Patent Right	Date	March 24, 2023	Court	Tokyo District Court, 46th Civil Division
	Case number	2022 (Wa) 5905		
- A case in which a claim for compensation for damages on the grounds of infringement of a patent right under a patent for an invention titled "COMPOSITION FOR PROMOTING INCREASE IN SUBCUTANEOUS TISSUE AND SUBCUTANEOUS ADIPOSE TISSUE" was dismissed.				

Summary of the Judgment

The present case is one in which the Plaintiff, who holds a patent right (hereinafter referred to as "the present patent right") for an invention titled "COMPOSITION FOR PROMOTING INCREASE IN SUBCUTANEOUS TISSUE AND SUBCUTANEOUS ADIPOSE TISSUE," claims for compensation for damages against the Defendant pursuant to Article 709 of the Civil Code and Article 102, paragraph (2) of the Patent Act on the grounds that a pharmaceutical agent for blood breast augmentation manufactured by the Defendant falls within the technical scope of the patented invention.

While the issues in the present case are wide-ranging, this judgment held that the pharmaceutical agent manufactured by the Defendant could not be recognized as falling within the technical scope of the patented invention, and dismissed the Plaintiff's claim.

The invention pertaining to the present patent right (hereinafter referred to as "the present invention") is a product, and is defined as "comprising autologous plasma, a basic fibroblast growth factor (b-FGF), and a fat emulsion." On the grounds of the statement in the Defendant's website and the explanation to patients, etc., the Plaintiff asserted that the Defendant manufactured a pharmaceutical agent comprising all of three components: cell-free plasma gel, which corresponds to autologous plasma; trafermin, which contains the basic fibroblast growth factor; and intralipos, which is a type of the fat emulsion, and then administered the pharmaceutical agent to patients. In response, the Defendant did not dispute that the above three components were sometimes administered to patients. However, the Defendant asserted as follows: The Defendant manufactures two different pharmaceutical agents each comprising only a part of these three components, and administers them to each patient separately; neither of the two pharmaceutical agents comprises the above three components simultaneously; and thus, the Defendant does not manufacture the pharmaceutical agent that falls within the technical scope of the present invention.

This judgment pointed out as follows: Neither of the statement in the Defendant's website and the explanation to patients can be deemed as unnatural even if the two

pharmaceutical agents were manufactured and administered separately; and it is suggested that the Defendant considered that mixing the above three components in advance would cause inconvenience such as coagulation of the pharmaceutical agent, and attempted to avoid this. Then, this judgment held that it was insufficient to recognize that the Defendant prepared the pharmaceutical agent comprising these components simultaneously and administered it to the person to be treated.

Judgment rendered on March 24, 2023: Original issued on the same date to the court clerk
2022 (Wa) 5905, Case of seeking compensation for damages
Date of conclusion of oral argument: January 13, 2023

Judgment

Plaintiff: Kabushiki Kaisha Tokai Ika

Defendant: A

Main text

1. The Plaintiff's claim shall be dismissed.
2. The Plaintiff shall bear the court costs.

Facts and reasons

No. 1 Claim

The Defendant shall pay to the Plaintiff 10,000,000 yen and the amount accrued thereon at the rate of 3% per annum for the period from April 9, 2022 (the day following the date of service of the complaint) until the completion of the payment.

No. 2 Outline of the case, etc.

1. Outline of the case

In this case, the Plaintiff, who holds a patent right for an invention titled "Composition for promoting increase in subcutaneous tissue and subcutaneous adipose tissue," alleged that a pharmaceutical agent for blood breast augmentation manufactured by the Defendant falls within the technical scope of the patented invention. Based on this allegation, under Article 709 of the Civil Code and Article 102, paragraph (2) of the Patent Act, the Plaintiff demands that the Defendant pay 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, a day after a tort was committed (the day following the date of service of the complaint), until the completion of the payment.

2. Basic facts (facts for which there are no disputes between the parties or facts that are easily found based on the pieces of evidence cited below and the entire import of oral arguments)

(1)A. The Plaintiff is a stock company engaging in the business of selling, leasing, and otherwise handling medical devices. (No disputes)

B. The Defendant opened an aesthetic medical clinic around 2019 as an individual

proprietor and has been operating it up to the present as its director. (No disputes)
(2) The Plaintiff holds the following patent right (hereinafter referred to as the "Patent Right"; the patent pertaining to the Patent Right is referred to as the "Patent").

Patent number: Patent No. 5186050

Title of the invention: Composition for promoting increase in subcutaneous tissue and subcutaneous adipose tissue

Filing date: February 24, 2012

Registration date: January 25, 2013

(3) The statements in Claims 1 and 4 in the claims regarding the Patent Right are as follows (hereinafter the invention stated in Claim 4 is referred to as the "Invention," and the description pertaining to the Patent is referred to as the "Description").

A. Claim 1

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

B. Claim 4

A composition for breast augmentation characterized in that it comprises a composition for promoting increase in subcutaneous tissue that is used for breast augmentation which is stated in any one of Claims 1 to 3.

(4) In this case, the Plaintiff alleges that a pharmaceutical agent manufactured by the Defendant falls within the technical scope of the invention that cites the invention stated in Claim 1 out of the invention stated in Claim 4. The claims stated in (3) above can be segmented as follows.

A. Characterized in that it comprises autologous plasma, a basic fibroblast growth factor (b-FGF), and a fat emulsion

B. Used for breast augmentation

C. A composition for promoting increase in subcutaneous tissue

(5) The Defendant opened a clinic on June 20, 2019. From June 2019 to May 2020, the Defendant conducted various in vitro experiments after manufacturing a pharmaceutical agent in order to prepare for blood breast augmentation treatment. From June to November 2020, the Defendant administered the pharmaceutical agent it manufactured to trial subjects. In December 2020, the Defendant started blood breast augmentation treatment using the pharmaceutical agent it manufactured and has been conducting it to date.

(6) On January 25, 2021, the Patent Right lapsed due to non-payment of patent fees. (Exhibit Ko 1, Exhibit Otsu 11, and the entire import of oral arguments)

3. Issues

(1) Whether the Defendant manufactured a pharmaceutical agent in which trafermin, which is a basic fibroblast growth factor, and intralipos, which is a fat emulsion, are mixed in addition to "cell-free plasma gel" (Constituent Feature A) (Issue 1)

(2) Whether the pharmaceutical agent manufactured by the Defendant comprises autologous "plasma" (Constituent Feature A) (Issue 2)

(3) Whether the manufacturing of the pharmaceutical agent by the Defendant does not fall under the category of medical practice (Issue 3)

(4) Damages (Issue 4)

(5) Whether the Invention does not fall under the category of invention with industrial applicability and the Patent involves a ground for invalidation (Issue 5)

(6) Whether the Patent involves a ground for invalidation due to failure to fulfill the support requirement (Issue 6)

(7) Whether the manufacturing of the pharmaceutical agent by the Defendant in treatment conducted until November 2020 falls under the category of trial and research (Issue 7)

No. 3 Judgment of this court

1. Invention

The problem to be solved by the Invention is to "provide a composition for breast augmentation that is a composition for promoting increase in subcutaneous tissue and/or subcutaneous adipose tissue that can achieve recovery of a patient's own tissue and appearance by a safe and natural method, which promotes accumulation and increase of subcutaneous tissue and adipose tissue under the breast skin by generating and increasing adipose tissue around the lacteal gland while avoiding the possibility of burst and cancer development likely to be caused by a breast implant that has been used in conventional breast augmentation treatment, such as cohesive silicon or silicon gel bag, and avoiding induration caused as a result of hyaluronic acid becoming subcutaneous tissue due to injection of hyaluronic acid, as well as a breast augmentation method using the same composition" (paragraph [0012] of the Description). The Invention is an invention of a composition for promoting increase in subcutaneous tissue that is used for breast augmentation which is characterized in that it comprises autologous plasma, a basic fibroblast growth factor (b-FGF), and a fat emulsion to solve said problem.

2. Whether the Defendant manufactured a pharmaceutical agent in which trafermin, which is a basic fibroblast growth factor, and intralipos, which is a fat emulsion, are

mixed in addition to "cell-free plasma gel" (Constituent Feature A) (Issue 1)

(1) As mentioned in 1. above, the Invention is an invention of a composition, and the composition is "characterized in that it comprises autologous plasma, a basic fibroblast growth factor (b-FGF), and a fat emulsion" (Constituent Feature A). The Plaintiff alleges as follows: the Defendant has mixed trafermin, which is a basic fibroblast growth factor (b-FGF), and intralipos, which is a fat emulsion, in addition to "cell-free plasma gel" and administered the mixture to a person to be treated; therefore, the Defendant manufactured a pharmaceutical agent containing these components. On the other hand, the Defendant alleges as follows: the Defendant has separately administered two types of pharmaceutical agents, a pharmaceutical agent in which blood plasma, a growth factor, and other pharmaceutical agent are mixed and a pharmaceutical agent containing emulsifier, nutrient, etc., into a patient's body and has never manufactured a pharmaceutical agent in which these two types of pharmaceutical agents are mixed.

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

A. On April 8 and 26, 2021, the Defendant conducted blood breast augmentation treatment to the person to be treated in question (hereinafter referred to as the "Person to Be Treated") as a "trial subject."

The document delivered at that time, which starts with the term "Side effects," included the following statement: "… 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 …." Therefore, the document included a statement presupposing administration of trafermin and intralipos to the same person. Trafermin is a pharmaceutical agent that is clinically used as a genetically modified basic fibroblast growth factor. Intralipos is a type of fat emulsion.

In addition, there was the following statement in the "written approval and application (written oath) for breast augmentation operation by injection method" delivered to the Person to Be Treated: "□ This is an operation for breast augmentation 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 Defendant did not explain to the Person to Be Treated that two types of pharmaceutical agents, trafermin and intralipos, are to be administered separately.

(For this section, Exhibits Ko 2, 5, and 6)

B. As of July 21, 2021, there was an explanation about blood breast augmentation treatment conducted by the Defendant on the Defendant's website. In the explanation, there was the following statement in the " INJECTION" section.

"Take blood and centrifuge it to completely remove blood platelets (a type of cell component contained in blood) that causes lumps. In conventional methods, a material called PPP gel that is extracted from a patient's own blood by centrifugation could not be denied. However, at our clinic, we avoid the cause of lumps by also using cell-free plasma gel obtained by completely removing cell components. 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. We reduce the rate of absorption into the body and can expect the effect of rejuvenating and increasing the fitness of the breasts by adding our own reinforcing material that has the effect of thickening the aforementioned combination to further increase the retention rate. …"

Moreover, following the aforementioned statement, a pattern diagram of an infusion package and that of the process of inserting a syringe filled with a pharmaceutical agent into the breast were placed side by side. Under the diagrams, there was the following statement: "Our clinic does not use TPP (platelet-poor plasma) gel that causes lumps at all but uses "cell-free plasma gel" obtained by removing cell components from the blood taken from a patient. Therefore, no lumps will develop after the treatment, and very soft breasts will be the result. …" (Exhibit Ko 3)

(3) According to (2)A. above, it is found that the Defendant administered trafermin, which contains a basic fibroblast growth factor, and intralipos, which is a type of fat emulsion, to the Person to Be Treated in the blood breast augmentation treatment that the Defendant gave to the Person to Be Treated on April 8 and 26, 2021. In addition, according to (2)B. above and the entire import of oral arguments, it is also found that at that time, the Defendant also administered "cell-free plasma gel" comprising blood plasma from which cell components, including blood platelets, had been completely removed (incidentally, the parties dispute over whether the "cell-free plasma gel" falls under the category of "blood plasma" of Constituent Feature A; No. 2, 4.(2) above).

Here, in the document starting with the term "Side effects," etc. mentioned in (2)A. above, it is stated that trafermin and intralipos are administered. However, it is not stated that a pharmaceutical agent comprising these components is first prepared and then administered to a person to be treated. In addition, the statement in the "written approval and application (written oath) for breast augmentation operation by injection

method" cannot be considered to mean that the components stated therein are first mixed and then administered.

Consequently, based on the statement in the document mentioned in (2)A. above, it cannot be found that the Defendant has administered trafermin and intralipos after mixing them in advance.

(4)A. The Plaintiff points out the statement on the Defendant's website mentioned in (2)B. above as evidence showing that the Defendant has administered trafermin and intralipos after mixing them in advance.

The Defendant's website explains the content of the injection in the "INJECTION" section but does not state anything about a specific administration method. Although there is the statement "… we also combine a growth factor and an emulsifier, in addition to cell-free plasma gel," when reading the relevant part from the beginning, use of "cell-free plasma gel" is emphasized as a ground for the superiority of the Defendant's treatment compared to other treatments, and following that, it is just additionally stated that other components are also "combined." From this, it can be considered natural to understand that the aforementioned phrase "are combined" just means that all of these pharmaceutical agents are administered into the body. It is thus impossible to find the fact alleged by the Plaintiff from the aforementioned phrase.

Moreover, on the Defendant's website, there is a pattern diagram of the process of inserting a syringe under the aforementioned statement. In the diagram, it is not stated that the injection is given multiple times. However, this diagram is merely an image diagram of administration of a pharmaceutical agent by inserting a syringe into the breast, and based on this pattern diagram, it is impossible to consider that the Defendant assumes only a one-time injection of a single pharmaceutical agent.

The relevant part of the Defendant's website does not contain any statement that clearly indicates that the Defendant injects the aforementioned two types of pharmaceutical agents separately. However, in the aforementioned part of the Defendant's website, the Defendant intends to show off "cell-free plasma gel" as a ground for the superiority of own treatment, and it can be said that the Defendant places easy-to-understand explanation and pattern diagrams there for that purpose. Therefore, the specific method of administering the pharmaceutical agents is not a point of focus in that part of the Defendant's website. Taking this into account, even if the Defendant has administered the aforementioned two types of pharmaceutical agents separately, it is not found to be particularly unnatural that the Defendant did not state such administration method on the website.

Therefore, the statement on the Defendant's website is not sufficient to find that

the Defendant has administered trafermin and intralipos after mixing them in advance.
B. In addition, the Defendant did not explain to the Person to Be Treated that the two types of pharmaceutical agents, trafermin and intralipos, are to be administered separately ((2)A. above).

However, it is also not found that the Defendant explained to the Person to Be Treated that a single pharmaceutical agent is to be administered. Although it must be important to explain each pharmaceutical agent to be administered from the perspective of side effects, allergy, or the like, there is no sufficient evidence to find such circumstances as that there was knowledge that the risk of side effects, etc. especially increases in general if multiple components are administered not as a single pharmaceutical agent but separately as multiple pharmaceutical agents. Therefore, it cannot be found that it was particularly unnatural not to explain that multiple active components are to be administered separately as multiple pharmaceutical agents before administration.

Therefore, the fact that the Defendant did not explain to the Person to Be Treated that the two types of pharmaceutical agents, trafermin and intralipos, are to be administered separately is not sufficient to find that the Defendant has administered them after mixing them in advance.

C. From the beginning of this lawsuit, the Defendant alleges as follows: the Defendant avoided administering a pharmaceutical agent prepared by mixing blood plasma from which cell components are completely removed (NCP) and other pharmaceutical agents pertaining to blood breast augmentation because the Defendant had gained, from experiment using such blood plasma, the knowledge that if these components are mixed in advance, it may become difficult to inject the mixture depending on the apparatus used because the mixture is solidified or gets thicker. The Defendant then submits a written experimental result report stating that if the components are mixed as stated in the working example of the Description, they turn into a form like soy milk skin (Exhibit Otsu 12). Although there is no evidence supporting that the experiment in the same written report was conducted by a method as stated in the Description (whether or not the aforementioned phenomenon also occurs even under appropriate conditions is not clear), the written report at least shows that based on the idea that these components will be solidified, etc. if they are mixed in advance, the Defendant intended to avoid such a method.

(5) In consideration of the aforementioned circumstances, the Defendant is found to have administered trafermin and intralipos, as well as "cell-free plasma gel," to the Person to Be Treated in blood breast augmentation treatment, but it cannot be found

that the Defendant prepared a pharmaceutical agent comprising these components simultaneously and administered it to the Person to Be Treated. Therefore, it is not found that the Defendant manufactured a pharmaceutical agent that fulfills Constituent Feature A and administered it to the Person to Be Treated.

In addition, other relevant pieces of evidence are not sufficient to find that the Defendant has prepared and manufactured a pharmaceutical agent comprising components that correspond to Constituent Feature A simultaneously.

No. 4 Conclusion

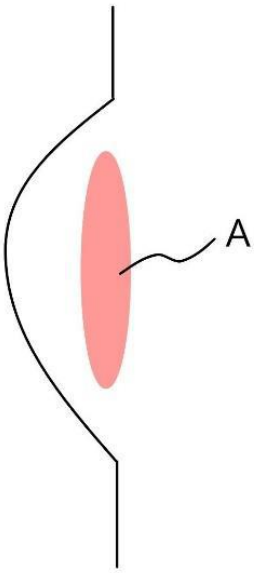
For the reasons described above, the Defendant is not found to have manufactured a pharmaceutical agent that fulfills Constituent Feature A. Therefore, the Plaintiff's claim is groundless without the need to make determinations concerning other issues.

Tokyo District Court, 46th Civil Division
Presiding judge: SHIBATA Yoshiaki
Judge: SAEKI Ryoko
Judge: NAKADA Kenji

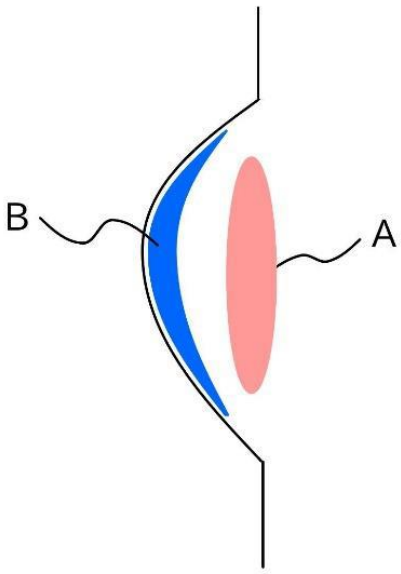
Attachment

Pharmaceutical agent injection procedure

[1]



[2]



[3]