctor who actually takes charge of the treatment would play an important role. In addition, prior art indicated as Cited Document 1 (Exhibit Ko 8) in the examination phase discloses a product combining plate rich plasma (PRP) and a basic fibroblast growth factor (b-FGF), and the document also states a suggestion to use the product in breast augmentation. Thus, it should be said that the characteristics of the Invention that differ from those of prior art are the fact that the Invention adopted "plasma among autologous blood components, wherein the plasma is a liquid component making up half of the blood components," instead of plate rich plasma (PRP), as the blood component to be used, in order to secure a sufficient amount of composition for use in breast augmentation, and the fact that lipid emulsion was added in order to generate and increase a greater amount of adipose tissue. In addition, it must be said that it is unclear to what extent the composition for breast augmentation relating to the Invention has been capable of providing breast augmentation by a safe and natural process, from the viewpoint of the problem to be solved by the Invention, i.e., to provide a composition for breast augmentation that is a composition for promoting an increase in subcutaneous tissue, which enables recovery of autologous tissue and recovery of appearance by a safe and natural process.

C. The modes of the Appellee's acts of infringing the Patent Right and other relevant circumstances will be examined.

According to the indicated evidence and the entire import of oral arguments, the following are found: [i] while the Appellee provided the Operation at the Clinic to those who applied for monitor recruitment from May 27, 2020, and then to those who applied for open recruitment from December 2020, by receiving consideration, and the Operation had been performed a large number of times by July 25, 2021, which is the day before the start of the period during which the Patent Right has no effect pursuant to the provisions of Article 112-3, paragraph (2), item (i) of the Act (July 26, 2021 to January 9, 2023) (Exhibits Otsu 45, 47, and 52 to 58); and [ii] the Appellee established a medical corporation on September 22, 2022 and submitted a notification of establishment of a clinic by that medical corporation on November 1, 2022, and from that date onward, the Operation was performed by the clinic operated by that medical corporation, and the sales from the Operation became a revenue of that medical corporation (Exhibits Otsu 40 and 41).

In addition to these facts, according to the facts found in 2. (1) above and evidence (Exhibits Ko 3, 4, and 9), the Appellee was aware of the existence of the Patent, and

launched the working of the Invention after obtaining a written opinion regarding the Patent of a patent attorney (meanwhile, the opinion to the effect that the Patent has grounds for invalidation and that the Patent Right is not effective against the Appellee's acts cannot be accepted, as already mentioned). While the infringing period is approximately one year and two months from May 27, 2020 to July 24, 2021 (the last day on which the patent-infringing Operation was performed), it is found that, during this period, the Appellee placed advertisements highlighting "blood breast augmentation" and generated about 170 million yen in sales from the charges for breast augmentation operations alone as mentioned below, and the working of the Invention by the Appellee used the method stated as a working example in the Description, etc. except for replacing "autologous plasma" with "plasma from which cell components are completely removed (NCP)" and adding hyaluronic acid and placenta, etc., and there appears to be an intention to work the disclosed Invention without the patentee's permission. On the other hand, the following are also found: when administering the composition relating to the Invention to the person to be treated, the skill of the Appellee, who is a doctor, would be important, as mentioned above, and it should be considered that the consideration for the Operation includes consideration for such techniques; it also appears that the Appellee gained clients through commensurate sales promotion, spending approximately 20 million yen as advertising and promotion costs even only during about three months from October 2020 to December of that year (Exhibits Otsu 37 to 39 and 51); and there are also other clinics that perform breast augmentation mammoplasty using plasma or fibroblasts (Exhibit Otsu 64).

D. As described above, when comprehensively taking into consideration the circumstances such as the trends of general license fee rates, the characteristics and effects of the Invention, and the modes of patent right infringement by the Appellee, as well as the fact that, when calculating the amount of damage pursuant to Article 102, paragraph (3) of the Act, it is possible to hypothesize that an agreement on the license fee is reached with the infringer based on the premise that the patent right had been infringed (paragraph (4) of that Article), the fact that an amount equivalent to consumption tax may be taken into account when determining the license fee, and other various circumstances surrounding the present case, it is reasonable to find that the value of damage to be calculated pursuant to Article 102, paragraph (3) of the Act is an amount obtained by multiplying the sales amount obtained by the Appellee as consideration for the Operation (the charges for breast augmentation) by 8%.

(2) Regarding the sales amount from the charges for breast augmentation and the value of damage under Article 102, paragraph (3) of the Act

A. According to evidence (Exhibits Otsu 45, 47, and 52 to 58) and the entire import of oral arguments, the amount obtained by the Appellee as consideration for the Operation (the amount obtained by deducting the amount of discount from the amounts that are found to be consideration for the Operation, such as those for which "blood mamma" or "HY mamma" ["mamma" being an abbreviation for "mammoplasty"] is stated in the sales slip) from May 27, 2020 to July 24, 2021, which is a period during which the acts of infringing the patent right relating to the Invention are found to have been committed, is as stated in each space of the "Sales amount" column in Attachment 1 "List of Acceptable Amounts," and the amount obtained by multiplying the sales amount of each month by 8% as mentioned in (1) above (any number after the decimal point is rounded down) is as stated in each space of the "Acceptable amount" column in that Attachment. The total amount of damage calculated pursuant to Article 102, paragraph (3) of the Act comes to 13,632,196 yen.

Even with all evidence produced in the present case, occurrence of damage cannot be found for any of the period subject to the Appellant's claim for compensation for damage excluding the period mentioned above.

B. Meanwhile, matters that are or are not considered in calculating the sales amount are supplementarily explained below.

The Appellant argues that not only the charges for breast augmentation, but also option fees, in the Operation should be included in the calculation. However, option fees are consideration for services provided according to the demand of the person to be treated, such as intravenous anesthesia and anti-swelling treatment, and are not inevitably charged when working the Invention, so they are not considered in calculating the sales amount. The Appellant argues that the amount of discount should not be considered, but the Appellee offered a discount to almost all of the persons to be treated, and the regular fee can hardly be recognized. Thus, it is reasonable to make the amount which the Appellee actually received as consideration for the Operation subject to calculation, and therefore, the amount obtained by deducting the amount stated as the "discount amount" on the slip from the amount of the charge for breast augmentation stated thereon will be subject to calculation.

The Appellee argues that the amount of charges that were later returned to clients should be deducted, but as it is a circumstance that occurred after already working the Invention, such amount will not be considered in the calculation of the sales amount.

(3) Regarding the amount equivalent to consumption tax

As mentioned in (1) D. above, when calculating the value of damage pursuant to Article 102, paragraph (3) of the Act, it is determined reasonable to adopt an amount

obtained by multiplying the sales amount obtained by the Appellee as consideration for the Operation (the charges for breast augmentation) by 8%, as a result of comprehensively taking into consideration various circumstances surrounding the present case, including the fact that an amount equivalent to consumption tax may be taken into account when determining the license fee, so there is no need to further take into consideration the amount equivalent to consumption tax.

(4) Regarding damages equivalent to attorneys' fees

In light of various circumstances of the present case, it is reasonable to recognize the amount equivalent to attorneys' fees to be 1.40 million yen. Meanwhile, it is construed that the initial date for the calculation of delay damages relating to this amount is claimed to be the first day of the month following July 2021, which is the last month of infringement, (August 1, 2021).

(5) Summary

According to the above, the Appellant's claims that were expanded in the present instance are well-grounded to the extent of seeking payment of 15,032,196 yen and delay damages accrued thereon at the rate of 3% per annum for the periods from the dates stated in the "Initial date for the calculation of delay damages" column of Attachment 1 "List of Acceptable Amounts" for the amounts respectively stated in the "Acceptable amount" column of that list until the completion of the payment.

11. Conclusion

Thus, without having to determine the other issues, the Appellant's claim for 10 million yen and delay damages accrued thereon in prior instance is well-grounded and should be upheld, and the judgment in prior instance which dismissed this claim is unreasonable and the present appeal is well-grounded; therefore, the judgment in prior instance should be revoked and the Appellant's abovementioned claim should be upheld, and while a part of the Appellant's expanded claim in the present instance is also well-grounded and should be upheld, the rest of the expanded claim is groundless and will be dismissed, and the judgment is rendered as indicated in the main text.

In the proceedings of the present case, the so-called solicitation of third-party opinions was conducted based on the provisions of Article 105-2-11 of the Act. The written opinions submitted to court all contained valuable opinions based on the actual situation of the relationship between medical care and patents, and were beneficial for the court's proceedings and determinations. We would like to express our deep gratitude to all persons concerned.

Intellectual Property High Court, Special Division

Presiding judge: HONDA Tomonari
Judge: MIYASAKA Masatoshi
Judge: SHIMIZU Hibiku
Judge: NAKADAIRA Ken
Judge: AMANO Kenji

(Attachment 1)

List of Acceptable Amounts

Year of aggregation	Month of aggregation	Sales amount	Acceptable amount	Initial date for the calculation of delay damages
2020	May	132,000	¥10,560	Jun. 1, 2020
	Jun.	2,024,548	¥161,963	Jul. 1, 2020
	Jul.	1,862,093	¥148,967	Aug. 1, 2020
	Aug.	4,323,003	¥345,840	Sep. 1, 2020
	Sep.	2,376,366	¥190,109	Oct. 1, 2020
	Oct.	668,183	¥53,454	Nov. 1, 2020
	Nov.	4,134,547	¥330,763	Dec. 1, 2020
	Dec.	13,286,822	¥1,062,945	Jan. 1, 2021
2021	Jan.	21,665,929	¥1,733,274	Feb. 1, 2021
	Feb.	20,247,043	¥1,619,763	Mar. 1, 2021
	Mar.	22,435,482	¥1,794,838	Apr. 1, 2021
	Apr.	22,398,142	¥1,791,851	May 1, 2021
	May	25,639,393	¥2,051,151	Jun. 1, 2021
	Jun.	17,226,683	¥1,378,134	Jul. 1, 2021
	Jul.	11,982,300	¥958,584	Aug. 1, 2021
Damages equivalent to attorneys' fees			¥1,400,000	Aug. 1, 2021
Total		**170,402,534**	**¥15,032,196**	

(Attachment 2)

List of the Amounts Claimed

Year of aggregation	Month of aggregation	Charges for breast augmentation	Charges for breast augmentation (including options)	Amount claimed for each month	Initial date for the calculation of delay damages
2020	May	300,000	370,000	¥166,144	Jun. 1, 2020
	Jun.	3,100,000	3,498,500	¥1,570,963	Jul. 1, 2020
	Jul.	2,918,400	3,048,200	¥1,368,760	Aug. 1, 2020
	Aug.	5,600,000	6,080,000	¥2,730,157	Sep. 1, 2020
	Sep.	3,190,910	3,195,910	¥1,435,088	Oct. 1, 2020
	Oct.	1,100,000	1,290,000	¥579,260	Nov. 1, 2020
	Nov.	4,200,000	4,433,000	¥1,990,590	Dec. 1, 2020
	Dec.	16,700,000	17,468,000	¥7,843,814	Jan. 1, 2021
2021	Jan.	27,854,546	29,044,637	¥13,042,176	Feb. 1, 2021
	Feb.	28,409,091	29,669,091	¥13,322,581	Mar. 1, 2021
	Mar.	25,643,637	27,543,637	¥12,368,169	Apr. 1, 2021
	Apr.	24,380,000	26,767,000	¥12,019,428	May 1, 2021
	May	29,510,001	31,215,301	¥14,016,889	Jun. 1, 2021
	Jun.	21,760,910	23,181,310	¥10,409,314	Jul. 1, 2021
	Jul.	15,028,182	15,893,182	¥7,136,659	Aug. 1, 2021
	Total	**209,695,677**	**222,697,768**	**¥99,999,992**	

(Attachment 3)

List of Abbreviations

The Patent	The patent of Patent No. 5186050 (filing date: February 24, 2012; registration date: January 25, 2013)
The Patent Right	The patent right relating to the Patent
The Description, etc.	The description, claims, and drawings attached to the written application for the Patent (their contents are as shown in Exhibit Ko 2)
The Clinic	A clinic called "Y'" which the Appellee operated in Metropolitan Tokyo from around 2019 to around 2022 and where the Appellee had provided aesthetic medical services, such as breast augmentation operations
The Invention	Of the invention stated in Claim 4 of the claims in the Description, etc., the one citing the invention stated in Claim 1
Doctor A, the Applicant	A doctor who is the inventor of the Invention and the applicant of the Patent (hereinafter the names of third parties are indicated by symbols)
The Operation	A blood breast augmentation operation called "3 WAY blood breast augmentation" which the Appellee had provided at the Clinic by using "cell-free plasma gel"
NCP	Plasma from which cell components have been completely removed
The Pharmaceutical Agent Notebook	A handwritten notebook which had been prepared at the Clinic for recording the components, etc. used in the Operation (Exhibit Ko 29 and Exhibits Otsu 60 and 62)
Subject B	A person who received the Operation at the Clinic on April 8, 2021 and April 26, 2021
Nurse C	A nurse who was working at the Clinic
Assistance Nurse D	An assistance nurse who was working at the Clinic