judgedate
August 27, 2019

caseid
2018 (Gyo-Hi) 69

casename
Case of seeking rescission of the JPO decision

casetitle
Judgment concerning the case in which the court determined that the determination of the court of prior instance contains illegality in that, regarding the issue of whether patented inventions pertaining to the medicinal use of a compound involves an inventive step, the court of prior instance determined that the effect of the patented inventions is not unpredictable and outstanding.

summary_judge
The court of prior instance immediately determined that the effect of patented inventions pertaining to the medicinal use of a compound is not unpredictable and outstanding based only on the fact that the existence of several other compounds that have effects of the same level as the compound was known as of the base time for determining the involvement of an inventive step in the patented inventions, on the premise that a person skilled in the art could have easily conceived of applying the compound to the intended use pertaining to the patented inventions, without sufficiently examining the effect of the patented inventions from the perspectives of whether the effect is one that a person skilled in the art could not have predicted as an effect produced by the structures of the patented inventions as of the aforementioned base time and whether the effect is an outstanding effect that goes beyond the scope of effect that a person skilled in the art could have predicted based on those structures. This determination of the court of prior instance contains illegality.

court_second
Intellectual Property High Court, Judgment of November 21, 2017

references
Article 29, paragraph (2) of the Patent Act

2018 (Gyo-Hi) 69 Case of seeking rescission of the JPO decision
August 27, 2019 Judgment of the Third Petty Bench

Main text

The judgment in prior instance shall be quashed.
This case shall be remanded to the Intellectual Property High Court.

Reasons

Concerning the reasons for a petition for acceptance of final appeal stated by the counsel for final appeal, MIMURA Ryoichi, et al. (however, except for the reasons excluded)

1. Regarding a patent pertaining to an eye drop for treating allergic eye diseases in humans (Patent No. 3068858; hereinafter referred to as the "Patent"), the Appellee of Final Appeal filed a request for a trial for patent invalidation while designating the Appellants of Final Appeal, who jointly own the patent right, as respondents, but received a JPO decision to dismiss the same request. Therefore, in this case, the Appellee seeks the rescission of this JPO decision. Regarding the issue of whether the inventions pertaining to the Patent involve an inventive step, the parties dispute whether those inventions have an unpredictable and outstanding effect.

2. The outline of facts determined by the court of prior instance is as follows.

(1) The Patent

The Patent is for an invention titled "Topical ophthalmic formulation containing doxepin derivatives to treat allergic eye diseases," and the patent application for the Patent was filed on May 3, 1996 with a priority claim based on a patent application filed in the United States on June 6, 1995 (hereinafter the date of the same application that serves as a basis for the priority claim is referred to as the "priority date"). The establishment of the Patent was registered on May 19, 2000.

The inventions pertaining to the Patent relate to a drug that applies a publicly known oxepin derivative "11-(3-dimethylaminopropylidene)-6,11-dihydrodibenz[b,e]oxepin-2-acetic acid" (hereinafter referred to as the "Compound") to the intended use of "human conjunctival mast cell stabilization (inhibition of histamine release from human conjunctival mast cells) as an eyedrop for treating allergic eye diseases in humans.

(2) Background to the request for an invalidation trial, etc.

A. In February 2011, the Appellee filed a request for a trial for patent invalidation in relation to the Patent, and the request was pending at the JPO as Invalidation Trial No. 2011-800018. In August 2012, the Appellants filed a request for correction of the claims pertaining to the Patent (hereinafter this correction is referred to as "Correction 1"). The

statement of the claims after Correction 1 is as indicated in Attachment 1.

In January 2013, while accepting Correction 1, the JPO determined that the reasons for invalidation regarding the lack of an inventive step based on Cited Document 1 as the primary cited document are groundless because the matter required to identify the invention, "human conjunctival mast cell stabilization," out of the inventions pertaining to Claims 1 and 2 in the claims after Correction 1 cannot be considered to have been motivated by the statements in Cited Documents 1 and 2. The JPO thus rendered a decision that the aforementioned request for a trial for patent invalidation is to be dismissed (hereinafter referred to as the "Former JPO Decision").

Cited Document 1 is a paper distributed prior to the priority date, which describes matters, such as the result of an experiment wherein an eye drop containing a hydrochloride of a cis-isomer of the Compound for controlling allergic conjunctivitis (hereinafter referred to as "Cited Invention 1) was administered to the eyes of guinea pigs and its effect on conjunctivitis was examined. Cited Document 2 is a publication of unexamined patent application (Japanese Unexamined Patent Application Publication No. 1988-10784).

B. In March 2013, the Appellee filed an action to seek the rescission of the Former JPO Decision. In July 2014, the Intellectual Property High Court determined that the aforementioned determination of the Former JPO Decision is erroneous because it is found that in making an attempt to apply Cited Invention 1 as an eye drop for allergic eye diseases in humans, a person skilled in the art who has learned of Cited Documents 1 and 2 could have confirmed that the compound pertaining to Cited Invention 1 has a human conjunctival mast sell stabilizing action and could have easily conceived of applying the same to the intended use as a human conjunctival mast cell stabilizing agent. The Intellectual Property High Court thus rendered a judgment to rescind the Former JPO Decision (hereinafter referred to as the "Former Judgment"), and the Former Judgment became final and binding.

C. The JPO conducted further proceedings regarding the aforementioned trial for patent invalidation. In February 2016, the Appellants filed a request for correction of the claims pertaining to the Patent (hereinafter this correction is referred to as "Correction 2"; the claims after Correction 2 consist only of Claim 1 and Claim 5). The statement of Claim 1 in the claims after Correction 2 (hereinafter the invention pertaining this claim is referred to as "Invention 1") is the same as the statement of Claim 1 in the claims after Correction 1. The statement of Claim 5 in the claims after Correction 2 (hereinafter the invention pertaining to this claim and Invention 1 are collectively referred to as the "Inventions") is as indicated in Attachment 2.

In December 2016, while accepting Correction 2, the JPO determined as follows: differences between Invention 1 and Cited Invention 1 are matters that a person skilled in the art who has learned of Cited Documents 1 and 2 could have easily conceived of or merely design matters, but the Compound has a particularly outstanding effect that a person skilled in the art could not have predicted based on Cited Documents 1 and 2 and common general technical knowledge as of the priority date; therefore, it cannot be said that a person skilled in the art could have easily made the Inventions. Based on this determination, the JPO rendered a decision that the aforementioned request for a trial for patent invalidation is to be dismissed (hereinafter referred to as the "JPO Decision").

(3) Effect of the Inventions

A person skilled in the art who has learned of the description pertaining to the patent application for the Patent (hereinafter referred to as the "Description") recognizes the histamine release inhibitory effect of the Compound pertaining to the Inventions as follows: in the experiment stated in the Description (wherein a drug is applied to a cell group prepared by culturing human conjunctival mast cells and the inhibition ratio of histamine release from the same cells is measured), the inhibition ratio of histamine release from human conjunctival mast cells of the Compound (cis-isomer) increased along with an increase of the concentration within the concentration range from 30 μM to 2,000 μM; a high histamine release inhibition ratio of 66.7% was exhibited at 1,000 μM; a high ratio of 92.6% was kept even at 2,000 μM, which was a twofold concentration of the above; in contrast, disodium cromoglycate and nedocromicl sodium known as anti-allergic drugs failed to significantly inhibit histamine release from human conjunctival mast cells within the concentration range up to 2,000 μM.

(4) Statements in publicly known publications as of the priority date

A. Cited Documents 1 and 2 contain no statement regarding whether the Compound has an action to inhibit histamine release from human conjunctival mast cells and the level of the effect in the case where the Compound has that action.

B. Publications distributed prior to the priority date disclosed the following content: regarding compounds other than the Compound, an allergic reaction induction test was conducted on 11 to 30 patients with Japanese cedar pollinosis by administering a cedar antigen solution to their eyes after administering a predetermined concentration of eye drop thereto, and the histamine release inhibitory ratio in the lacrimal fluid was measured 5 and 10 minutes after the induction; as a result, the average values 5 and 10 minutes after the induction were [i] 79.0% and 82.5% for a 0.0003% procaterol hydrochloride eye drop, 81.6% and 89.5% for a 0.001% procaterol hydrochloride eye drop, and 81.7% and 90.7% for a 0.003% procaterol hydrochloride eye drop, [ii] 67.5% and 67.2% for a 0.05%

ketotifen eye drop, [iii] 73.8% and 67.5% for a 2% disodium cromoglycate eye drop, and [iv] 69.6% and 69.0% for a 0.1% pemirolast potassium eye drop and 71.8% and 61.3% for a 0.25% pemirolast potassium eye drop.

3. Based on the aforementioned facts, the court of prior instance determined as summarized below, and ruled that the determination of the JPO Decision concerning the effect of the Inventions contains an error because the Inventions cannot be considered to have an outstanding effect that is hard to predict on the premise of the structures of the Inventions, which a person skilled in the art can easily conceive of based on Cited Invention 1 and the invention stated in Cited Document 2. The court of prior instance thus rescinded the JPO Decision.

According to the Former Judgement, as mentioned in 2.(2)B. above, a person skilled in the art who has learned of Cited Documents 1 and 2 could have easily conceived of applying the compound pertaining to Cited Invention 1 to the intended use as a human conjunctival mast cell stabilizing agent. Therefore, it cannot be said that the effect of the Compound to inhibit histamine release from human conjunctival mast cells is an outstanding effect that is hard to predict for a person skilled in the art.

In addition, it cannot be said that the histamine release inhibitory effect of a human conjunctival mast cell stabilizing agent that contains the Compound pertaining to the Inventions, which is stated in the Description, is an outstanding effect that goes beyond the scope that can be predicted by a person skilled in the art based on the state of the art at that time, taking into account the following circumstances and various other circumstances: as the state of the art on the priority date, it was known that in addition to the Compound, there were several other compounds that exhibit a high histamine release inhibition ratio of around 70% to 90% if they are administered to eyes at a predetermined concentration, as mentioned in 2.(4)B. above (hereinafter these compounds are referred to as "Other Compounds") and that some of them keep a high histamine release inhibitory effect over the range of concentrations of 2.5- to 10-times.

4. However, the aforementioned determination of the court of prior instance cannot be upheld for the following reasons.

According to the aforementioned facts, Other Compounds also have a histamine release inhibitory effect similar to that of the Compound, but all of them have a different structure from that of the Compound, and neither relate to Cited Invention 1 nor indicate any association with Cited Document 2. In addition, Cited Documents 1 and 2 contain no statement regarding whether the Compound has an action to inhibit histamine release from human conjunctival mast cells and the level of the effect in the case where the Compound has that action. Under such circumstances, it cannot be said that a person

skilled in the art could have immediately predicted the level of the effect of the Inventions based on the fact that it was known as of the priority date that there were Other Compounds that have effects of the same level as the Compound. In addition, also taking into account the fact that the effect of the Inventions relates to the medicinal use of a compound, it should also be said that it cannot be denied that the Inventions have an outstanding effect that goes beyond the scope of effect that a person skilled in the art could have predicted based on the structures of the Inventions only on the grounds that the existence of Other Compounds that have effects of the same level as the Compound but differ from the Compound in structure was known as of the priory date.

Nevertheless, the court of prior instance has not made clear the specific content of various circumstances to be considered other than the fact that the existence of Other Compounds was known as of the priority date, nor has it found any other circumstances, etc. where the level of the effect of the Compound can be presumptively recognized based on the levels of the effects of Other Compounds.

Consequently, in the end, it must be considered that the court of prior instance rescinded the JPO Decision by immediately denying that the effect of the Inventions is unpredictable and outstanding based only on the fact that the existence of Other Compounds that have effects of the same level as the Compound was known as of the priority date, on the premise that a person skilled in the art could have easily conceived of applying the Compound to the intended use pertaining to the Inventions, without sufficiently examining the issue of whether the effect of the Inventions, in particular its level, is unpredictable and outstanding from the perspectives of whether the effect is one that a person skilled in the art could have not predicted as an effect produced by the structures of the Inventions as of the priority date and whether the effect is an outstanding effect that goes beyond the scope of effect that a person skilled in the art could have predicted based on those structures. Such determination of the court of prior instance must be considered to contain illegality of the erroneous interpretation and application of laws and regulations.

5. For the reasons described above, the aforementioned determination of the court of prior instance contains a violation of laws and regulations that has clearly influenced the judgment. The argument made by the counsel for final appeal is well-grounded as an argument to this effect, and the judgment in prior instance should inevitably be quashed. This case is remanded to the court of prior instance to be further examined in relation to whether the Inventions have an unpredictable and outstanding effect, etc.

Accordingly, the Court unanimously decides as set forth in the main text of the judgment.

Presiding judge: YAMASAKI Toshimitsu
Judge: TOKURA Saburo
Judge: HAYASHI Keiichi
Judge: MIYAZAKI Yuko
Judge: UGA Katsuya

(Attachment 1)

[Claim 1] An ophthalmic stabilizing agent for human conjunctival mast cells prepared as a topically administrable eye drop for treating allergic eye diseases in humans, comprising a therapeutically effective amount of 11-(3-dimethylaminopropylidene)-6,11-dihydrodibenz[b,e]oxepin-2-acetic acid, or a pharmaceutically acceptable salt thereof.

[Claim 2] A topically administrable ophthalmic composition for treating allergic eye diseases in humans, which is a compound that produces a human conjunctival mast cell stabilizing effect, comprising a therapeutically effective amount of 11-(3-dimethylaminopropylidene)-6,11-dihydrodibenz[b,e]oxepin-2-acetic acid, or a pharmaceutically acceptable salt thereof, wherein said 11-(3-dimethylaminopropylidene)-6,11-dihydrodibenz[b,e]oxepin-2-acetic acid is (Z)-11-(3-dimentylaminopropylidene)-6,11- dihydrodibenz[b,e]oxepin-2-acetic acid, and substantially not comprising (E)-11-(3- dimentylaminopropylidene)-6,11-dihydrodibenz[b,e]oxepin-2-acetic acid.

(Attachment 2)

[Claim 5] An ophthalmic stabilizing agent for human conjunctival mast cells prepared as a topically administrable eye drop for treating allergic eye diseases in humans, comprising a therapeutically effective amount of 11-(3-dimethylaminopropylidene)-6,11-dihydrodibenz[b,e]oxepin-2-acetic acid, or a pharmaceutically acceptable salt thereof, wherein said 11-(3-dimethylaminopropylidene)-6,11-dihydrodibenz[b,e]oxepin-2-acetic acid is (Z)-11-(3-dimentylaminopropylidene)-6,11-dihydrodibenz[b,e]oxepin-2-acetic acid, and substantially not comprising (E)-11-(3-dimentylaminopropylidene)-6,11-dihydrodibenz[b,e]oxepin-2-acetic acid, which inhibits histamine release from human conjunctival mast cells by 66.7% or more.