Date	January 28, 2010	Court	Intellectual Property High Court, Third Division
Case number	2009 (Gyo-Ke) 10033		

A case in which, with respect to the JPO decision which found that the requirement under Article 36, paragraph (6), item (i) of the Patent Act was not satisfied only because the "detailed explanation of the invention," contained in the description of the patent application with regard to the invention relating to the use of a drug, does not include "pharmacological data or a statement that can be deemed to be equivalent thereto," the court rescinded said decision on the grounds that it was illegal due to the defects in the reasons attached thereto, except where there are special circumstances.

References:
Article 36, paragraph (6), item (i) of the Patent Act

The plaintiff filed a patent application with regard to an invention relating to the use of a drug, entitled "use of Flibanserin for the treatment of a sexual disorder," but was given a decision of refusal by the examiner of the Japan Patent Office (JPO). In the trial procedure before the JPO, the plaintiff's request for a trial against this decision of refusal was also dismissed by the trial examiner. The plaintiff filed a suit with this court to seek rescission of the JPO decision of dismissal.

The JPO decided that the plaintiff's request for a trial against the examiner's decision of refusal should be dismissed for the following reasons. (1) In the case of an invention relating to the use of a drug, it is difficult in general to predict the drug's usefulness only by referring to the name of its active ingredient or its chemical structure. Even where the detailed explanation of the invention discloses, to some extent, an effective dose, method of administration or matters necessary for preparation, it is still impossible for a person ordinarily skilled in the art to know whether or not the drug is actually useful in the relevant use, by referring to such information alone. Therefore, in such case, the detailed explanation of the invention must include pharmacological data or a statement that should be deemed to be equivalent thereto, thereby proving the usefulness of such use. (2) In this case, the detailed explanation of the invention, contained in the description of the patent application in question, includes nothing to prove the usefulness of Flibanserin in the invented use as claimed in the application. (3) Consequently, the statement of the scope of claims regarding the invention in question does not satisfy the requirement under Article 36, paragraph (6), item (i) of the Patent Act, "the invention for which a patent is sought is stated in the detailed explanation of the invention."

In this judgment, the court rescinded the JPO decision, holding as follows. (1) The

provisions of Article 36, paragraph (6), item (i) of the Patent Act are laid down for the purpose of excluding the possibility that too broad an exclusive right will be granted based on the statement of the "scope of claims," as compared to the statement in the "detailed explanation of the invention." Therefore, when construing the provisions of Article 36, paragraph (6), item (i) of the Patent Act, it is sufficient to compare the statement of the scope of claims and the statement of the detailed explanation of the invention and examine whether the scope of the former goes beyond the scope of the latter, applying a construction method that is necessary and in line with the purpose. In the process of construing said provisions and making a determination, it is impermissible to apply completely the same method as that applicable when examining whether the requirement under paragraph (4), item (i) of said Article (enablement requirement) is satisfied, except where there are special circumstances. (2) "Pharmacological data or a statement that should be deemed to be equivalent thereto" can be a prerequisite necessary for examining whether the requirement under Article 36, paragraph (4), item (i) of the Patent Act is satisfied with regard to an invention relating to the use of a drug, but except where there are special circumstances, it cannot be regarded as a necessary prerequisite in terms of satisfaction of the requirement under paragraph (6), item (i) of said Article. (3) In this case, since there are no such special circumstances, and the statement of the scope of claims does not go beyond the scope of technical matters disclosed in the detailed explanation of the invention, the requirement under Article 36, paragraph (6), item (i) of the Patent Act is satisfied. (4) Consequently, the JPO decision is illegal for the defects in the reasons attached thereto, in that it found that the requirement under Article 36, paragraph (6), item (i) of the Patent Act was not satisfied only because of the lack of "pharmacological data or a statement that can be deemed to be equivalent thereto."

Judgment rendered on January 28, 2010

2009 (Gyo-Ke) 10033, Case of Seeking Rescission of a JPO Decision

Date of conclusion of oral argument: November 11, 2009

Judgment

Plaintiff: *Boehringer Ingelheim Pharma GmbH* & Co. KG

Counsel attorney: TSUJII Koichi

Same as above: TAKAISHI Hideki

Same as above: OWADA Atsuko

Counsel subagent attorney: SATAKE Shoichi

Counsel patent attorney: HAKODA Atsushi

Same as above: TASHIRO Gen

Counsel subagent patent attorney: SHINTANI Masafumi

Defendant: Commissioner of the Japan Patent Office

Designated representative: TSUKANAKA Tetsuo

Same as above: ANABUKI Tomoko

Same as above: KITAMURA Akihiro

Same as above: KOBAYASHI Kazuo

Main Text

1. The JPO decision rendered regarding Trial against Examiner's Decision of Refusal No. 2006-27319 on September 29, 2008, shall be rescinded.

2. The defendant shall bear the court costs.

Facts and reasons

No. 1 Claims

The same as the main text of this judgment.

No. 2 Facts undisputed by the parties

1. Progress of procedures at the JPO

The plaintiff filed a patent application (Patent Application No. 2003-537639; hereinafter referred to as the "Application") whose international application date is October 4, 2002 (priority claim under the Paris Convention: October 20, 2001 (priority date); Europe (priority country)), in relation to an invention titled "use of flibanserin in the treatment of sexual disorders." However, an examiner's decision of refusal was rendered on September 4, 2006. In response to this, the plaintiff filed a request for a trial against the examiner's decision of refusal (Trial against Examiner’s Decision of Refusal No. 2006-27319) on December 4 of the same year.

On September 29, 2008, the JPO rendered a decision (hereinafter referred to as the "JPO Decision"; additional period: 90 days) to the effect that "The request for a trial in question shall be dismissed." A certified copy of the JPO Decision was serviced to the plaintiff on October 14 of the same year.

2. Scope of claims

The statement of Claim 1 in the scope of claims in the description (Exhibits Ko No. 3 and No. 4; hereinafter referred to as the "Description") amended by a written amendment (Exhibit Ko No. 4) dated December 26, 2005, pertaining to the Application is as follows (hereinafter the invention claimed in Claim 1 is referred to as the "Invention").

"Use of flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof, for the preparation of a medicament for the treatment of sexual desire disorders."

3. Reasons for the JPO Decision

The reasons for the JPO Decision are as stated in a copy of the written JPO Decision attached to this judgment. The gist thereof is as follows.

(1) For a use invention concerning a medicine, it is generally difficult to predict its usefulness based only on the names and chemical structures of the active ingredients. Even if the effective dose, administration method and matters necessary for preparation are stated in the detailed explanation of the invention to a certain extent, a person ordinarily skilled in the art cannot know whether the medicine is actually useful in that use based only on such statements. Therefore, in order to say that the invention for which a patent is sought is that which is stated in the detailed explanation of the invention, it is necessary that the usefulness of that use is proven based on a statement of pharmacological data or a statement that should be equated with such data in the detailed explanation of the invention.

(2) The detailed explanation of the invention in the Description includes no statement that proves the usefulness of flibanserin in the medicinal use of the Invention.

(3) Therefore, the statement of the scope of claims pertaining to the Invention does not fulfill the requirement provided for in Article 36, paragraph (6), item (i) of the Patent Act (hereinafter referred to as the "Act"), "the invention for which a patent is sought is stated in the detailed explanation of the invention."

No. 3 Allegations of the parties

1. Allegations of the plaintiff concerning the grounds for the rescission of the JPO Decision

As stated below, the JPO Decision contains [i] an error in its interpretation of the provisions of Article 36, paragraph (6), item (i) of the Act, "the invention for which a patent is sought is stated in the detailed explanation of the invention," and [ii] an error in its determination to the effect that the statement of the scope of claims of the Application does not fulfill the requirement provided for in Article 36, paragraph (6), item (i) of the Act.

(1) Error in the interpretation of the requirement provided for in Article 36, paragraph (6), item (i) of the Act

A. The JPO ruled that for a use invention concerning a medicine, it is necessary to make "a statement of pharmacological data or a statement that should be equated with such data" in order to fulfill the requirement provided for in Article 36, paragraph (6), item (i) of the Act, "the invention for which a patent is sought is stated in the detailed explanation of the invention."

However, the interpretation of the requirement provided for in Article 36, paragraph (6), item (i) of the Act in the JPO Decision is unreasonable as stated below.

In the judgment of the Special Division of the Intellectual Property High Court of November 11, 2005, on 2005 (Gyo-Ke) 10042 (hereinafter referred to as the "Judgment of the Grand Panel of the Intellectual Property High Court" in some cases), the court held as follows: "Whether the statement of the scope of claims complies with the description support requirement should be determined by examining, through comparison between the statement of the scope of claims and that of the detailed explanation of the invention, whether the invention stated in the scope of claims is the same as the invention stated in the detailed explanation of the invention, and whether the invention is described to the extent that a person ordinarily skilled in the art can recognize that the invention can solve the target problem in reference to the statement of the detailed explanation of the invention, or whether the invention is described to the extent that a person ordinarily skilled in the art can recognize that the invention can solve the target problem in light of common general technical knowledge as of the filing of the Application, without reference to the statement in the detailed explanation or any suggestion therefrom." However, said judgment does not permit setting a different determination standard for each technical field of inventions regarding compliance with Article 36, paragraph (6), item (i) of the Act (Article 36, paragraph (5), item (i) of the Patent Act prior to revision by Act No. 116 of 1994).

The JPO ruled that in relation to a use invention concerning a medicine, it is necessary to make a "statement of pharmacological data or a statement that should be equated with such data" in order to comply with the requirement under Article 36, paragraph (6), item (i) of the Act. However, making such a statement a requirement means setting a determination standard (requirement) that differs from the determination standard (requirement) indicated in the Judgment of the Grand Panel of the Intellectual Property High Court, that is, "the invention is stated so that a person ordinarily skilled in the art can recognize that the problem to be solved by the Invention can be solved," which deviates from the purpose of said judgment.

It is certainly necessary to indicate the usefulness of a use in relation to a use invention concerning a medicine. However, it is not always necessary to make a "statement of pharmacological data or a statement that should be equated with such data" in order to prove the

usefulness of the use. A statement based on which a person ordinarily skilled in the art can confirm the usefulness of the use should be considered sufficient. It is sufficient to determine whether a medicine has a pharmacological action proven by pharmacological data on the occasion of sales approval under the Pharmaceutical Affairs Act, and it is not necessary that such fact be stated in the description originally attached to the application (hereinafter referred to as the "Description Originally Attached to the Application"). The idea of not protecting a claimed invention as an invention unless there is such a statement is unreasonable.

As above, the determination in the JPO Decision to the effect that a statement of "pharmacological data or a statement that should be equated with such data" is required under Article 36, paragraph (6), item (i) of the Act in determining the patentability of a "use invention concerning a medicine" contains an error in the interpretation of the requirement provided for in paragraph (6), item (i) of said Article.

B. The interpretation of the requirement provided for in Article 36, paragraph (6), item (i) of the Act in the JPO Decision goes against the international harmonization of patent systems for the following reasons.

At the USPTO and the EPO, it is sufficient if the Description Originally Attached to the Application of a medicinal use invention includes a statement to the effect that the usefulness of the use has been specifically confirmed. A "statement of pharmacological data or a statement that should be equated with such data" is not required. An examiner's decision to grant a patent has been rendered for both the corresponding U.S. patent application and corresponding European patent application of the Application (Exhibits Ko No. 5 and No. 6). Therefore, it goes against international harmonization and is unreasonable if only the JPO requires a "statement of pharmacological data or a statement that should be equated with such data" in the detailed explanation of the invention in the Description as of the filing of the Application.

In addition, it violates Article 29.1 and Article 27.1 of the TRIPS Agreement if only the JPO requires a "statement of pharmacological data or a statement that should be equated with such data" in the detailed explanation of the invention in the Description as of the filing of the Application.

C. The interpretation of the requirement provided for in Article 36, paragraph (6), item (i) of the Act in the JPO Decision violates the purpose of the Patent Act for the following reasons.

In light of the purpose of the Patent Act, i.e., "through promoting the protection and the utilization of inventions, to encourage inventions, and thereby to contribute to the development of industry," where a person (inventor) found a "(new) use" but said person was taking a long time to collect data to specifically confirm the usefulness of the "(new) use," while another person promptly collected data, it is not appropriate to protect said other person as the patentee.

In particular, no animal or test-tube experiment-based rating method has been established in

relation to the "sexual desire enhancing" effect of the Invention prior to the priority date of the patent in question. Therefore, a clinical test was necessary to rate the relationship between the active ingredient and its effect. As it is necessary to explain to doctors and test subjects about the ingredient in order to conduct a clinical test, it is difficult to eliminate the possibility of secrets being divulged. Consequently, it is necessary to immediately file a patent application before conducting a clinical test, and there is thus the reasonableness of permitting such filing of a patent application.

D. The JPO Decision contains an error in its interpretation to the effect that the content of the requirement under Article 36, paragraph (6), item (i) of the Act is the same as that of the requirement under paragraph (4), item (i) of said Article.

Article 36, paragraph (4), item (i) of the Act requires that the statement of the detailed explanation of the invention is "clear and sufficient as to enable any person ordinarily skilled in the art … to work the invention." In the JPO's practice (Examination Guidelines), it is also required, in relation to Article 36, paragraph (4), item (i) of the Act, to clearly state the compounds applied, the pharmacological test system adopted, and the results obtained, as well as the relevance between the pharmacological test system and the medicinal use of the invention of medicine claimed in the claims, in a description.

However, the reason for the JPO Decision in this case is non-fulfillment of the requirement provided for in Article 36, paragraph (6), item (i) of the Act, "the invention for which a patent is sought is stated in the detailed explanation of the invention." Therefore, the JPO Decision contains an error in its interpretation to the effect that the content of the requirement under paragraph (6), item (i) of said Article is the same as that of the requirement under paragraph (4), item (i) of said Article.

(2) Error in the finding to the effect that the statement of the scope of claims of the Application does not fulfill the requirement under Article 36, paragraph (6), item (i) of the Act

As stated below, the statement of the scope of claims of the Application fulfills the requirement under Article 36, paragraph (6), item (i) of the Act.

A. As stated below, the detailed explanation of the invention in the Description includes a statement that enables a person ordinarily skilled in the art to recognize that the problem to be solved by the invention (sexual desire enhancement) can be solved.

(A) The Description states as follows: "Flibanserin shows affinities for the 5-HT_{1A} and 5-HT_2 receptors. It is therefore a promising therapeutic agent for the treatment of a variety of diseases, for instance, depression, schizophrenia and anxiety. In studies of male and female patients suffering from sexual dysfunction, it has been found that flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof, displays sexual desire enhancing properties" (Exhibit Ko No. 3; paragraph [0003]). The Description thereby states that the

inventor has confirmed that flibanserin displays sexual desire enhancing properties in the studies of male and female patients suffering from sexual dysfunction.

Moreover, specific administration methods are stated with regard to the forms of administration of flibanserin, which had been studied for the purpose of the treatment of depression, specifically, "tablet," "coated tablet," "capsule," "ampoule solution," and "suppository," in paragraphs [0008] to [0013] in the Description.

(B) The sexual desire enhancing properties of the Invention relate to improvement of the human psychological component. Therefore, it is impossible to determine whether sexual desire has been enhanced based on the appearance of patients who have been administered flibanserin. There is no other choice but to determine it based on medical interviews (questionnaires) with patients who have been administered flibanserin (Exhibits Ko No. 7 and No. 24 to No. 27). There has been no established animal or test-tube experiment-based sexual desire rating method prior to the priority date of the Application (as stated in the paper of Exhibit Ko No. 10 published in 2004, a model of animal experiment-based sexual desire rating was established at that time; Exhibits Ko No. 21 to No. 23 and No. 31 are also to the same effect). For example, the ASEX scale (Exhibit Ko No. 7), which was made by the University of Arizona in 1997, etc., were known as forms of a questionnaire to rate sexual desire (see Exhibit Ko No. 18, Doctor of Medicine C's written opinion).

Consequently, a person ordinarily skilled in the art can understand that the statement, "it has been found that flibanserin … displays sexual desire enhancing properties" (Exhibits Ko No. 3 and No. 4; paragraph [0003]), means that the results of questionnaires with patients who have been administered flibanserin revealed that flibanserin has such properties (see Exhibit Ko No. 18, Doctor of Medicine C's written opinion).

In this regard, the defendant alleges that a person ordinarily skilled in the art cannot understand that the effect of the Invention has been confirmed based on the results of the questionnaires because there have been actual cases where an applicant filed an application for a new medicine by developing a new animal experiment-based rating method and thereby rating the effect by said method (Exhibit Otsu No. 6). However, Exhibit Otsu No. 6 relates to disorders of female sexual arousal (diseases of organs relating to human sexual activity, such as the pelvis and sexual organ), and does not concern diseases with human sexual desire, that is, Hypoactive Sexual Desire Disorder, as in the case of the Invention. For Hypoactive Sexual Desire Disorder, no animal experiment-based sexual desire rating model had been established as of the priority date of the Invention. Therefore, the defendant's allegation is unreasonable.

(C) The inventor of the Invention had engaged in a study intended for the treatment of depression. As prescription medicines for depression sometimes presented with sexual dysfunction as a side effect (Exhibit Ko No. 9), the inventor analyzed the results of

questionnaires with patients suffering from depression, which were conducted in a clinical test of flibanserin for the treatment of depression with regard to the patients' symptoms before and after the administration of flibanserin with the aim of confirming whether the patients present sexual dysfunction. It was thereby confirmed that flibanserin displays sexual desire enhancing properties among prescription medicines for depression. Based thereon, the inventor invented a medicament for the treatment of sexual desire disorders whose active ingredient is flibanserin.

According to the results of HAMD (*Hamilton* Depression Rating Scale), which is a major rating item for major depressive disorder (MDD), paroxetine displays a more potent depression alleviation effect than flibanserin (Exhibit Ko No. 33-2). On the other hand, the result of an ASEX questionnaire (Exhibit Ko No. 33-1; slide p. 9) reveals that flibanserin displays more significant sexual desire enhancing properties than paroxetine that displays a more potent depression alleviation effect. The result of the ASEX questionnaire shows that flibanserin displays unique sexual desire enhancing properties that are not based on a side effect of the depression alleviation effect.

(D) As mentioned above, the detailed explanation of the invention in the Description states that the substance of the Invention is a specific compound, flibanserin, and that this specific compound displays "sexual desire enhancing properties," as well as the way in which this specific compound is administered. Based thereon, a person ordinarily skilled in the art can understand that the effect found based on the results of the questionnaires with the patients after they were administered flibanserin is stated in the Description. Therefore, it can be said that there is a statement that enables a person ordinarily skilled in the art to recognize that the problem to be solved by the Invention (sexual desire enhancement) can be solved. Consequently, the statement of the scope of claims of the Invention fulfills the requirement under Article 36, paragraph (6), item (i) of the Act.

(E) The plaintiff submitted experiment data through a written amendment dated February 21, 2007 (Exhibit Ko No. 1), and a written opinion dated August 7, 2006 (Exhibit Ko No. 2). These data reinforced the proof of the usefulness of the use of the Invention stated in the Description by studies covering many test subjects.

B. Even if the content of the requirement under Article 36, paragraph (6), item (i) of the Act is interpreted as being the same as that of the requirement under Article 36, paragraph (4), item (i) of the Act, the statement of the detailed explanation of the invention in the Description fulfills the requirement under Article 36, paragraph (6), item (i) of the Act.

That is, [i] "flibanserin" was included in the List of INNs (International Nonproprietary Names) in 1997 (Exhibit Ko No. 8), and the composition was specified and was stated in European patent application EP-A 526434, which discloses a manufacturing process thereof (Exhibit Ko No. 3; paragraph [0001]). [ii] With regard to the statement in the Description, "In

studies of male and female patients suffering from sexual dysfunction, it has been found that flibanserin … displays sexual desire enhancing properties" (Exhibits Ko No. 3 and No. 4; paragraph [0003]), a person ordinarily skilled in the art can understand that this is an effect found based on the results of the questionnaires with the patients after they were administered flibanserin and that the test was conducted through the questionnaires. [iii] It is obvious that the statement to the effect that "it has been found that flibanserin … displays sexual desire enhancing properties" was made based on said questionnaires and that there is relevance between said questionnaires and the use. Therefore, the statement is considered as fulfilling said requirement.

2. Defendant's counterargument

(1) Error in the interpretation of the requirement provided for in Article 36, paragraph (6), item (i) of the Act

A. The plaintiff alleges that there is an error in the interpretation in the JPO Decision to the effect that for a medicinal use invention, it is necessary to make a "statement of pharmacological data or a statement that should be equated with such data" in order to fulfill the requirement provided for in Article 36, paragraph (6), item (i) of the Act, "the invention for which a patent is sought is stated in the detailed explanation of the invention."

However, the plaintiff's allegation is groundless as stated below.

The problem to be solved by a medicinal use invention is to select and provide a substance that is useful in relation to a use, that is, the treatment or prevention of a disease. The process therefor is carried forward by determining whether a substance has physiological activity (pharmacological effect) that is useful as a medicine through screening of the physiological activity (pharmacological effect) of the substance, by analyzing pharmacological data, and by selecting a substance that is useful as a medicine (Exhibit Otsu No. 1). For a medicinal use invention, it is difficult to predict its usefulness based only on the names and chemical structures of the active ingredients. Even if the effective dose, administration method and matters necessary for preparation are stated in the detailed explanation of the invention to a certain extent, a person ordinarily skilled in the art cannot know whether the medicine is actually useful in that use based only on such statements. Therefore, in order to say that the invention for which a patent is sought is that which is stated in the detailed explanation of the invention, it is necessary that the usefulness of that use is proven based on a "statement of pharmacological data or a statement that should be equated with such data" in the detailed explanation of the invention.

In the Judgment of the Grand Panel of the Intellectual Property High Court, the court held as follows: "It should be said that, in order to obtain a patent by stating an invention as such in the scope of claims, the detailed explanation of the invention in the description must be such

that a person ordinarily skilled in the art can recognize that the problem to be solved by the invention can be really solved." In light of the aforementioned property of medicinal use inventions, it does not conflict with the Judgment of the Grand Panel of the Intellectual Property High Court to interpret that, for a medicinal use invention, the requirement provided for in Article 36, paragraph (6), item (i) of the Act requires a "statement of pharmacological data or a statement that should be equated with such data."

B. The plaintiff alleges that it goes against the international harmonization of patent systems and violates Article 29.1 and Article 27.1 of the TRIPS Agreement to interpret Article 36, paragraph (6), item (i) of the Act as requiring a "statement of pharmacological data or a statement that should be equated with such data in the detailed explanation of the invention in the description as of the filing of the patent application."

However, the aforementioned allegation of the plaintiff is groundless. Even if the USPTO and the EPO have determined to grant a patent for the corresponding inventions of the Invention, such determinations made by the patent offices of foreign countries cannot be recognized as having an effect on the propriety of the interpretation that Article 36, paragraph (6), item (i) of the Act requires a "statement of pharmacological data or a statement that should be equated with such data in the detailed explanation of the invention in the description as of the filing of the patent application."

In addition, Article 29.1 of the TRIPS Agreement provides for the disclosure which the Members shall require that an applicant for a patent make, and Article 27.1 of the TRIPS Agreement provides that patents shall be available and patent rights enjoyable without discrimination as to the field of technology, etc. on the condition of following certain provisions. Therefore, the aforementioned provisions of the TRIPS Agreement do not preclude the interpretation to the effect that Article 36, paragraph (6), item (i) of the Act requires a "statement of pharmacological data or a statement that should be equated with such data."

C. The plaintiff alleges as follows: If a "statement of pharmacological data or a statement that should be equated with such data" is required, where a person (inventor) found a "(new) use" but said person was taking a long time to collect data to specifically confirm the usefulness of the "(new) use," while another person promptly collected data, said other person would be protected as the patentee, which goes against the purpose of the Patent Act, that is, "through promoting the protection and the utilization of inventions, to encourage inventions, and thereby to contribute to the development of industry."

However, the aforementioned allegation of the plaintiff is groundless.

As the requirement under Article 36, paragraph (6), item (i) of the Act, the usefulness of flibanserin as a medicament for the treatment of sexual desire disorders must be proven based on a statement of pharmacological data or a statement that should be equated with such data.

However, in this case, the detailed explanation of the invention in the Description neither refers to the questionnaires concerning sexual desire disorders that the inventor of the Invention allegedly conducted nor does it state the fact that the Invention was made in the process of a clinical test of flibanserin for the treatment of depression. Therefore, the requirement under Article 36, paragraph (6), item (i) of the Act is not fulfilled.

According to the plaintiff's allegation, the inventor of the Invention had engaged in a study intended for the treatment of depression. As prescription medicines for depression sometimes presented with sexual dysfunction as a side effect (Exhibit Ko No. 9), the inventor analyzed the results of questionnaires with patients suffering from depression, which were conducted in a clinical test of flibanserin for the treatment of depression, with regard to the patients' symptoms before and after the administration of flibanserin, with the aim of confirming whether the patients present sexual dysfunction. Surprisingly, as an unpredictable result, it was confirmed that flibanserin displays sexual desire enhancing properties amongst prescription medicines for depression. Based thereon, the inventor came to invent a medicament for the treatment of sexual desire disorders whose active ingredient is flibanserin.

Granted that the inventor gained such recognition, the plaintiff could have made a statement that proves the usefulness of flibanserin as a medicament for the treatment of sexual desire disorders by way of making a "statement of pharmacological data or a statement that should be equated with such data" by stating a specific fact which serves as the ground on which the inventor determined that flibanserin is useful as a medicament for the treatment of sexual desire disorders in the aforementioned clinical test of flibanserin for the treatment of depression, that is, the content of said clinical test and the content and results of the questionnaires conducted therein, as well as the analysis method, etc. thereof, in the Description to the extent that a person ordinarily skilled in the art could recognize that flibanserin is useful as a medicament for the treatment of sexual desire disorders. However, there is no such statement. Therefore, the requirement under Article 36, paragraph (6), item (i) of the Act is not fulfilled.

D. The plaintiff alleges that the JPO Decision contains an error in that it interprets the content of the requirement under Article 36, paragraph (6), item (i) of the Act as being the same as that of the compliance requirement under paragraph (4), item (i) of said Article. Moreover, the plaintiff points out that a determination standard that is the same as that for the compliance requirement under paragraph (4), item (i) of said Article is also used in the JPO's practice (Examination Guidelines).

However, the aforementioned allegation of the plaintiff is groundless. That is, whether the statement of the scope of claims in the Description fulfills the requirement under paragraph (6), item (i) of said Article should be determined in light of said provisions, and that determination contains no error. In addition, the Examination Guidelines are determination standards that were

prepared for the purpose of contributing to securing the fairness and reasonableness of the JPO's determinations concerning whether a patent application fulfills the requirements for patentability as provided for in the Patent Act, and are not rules of law. Therefore, the JPO Decision will not become illegal based on whether a determination that conflicts with the Examination Guidelines has been made in the trial.

Incidentally, the current Examination Guidelines (Part VII, Chapter 3 "Medicinal Inventions," 1.1.1 "Article 36(6)(i) of the Patent Act"; Exhibit Otsu No. 2) cite the case where there is no statement of a pharmacological test method, pharmacological data, etc. as an example of a case of non-fulfillment of the requirement under paragraph (6), item (i) of said Article. Specifically, they cite a case where "[i] While an antiemetic drug having an ingredient A as an active ingredient is claimed for a patent, neither a pharmacological test method nor pharmacological data, etc., which could prove that ingredient A has antiemetic action, is disclosed in the detailed explanation of the invention, and furthermore, it cannot be presumed from the common general technical knowledge as of the filing of the patent application that ingredient A is effective as an antiemetic drug."

(2) Error in the finding to the effect that the statement of the scope of claims of the Application does not fulfill the requirement under Article 36, paragraph (6), item (i) of the Act

A. The plaintiff alleges that the statement of the detailed explanation of the invention in the Description is made to the extent that a person ordinarily skilled in the art can recognize that the problem to be solved by the Invention (sexual desire enhancement) can be solved. That is, the plaintiff alleges as follows: When seeing the statement in paragraph [0003] in the Description, a person ordinarily skilled in the art can understand that the effect found based on the results of the questionnaires conducted after the patients were administered flibanserin is stated in the Description; in that case, it can be said that there is a statement to the extent that a person ordinarily skilled in the art can recognize that the problem to be solved by the Invention (sexual desire enhancement) can be solved; therefore, the statement of the detailed explanation of the Invention fulfills the requirement provided for in Article 36, paragraph (6), item (i) of the Act.

However, the aforementioned allegation of the plaintiff is groundless as stated below.

(A) In order to say that the statement of the detailed explanation of the Invention is made in a manner that a person ordinarily skilled in the art can recognize that the Invention can solve the problem (provision of a medicament for the treatment of sexual desire disorders), it is not sufficient that the detailed explanation of the invention states that the Invention can solve the problem (provision of a medicament for the treatment of sexual desire disorders), but it is necessary that the statement of the detailed explanation of the Invention is made to the extent that a person ordinarily skilled in the art can technically understand that the problem (provision of a medicament for the treatment of sexual desire disorders) can be solved, based on objective

facts.

The Description states that "In studies of male and female patients suffering from sexual dysfunction, it has been found that flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof, displays sexual desire enhancing properties" (Exhibits Ko No. 3 and No. 4; paragraph [0003]). However, the Description states no specific explanations about the study conducted, the results of the study obtained, the test method adopted in the study, and the test data obtained.

In filing a patent application for a new invention of a medicine, the method for rating its usefulness as a medicine is not limited to a specific one. Therefore, it is considered that the inventor of the Invention developed a new animal experiment-based rating method with a high predictability and recognized flibanserin's sexual desire enhancing properties based on the results of the experiment (for example, see the example of an application in Exhibit Osu No. 6), and it is also considered that the inventor recognized flibanserin's sexual desire enhancing properties by analyzing the results of existing animal experiments again in detail from a new perspective. Consequently, it cannot be said that a person ordinarily skilled in the art could understand, from the statement in the Description, that the Description states the knowledge that was recognized based on the results of the questionnaires conducted after the patients were administered flibanserin. In addition, there is also no ground for the plaintiff's allegation that there was no established animal model that serves as an indicator of pharmacological treatment of HSDD prior to the priority date of the Invention, as shown in Exhibits Ko No. 21, No. 31, No. 22, No. 23, and No. 10.

The plaintiff alleges that according to the results of HAMD (*Hamilton* Depression Rating Scale), which is a major rating item for major depressive disorder (MDD), paroxetine displays more potent depression alleviation effect than flibanserin. However, none of the slides in Exhibit Ko No. 33-1 shows the results of HAMD (*Hamilton* Depression Rating Scale) in relation to flibanserin and paroxetine. In addition, Exhibits Ko No. 28 to No. 30 that are cited in Slide 6 (Exhibit Ko No. 33-1), which is a slide concerning HAMD (*Hamilton* Depression Rating Scale), which is a major rating item for major depressive disorder (MDD), state nothing about the depression alleviation effect of paroxetine in comparison with flibanserin.

Consequently, there is no ground for the plaintiff's allegation to the effect that "The result of an ASEX questionnaire (Slide 9 in Exhibit Ko No. 33-1) reveals that flibanserin displays more significant sexual desire enhancing properties than paroxetine that displays more potent depression alleviation effect; therefore, the result of the ASEX questionnaire reveals that flibanserin displays not the side effect of depression alleviation effect but unique sexual desire enhancing properties."

(B) Even if whether sexual desire could be enhanced was able to be determined based only on

medical interviews (questionnaires) with patients who were administered flibanserin as of the priority date of the Application, as alleged by the plaintiff, and a person ordinarily skilled in the art could understand that the Invention was made based on medical interviews (questionnaires) with patients who were administered flibanserin, the subject patients, the treatment given, the medical interviews (questionnaires) conducted, the results obtained and the degree of alleviation of sexual dysfunction are not obvious to a person ordinarily skilled in the art from the statement of the detailed explanation of the invention in the Description. Therefore, it cannot be found that flibanserin's sexual desire enhancing properties were shown to the extent that a person ordinarily skilled in the art could recognize that flibanserin is useful as a medicament for the treatment of sexual desire disorders.

It is true that the detailed explanation of the invention in the Description states example preparations, such as "tablet." However, it states nothing about pharmacological tests in which these preparations were administered.

(C) The plaintiff submitted experiment data through a written amendment dated February 21, 2007 (Exhibit Ko No. 1), and a written opinion dated August 7, 2006 (Exhibit Ko No. 2). The plaintiff alleges that the usefulness of the use of the Invention stated in the Description was proven by these data. However, it is not permitted to satisfy the proof of a use invention concerning a medicine by submitting the results of a clinical study that are equivalent to pharmacological test data after filing of a patent application because it goes against the purpose of the patent system, that is, granting a patent on the premise of the disclosure of an invention. Consequently, the plaintiff's allegation is unreasonable.

B. The plaintiff alleges that the statement of the detailed explanation of the invention in the Description fulfills the requirement under Article 36, paragraph (6), item (i) of the Act even on the premise of the interpretation that said requirement is the same as the requirement under paragraph (4), item (i) of said Article.

However, the aforementioned allegation of the plaintiff is groundless. The detailed explanation of the invention in the Description states no pharmacological test system, and therefore [i] the pharmacological test system in which the compound was applied, [ii] the results obtained, and [iii] the relevance between the pharmacological test system and the medicinal use of the invention of a medicine claimed in the claims are not obvious. Consequently, there is also no ground for the plaintiff's allegation to the effect that the requirement under Article 36, paragraph (6), item (i) of the Act is fulfilled on the premise of the interpretation that said requirement is the same as the requirement under paragraph (4), item (i) of said Article.

No. 4 Court decision

The court determines that the JPO Decision contains an error in that it interpreted Article 36, paragraph (6), item (i) of the Act as providing that, for a medicinal use invention, it is necessary

to make a "statement of pharmacological data or a statement that should be equated with such data" in order to fulfill the requirement provided for in said item, "The statement of the scope of claims…shall comply with each of the following items: (i) the invention for which a patent is sought is stated in the detailed explanation of the invention," and ruled that the scope of claims of the Application does not fulfill the requirement under item (i) of said paragraph.

The reasons thereof are as stated below.

1. Relationship between Article 36, paragraph (4), item (i) of the Act and paragraph (6), item (i) of said Article

(1) Purposes of the provisions of Article 36, paragraph (4), item (i) of the Act and of paragraph (6), item (i) of said Article

Article 36 of the Act provides for the requirements concerning the matters required to be stated in an application to be submitted at the time of filing a patent application. Of those requirements, Article 36, paragraph (4), item (i) of the Act and paragraph (6), item (i) of said Article provide for the requirement in relation to the statement of the "detailed explanation of the invention" in a description attached to an application and the requirement in relation to the statement of the "scope of claims" attached to an application, respectively, in a distinguishable manner.

That is, Article 36, paragraph (4), item (i) of the Act provides, as a requirement for the statement of the "detailed explanation of the invention," that "the problem to be solved by the Invention, means for solving said problem and other matters necessary for a person ordinarily skilled in the art to which the invention pertains to understand the technical significance of the invention" (Article 24-2 of the Ordinance for Enforcement of the Patent Act) are stated in a manner that is "clear and sufficient as to enable any person ordinarily skilled in the art to which the invention pertains to work the invention." The purpose of said provisions is as follows: The patent system is a system to grant to a person who has disclosed an invention an exclusive right for a certain period of time in compensation for the disclosure of the technology; if a person requesting the grant of a patent can receive the granting of an exclusive right without disclosing to third parties the problem to be solved by the Invention, means for solving said problem and other matters necessary to understand the technical significance of the invention and without disclosing to third parties matters that are clear and sufficient so as to work the invention, it could cause the loss of the purpose of the patent system, that is, granting an exclusive right in compensation for the disclosure of an invention that is a useful creation of technical ideas; therefore, the provisions require a statement of the aforementioned matters in the "detailed explanation of the invention" in a description.

On the other hand, Article 36, paragraph (6), item (i) of the Act provides, as a requirement for the statement of the "scope of claims," that "the invention for which a patent is sought is

stated in the detailed explanation of the invention." Said item was established in order to effectuate the provisions of Article 68 and Article 70, paragraph (1) of the Act, which specifically provide that a patentee shall have the exclusive right to work the patented invention as a business (Article 68 of the Act) and that the technical scope of a patented invention shall be determined based upon the "statements in the scope of claims" attached to the application (Article 70, paragraph (1) of the Act). Where the statement of the "scope of claims" exceeds the scope of the technical matters stated and disclosed in the "detailed explanation of the invention," if an exclusive right is granted to cover such an extensive technical scope as well, it would depart from the purpose of the patent system, that is, granting an exclusive right to the extent that the technology was disclosed in compensation for the disclosure. Therefore, Article 36, paragraph (6), item (i) of the Act provides that such statement of the scope of claims shall not be permitted. For example, where, despite that it is considered, based on the statement of "working examples," etc. in the "detailed explanation of the invention," that only narrow and limited technical matters have been disclosed, the statement of the "scope of claims" includes an extensive technical scope that exceeds the technical matters disclosed, the statement of the "scope of claims" is not permitted as one that violates said item.

In this manner, the provisions of Article 36, paragraph (6), item (i) of the Act were established for the purpose of comparing the statement of the "scope of claims" with the statement of the "detailed explanation of the invention" and thereby eliminating the granting of an excessively extensive exclusive right.

(2) Determination of compliance with Article 36, paragraph (6), item (i) of the Act

In determining whether the "statement of the scope of claims" complies with Article 36, paragraph (6), item (i) of the Act, that is, whether the "statement of the scope of claims" fulfills the requirement that the "invention for which a patent is sought is stated in the detailed explanation of the invention," it is necessary to understand the technical matters disclosed in the "detailed explanation of the invention," as a premise of the determination. The content of disclosure in the "detailed explanation of the invention" as a premise for determining compliance with the requirement under Article 36, paragraph (6), item (i) of the Act should be understood based on a method that is necessary and reasonable to determine said compliance, taking into account that said item provides for the requirement in relation to the statement of the "scope of claims" and that said item was established in order to eliminate the granting of an excessively extensive exclusive right compared to the technical matters disclosed in the detailed explanation of the invention. On the other hand, with regard to the statement of the "detailed explanation of the invention," Article 36, paragraph (4), item (i) of the Act independently provides for the requirement that "the problem to be solved by the Invention, means for solving said problem and other matters necessary … to understand the technical significance …" shall

be stated in a manner that is "clear and sufficient as to enable … to work (the invention)." Therefore, if the statement of the detailed explanation of the invention does not comply with the requirement provided for in said item, there will be a reason for refusal of the application due to non-compliance itself or non-compliance will constitute an independent ground for invalidation (Article 123, paragraph (1), item (iv) of the Patent Act). Therefore, interpreting and determining compliance with the provisions of Article 36, paragraph (6), item (i) of the Act by a method that is totally the same as that of determining compliance with the requirement under Article 36, paragraph (4), item (i) of the Act, apart from the purpose of Article 36, paragraph (6), item (i) of the Act, that is, "eliminating the granting of an excessively extensive exclusive right compared to the technical matters disclosed in the detailed explanation of the invention," could end up with determining the same matter doubly. If it is permitted to make an interpretation based on the relationship in which the requirement under Article 6, paragraph (6), item (i) of the Act is not fulfilled whenever the statement of the detailed explanation of the invention does not fulfill the requirement provided for in paragraph (4), item (i) of said Article, there will be no meaning to establishing the provisions of paragraph (4), item (i) of said Article as a separate, independent requirement for patentability, in addition to paragraph (6), item (i) of said Article.

Consequently, in interpreting the provisions of Article 36, paragraph (6), item (i) of the Act, it is sufficient to determine whether the scope of the statement of the scope of claims exceeds that of the statement of the detailed explanation of the invention by comparing the former with the latter by a necessary and purposeful interpretation method. It should be said that it is not permitted to interpret and determine compliance with the requirement under said item by a method that is totally the same as that of determining compliance with the requirement under paragraph (4), item (i) of said Article unless there are special circumstances, such as where it significantly goes against the purpose of the patent system not to interpret the "detailed explanation of the invention" by a method as above as a premise for determining Article 36, paragraph (6), item (i) of the Act because the scope of claims is stated in a unique form.

In what follows, this case is considered from the aforementioned perspective.

2. Reasons for the JPO Decision

The JPO mentioned as in (1) and (2) below and determined that the Application does not fulfill the requirement under Article 36, paragraph (6), item (i) of the Act on the grounds that the detailed explanation of the invention of the Application "does not include any statement of pharmacological data or a statement that should be equated with such data which proves the usefulness of the flibanserin as a medicament for the treatment of sexual desire disorders" (underlines by the court).

(1) "For a use invention concerning a medicine, it is generally difficult to predict its usefulness based only on the names and chemical structures of the active ingredients. Even if the effective

dose, administration method and matters necessary for preparation are stated in the detailed explanation of the invention to a certain extent, a person ordinarily skilled in the art cannot know whether the medicine is actually useful in that use based only on such statements. Therefore, in order to say that the invention for which a patent is sought is that which is stated in the detailed explanation of the invention, it is necessary that the usefulness of that use is proven based on a "statement of pharmacological data or a statement that should be equated with such data" in the detailed explanation of the invention. If the detailed explanation of the invention does not include such a statement, the statement of the scope of claims must be regarded as not fulfilling the requirement provided for in Article 36, paragraph (6), item (i) of the Act" (line 22 to line 31 of page 2 of the written JPO Decision).

(2) "Considering this in relation to the Description, the invention claimed in Claim 1 of the Application is 'use of flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof, for the preparation of a medicament for the treatment of sexual desire disorders.' Claim 1 does not specify at all the way of 'using' flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof (hereinafter also referred to as "flibanserin"), for the preparation of a medicament for the treatment of sexual desire disorders.

On the other hand, the detailed explanation of the invention of the Application explains the Invention as follows: 'In studies of male and female patients suffering from sexual dysfunction, it has been found that flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof, displays sexual desire enhancing properties. Accordingly, the instant invention relates to the use of flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof for the preparation of a medicament for the treatment of sexual desire disorders' (paragraph [0003] in the Description).

In that case, the Invention is recognized as relating to a medicinal use invention that is a medicament for the treatment of sexual desire disorders that was made based on the finding of the fact that the flibanserin has a new pharmacological effect, that is, sexual desire enhancing properties. Therefore, in order to say that the Invention is that which is stated in the detailed explanation of the invention in the Description, it is necessary that the usefulness of the use is proven based on a statement of pharmacological data or a statement that should be equated with such data which proves the usefulness of the flibanserin as a medicament for the treatment of sexual desire disorders.

Therefore, considering the statement of the Description, the detailed explanation of the invention in the Description states nothing that can be regarded as pharmacological data that proves the usefulness of the flibanserin as a medicament for the treatment of sexual desire disorders" (line 32 of page 2 to line 20 of page 3 of the written JPO Decision).

"The statement in (a) to (f) in the detailed explanation of the invention in the Description …

cannot be regarded as a statement that should be equated with pharmacological data that prove that the flibanserin is useful as a medicament for the treatment of sexual desire disorders. Therefore, the detailed explanation of the invention in the Description states neither pharmacological data that proves the usefulness of the Invention as a medicine nor a statement that should be equated with such pharmacological data. … As mentioned above, the Application does not fulfill the requirement provided for in Article 36, paragraph (6), item (i) of the Patent Act" (line 23 of page 5 to line 7 of page 6 of the written JPO Decision).

3. Propriety of the reasons for the JPO Decision

(1) With regard to the Application, the JPO did not determine whether the scope of the statement of the "scope of claims" exceeds that of the statement of the "detailed explanation of the invention" by comparing the former with the latter but ruled that the requirement provided for in Article 36, paragraph (6), item (i) of the Act is not fulfilled only on the grounds that the "detailed explanation of the invention" in the Description does not include a statement of "pharmacological data that proves the usefulness" of the flibanserin as a medicament for the treatment of sexual desire disorders or "a statement that should be equated with such data."

However, it should be said that the JPO has not provided grounds that are sufficient to affirm that the requirement provided for in Article 36, paragraph (6), item (i) of the Act is not fulfilled unless the "detailed explanation of the invention" includes a statement of "pharmacological data that proves the usefulness or a statement that should be equated with such data."

A. In the reasons for the JPO Decision, the JPO states as follows: "For a use invention concerning a medicine, it is generally difficult to predict its usefulness based only on the names and chemical structures of the active ingredients. Even if the effective dose, administration method and matters necessary for preparation are stated in the detailed explanation of the invention to a certain extent, a person ordinarily skilled in the art cannot know whether the medicine is actually useful in that use based only on such statements. Therefore, in order to say that the invention for which a patent is sought is that which is stated in the detailed explanation of the invention, it is necessary that the usefulness of that use is proven based on a statement of pharmacological data or a statement that should be equated with such data" in the detailed explanation of the invention" (line 22 to line 29 of page 2 of the written JPO Decision). It is impossible to deny that this part applies in some cases in light of the purpose of Article 36, paragraph (4), item (i) of the Act in relation to the premise for determining the fulfillment of the requirement under said item.

From the perspective that it is necessary to disclose to third parties the problem to be solved by the Invention, means for solving said problem and other matters necessary to understand the technical significance of the invention and provide information that is clear and sufficient to

work the invention in order to obtain an exclusive right through obtainment of a patent, Article 36, paragraph (4), item (i) of the Act provides that the matters recognized as necessary therefor should be stated in the "detailed explanation of the invention." Then, it should be considered that, under the Japanese Patent Act that recognizes use inventions concerning medicines, clarification of the process of objectively verifying the usefulness of a use in the statement of the "detailed explanation of the invention" applies in many cases in general. It can be said that the most effective, appropriate, and reasonable method of clarifying the verification process is based on data indicating relevance between the medicine and the use. Therefore, if such data are not stated, the statement is regarded as not being clear and sufficient so as to work the invention in many cases.

In relation to the fulfillment of the requirement under Article 36, paragraph (6), item (i) of the Act, the JPO Decision states as follows: "it is necessary that the usefulness of that use is proven based on a statement of pharmacological data or a statement that should be equated with such data in the detailed explanation of the invention." However, regarding this part, it cannot be said that it is an indispensable condition (requirement) to make a statement of pharmacological data or a statement that should be equated with such data unless there are special circumstances. As mentioned above, the provisions of Article 36, paragraph (6), item (i) of the Act were established for the purpose of preventing the granting of an exclusive right that covers an extensive scope that exceeds the scope of technical matters stated in the "detailed explanation of the invention" by comparing the "scope of claims" and the "detailed explanation of the invention." In that case, the method of interpreting the content of the statement of the "detailed explanation of the invention" should be one that is necessary and purposeful to determine whether the "scope of claims" is within the scope of the technical matters stated in the "detailed explanation of the invention," in light of the purpose of said provisions. It should be considered sufficient to formally understand the technical matters stated and disclosed in working examples, etc. in the "detailed explanation of the invention" unless there are special circumstances.

Consequently, the part of the JPO Decision to the effect that the statement of the scope of claims does not fulfill the requirement provided for in Article 36, paragraph (6), item (i) of the Act unless the detailed explanation of the invention is stated in manner that "the usefulness of that use is proven based on a statement of pharmacological data or a statement that should be equated with such data" does not always apply. Consequently, the determination concluding that said statement goes against Article 36, paragraph (6), item (i) of the Act only on that ground should be regarded as being defective in the reasons unless there are special circumstances.

B. In the reasons for the JPO Decision, the JPO considered the specific statement of the detailed explanation of the invention, and ruled that "The detailed explanation of the invention in the

Description does not include a statement of pharmacological data that proves the usefulness of the Invention as a medicine or a statement that should be equated with such pharmacological data." Based on this ruling, the JPO concluded that the Application does not fulfill the requirement provided for in Article 36, paragraph (6), item (i) of the Act.

However, the JPO did not consider the scope of the technical matters that are understood based on the statement of the detailed explanation of the invention through comparison with the scope of claims, but only considered whether there is a statement of "pharmacological data or a statement that should be equated with such data" and thereby determined that the requirement under Article 36, paragraph (6), item (i) of the Act is not fulfilled on the grounds of the non-existence of such a statement. Therefore, the JPO Decision should be regarded as being illegal due to a defect in the reasons in that the JPO ruled that the requirement provided for in paragraph (6), item (i) of said Article is not fulfilled, without specifically considering the reasons for which the statement of the scope of claims of the Application exceeds the scope of the technical matters stated in the detailed explanation of the invention. In addition, in this case, there are no special circumstances, such as where there is the risk of inhibiting the development of industry unless considering that the statement in the description does not fulfill the requirement under Article 36, paragraph (6), item (i) of the Act because the scope of claims of the application is stated in a unique form.

C. The defendant alleges that it becomes a requirement for compliance with Article 36, paragraph (6), item (i) of the Act to make a "statement of pharmacological data or a statement that should be equated with such data" in the detailed explanation of the invention in the case of applying to medicinal use inventions the reasons for the Judgment of the Grand Panel of the Intellectual Property High Court to the effect that the "statement of the scope of claims" for an invention that includes an object specified by the scope indicated by a certain formula using multiple technical variables (parameters) that indicate characteristic values does not comply with the provisions of Article 36, paragraph (5), item (i) of the Patent Act prior to the revision by Act No. 116 of 1994 (Article 36, paragraph (6), item (i) of the current Act).

However, the defendant's allegation cannot be adopted as stated below.

As mentioned above, the holding in the Judgment of the Grand Panel of the Intellectual Property High Court concerns whether the "statement of the scope of claims" for the invention that includes an object specified by the scope indicated by a certain formula using multiple technical variables (parameters) that indicate characteristic values complies with the requirement provided for in Article 36, paragraph (5), item (i) of the Patent Act prior to the revision by Act No. 116 of 1994 (Article 36, paragraph (6), item (i) of the current Act). In said judgment, the court established a section titled "Comparison between the invention stated in the detailed explanation of the invention and the invention stated in the scope of claims," in No. 6,

1(4) in the reasons for the judgment, and considered the working examples and comparative examples indicated in the "statement of the detailed explanation of the invention." Then, the court held that the statement is not "recognized as stating the invention by disclosing specific examples so as to enable a person ordinarily skilled in the art to recognize that an intended effect (performance) can be achieved within the scope indicated by the formula." Furthermore, in No. 6, 1(5) in the reasons for the judgment, the court held as follows: "It goes against the purpose of the patent system, that is, granting a patent on the premise of the disclosure of an invention, and is not permitted to make the detailed explanation of the invention comply with the description support requirement by expanding or generalizing the content disclosed in the detailed explanation of the invention to the scope of the invention stated in the scope of claims … despite that the content disclosed in the detailed explanation of the invention can neither be expanded nor generalized to the scope of the invention stated in the scope of claims."

As above, the Judgment of the Grand Panel of the Intellectual Property High Court was rendered on the case in which [i] the statement of the "scope of claims" is specified by multiple parameters and its interpretation became an issue and [ii] whether the statement of the "scope of claims" exceeds the technical content stated and disclosed in the "detailed explanation of the invention" was examined through comparison of the statement of the "scope of claims" with the content disclosed in the statement of the "detailed explanation of the invention." On the other hand, this case is neither [i] a case where the JPO determined that there are doubts about the interpretation of the technical scope of the "scope of claims" on the ground that the "scope of claims" is stated in a unique form nor [ii] a case where the JPO determined that the scope of the statement of the "scope of claims" exceeds the scope of the statement of the "detailed explanation of the invention" by comparing the former with the latter. The case of the Judgment of the Grand Panel of the Intellectual Property High Court and this case differ in the premise in terms of the aforementioned points. Therefore, the defendant’s allegation that, by applying the holding in the Judgment of the Grand Panel of the Intellectual Property High Court to a medicinal use invention, it becomes a requirement for compliance with Article 36, paragraph (6), item (i) of the Act to make a "statement of pharmacological data or a statement that should be equated with such data" in the detailed explanation of the invention, lacks a premise that is necessary for applying the aforementioned holding in the same manner to this case.

Consequently, it is impossible to adopt the following defendant's allegation that is based on the holding in the Judgment of the Grand Panel of the Intellectual Property High Court: The Application for a use invention concerning a medicine should be regarded as not fulfilling the requirement under Article 36, paragraph (6), item (i) of the Act because the detailed explanation of the invention does not include a statement of pharmacological data or a statement that should be equated with such data.

D. As considered above, the JPO determined that the requirement under Article 36, paragraph (6), item (i) of the Act is not fulfilled only on the grounds of "absence of a statement of pharmacological data or a statement that should be equated with such data," on the premise that "a statement of pharmacological data or a statement that should be equated with such data" is always necessary in order to fulfill the requirement under paragraph (6), item (i) of said Article. Consequently, the determination in the JPO Decision is illegal due to a defect in the reasons.

(2) As above, the determination in the JPO Decision is illegal due to a defect in the reasons in that the JPO ruled, based on an erroneous premise concerning Article 36, paragraph (6), item (i) of the Act, that the statement of the scope of claims does not fulfill the requirement under said item. In addition, in light of specific cases, the JPO Decision contains an error in its determination to the effect that the statement of the scope of claims does not comply with Article 36, paragraph (6), item (i) of the Act, as mentioned below.

A. Statement of the "scope of claims" and that of the "detailed explanation of the invention"

The scope of claims of the Invention states "use of flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof, for the preparation of a medicament for the treatment of sexual desire disorders."

On the other hand, the detailed explanation of the invention in the Description (Exhibits Ko No. 3 and No. 4) includes the following statements.

"[0001] The invention relates to the use of flibanserin for the preparation of a medicament for the treatment of sexual desire disorders. …

[0003] Flibanserin shows affinities for the 5-HT_{1A} and 5-HT_2-receptor. It is therefore a promising therapeutic agent for the treatment of a variety of diseases, for instance, depression, schizophrenia and anxiety. In studies of male and female patients suffering from sexual dysfunction, it has been found that flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof, displays sexual desire enhancing properties. Accordingly, the instant invention relates to the use of flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof, for the preparation of a medicament for the treatment of sexual desire disorders. In a preferred embodiment, the invention relates to the use of flibanserin … for the preparation of a medicament for the treatment of disorders selected from the group consisting of Hypoactive Sexual Desire Disorder, loss of sexual desire, lack of sexual desire, decreased sexual desire, inhibited sexual desire, loss of libido, libido disturbance and frigidity. Particularly preferred according to the invention is the use of flibanserin … for the preparation of a medicament for the treatment of disorders selected from the group consisting of Hypoactive Sexual Desire Disorder, loss of sexual desire, lack of sexual desire, decreased sexual desire and inhibited sexual desire.

In a particularly preferred embodiment, the invention relates to the use of flibanserin … for

the preparation of a medicament for the treatment of disorders selected from the group of Hypoactive Sexual Desire Disorder and loss of sexual desire.

[0004] The observed effects of flibanserin can be achieved in men and women. However, according to a further aspect of the invention, the use of flibanserin …for the preparation of a medicament for the treatment of female sexual dysfunction is preferred. The beneficial effects of flibanserin can be observed regardless of whether the disturbance existed lifelong or was acquired, and independent of etiologic origin (…). Flibanserin can be optionally used in the form of its pharmaceutically acceptable acid addition salts. Suitable acid addition salts include for example … the hydrochloride and the hydrobromide, particularly the hydrochloride, is preferred.

[0005] Flibanserin, optionally used in the form of its pharmaceutically acceptable acid addition salts, may be incorporated into the conventional pharmaceutical preparation in solid, liquid or spray form. The composition may, for example, be presented in a form suitable for oral, rectal, parenteral administration or for nasal inhalation: preferred forms include for example, capsules, tablets, coated tablets, ampoules, suppositories and nasal spray. The active ingredient may be incorporated in excipients or carriers conventionally used in pharmaceutical compositions such as, for example, talc, … polysorbate 80. The compositions are advantageously formulated in dosage units, with each dosage unit being adapted to supply a single dose of the active ingredient. The dosage range applicable per day is preferably between 1.0 to 300 mg, more preferably between 2 to 200 mg. Each dosage unit may conveniently contain from 0.01 mg to 100 mg, preferably from 0.1 to 50 mg.

[0006] Suitable tablets may …Similarly, the tablet coating may consist of a number or layers to achieve delayed release, possibly using the excipients mentioned above for the tablets.

[0007] Syrups or elixirs containing the active substances or combinations thereof according to the invention may additionally contain a sweetener … or preservatives such as p-hydroxybenzoates. Solutions for injection are prepared in the usual way, e.g. with the addition of preservatives …, and transferred into injection vials or ampoules. Capsules containing one or more active substances or combinations of active substances may for example be prepared by …packing them into gelatine capsules.

Suitable suppositories may be made for example by mixing with …the derivatives thereof. The examples which follow illustrate the present invention without restricting its scope.

Moreover, paragraphs [0008] to [0013] in the detailed explanation of the invention in the Description state, as the working examples of the pharmaceutical compositions, the components, ingredient amount per tablet, and manufacturing method of the following six pharmaceutical formulations: A) tablet containing 100 mg flibanserin hydrochloride, B) tablet containing 80 mg flibanserin hydrochloride, C) coated tablet containing 5 mg flibanserin hydrochloride, D)

capsule containing 150 mg flibanserin hydrochloride, E) ampoule solution containing 50 mg flibanserin hydrochloride, and F) suppository containing 50 mg flibanserin hydrochloride.

B. Determination

According to the above, the "scope of claims" of the Invention cannot be regarded as stating a technical scope that exceeds the content of the statement of the "detailed explanation of the invention."

That is, the "detailed explanation of the invention" in the Description states the following facts: [i] that in studies of male and female patients suffering from sexual dysfunction, it has been found that flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof, displays sexual desire enhancing properties; [ii] that flibanserin is used for the preparation of a medicament for the treatment of disorders selected from the group consisting of Hypoactive Sexual Desire Disorder, loss of sexual desire, lack of sexual desire, decreased sexual desire, inhibited sexual desire, loss of libido, libido disturbance and frigidity; [iii] that the beneficial effects of flibanserin can be observed independent of etiologic origin; and [iv] that the use of such flibanserin for the preparation of a medicament for the treatment of female sexual dysfunction is preferred. Furthermore, the "detailed explanation of the invention" in the Description cites [v] the hydrochloride and the hydrobromide as examples of suitable acid addition salts, and states that, particularly, the hydrochloride is preferred; and also states [vi] the composition, ingredient amount and preparation method for six pharmaceutical formulations, specifically, two kinds of tablet, coated tablet, capsule, ampoule solution and suppository.

In that case, the technical matter pertaining to the statement in the scope of claims for the Invention, "use of flibanserin, optionally in the form of the pharmacologically acceptable acid addition salts thereof, for the preparation of a medicament for the treatment of sexual desire disorders" is understood as not exceeding the matters stated and disclosed in the aforementioned detailed explanation of the invention.

The detailed explanation of the invention in the Description includes no specific statement concerning the process of proving that the technical matters, such as that "flibanserin has sexual desire enhancing properties," are assured.

However, with regard to the lack of specific statements concerning the process of proving that the technical matters stated in the detailed explanation of the invention are assured, it is sufficient to determine the fulfillment of the requirement under Article 36, paragraph (4), item (i) of the Act in light of the purpose of said item, and it should not be determined as a premise for determining the fulfillment of the requirement provided for in Article 36, paragraph (6), item (i) of the Act, as instructed above (incidentally, in determining whether the requirement provided for in Article 36, paragraph (4), item (i) of the Act is fulfilled in the case where the specific process of proving whether the technical matters stated in the detailed explanation of

the invention are assured is not disclosed, a conclusion should be drawn in relation to whether a person ordinarily skilled in the art can understand the technical significance of the invention, such as the problem to be solved by the Invention and means for solving said problem, and can work the invention as of the filing of the patent application, comprehensively taking all circumstances into account, even if there is no such specific statement).

4. Conclusion

As above, the JPO Decision is illegal due to a defect in the reasons in that the JPO ruled that the statement of the scope of claims of the Application does not fulfill the requirement under Article 36, paragraph (6), item (i) of the Act. There is a reason for the grounds for the rescission alleged by the plaintiff. The judgment has been rendered in the form of the main text.

Intellectual Property High Court, Third Division

Presiding judge: IIMURA Toshiaki

Judge: OSUGA Shigeru

Judge: SAIKI Norio