

Battle of judges on unexpected and remarkable effect

Takanori Abe of **Abe & Partners** analyses a case which evaluates what to compare to determine unexpected and remarkable effect

The Supreme Court judged that the IP High Court's judgment in this case was illegal for denying that the effect of the patented invention was unexpected and remarkable with regard to the inventive step of the patented invention relating to the pharmaceutical use of the compound.

Summary of the case

Alcon Research and Kyowa Hakko Kirin jointly own a patent for an invention entitled "an eye drop for allergic eye diseases in humans" (JP3068858, the patent). The invention of the patent (the invention) relates to a drug as an eye drop for allergic eye diseases in humans, where publicly known oxepin derivative, 11-(3-dimethylaminopropylidene)-6,11-dihydrodibenz [b,e]oxepin-2-acetic acid (the compound), is applied for stabilisation of human conjunctival mast cells (inhibition of histamine release from human conjunctival mast cells).

Nakano filed a request for an invalidation trial of the patent and received a decision from the JPO that the request should be dismissed. She then instituted an action seeking to revoke the JPO's decision. The issue is whether the invention of the patent has an unexpected, remarkable effect with regard to the inventive step of the patented invention.

The patent was the recipient of a primary JPO decision, a secondary JPO decision and a former IP High Court judgment, before the present JPO decision.

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Judgment of November 21 2017, IP High Court

The IP High Court (Presiding Judge Takabe) judged as follows and revoked the present JPO decision. The present JPO decision concerning the effect of the invention is erroneous because the invention fails to have an unexpected, remarkable effect based on the structure of the invention, which a skilled person could have easily conceived based on the cited invention 1 and the invention described in the cited document 2.

According to the former IP High Court judgment, a skilled person, who has learned of cited documents 1 and 2, could have easily conceived of the idea of putting the compound of cited invention 1 to the use of a human conjunctival mast cell stabilising agent. Therefore, it cannot be said that the effect of the compound having a histamine release inhibitory action from human conjunctival mast cells is an unexpected, remarkable effect to a skilled person.

Furthermore, the state of the art of a skilled person as of the priority date of the present patent shows, in addition to the compound, that there existed several compounds (other compounds) that exhibited a high histamine release inhibition ratio of about 70% to 90% by instillation of a predetermined concentration of eye drop. Among them, some of the compounds kept a high histamine release inhibitory effect over the range of 2.5 times to 10-times the concentration. Considering these circumstances, it cannot be said that the histamine release inhibitory effect of a human conjunctival mast cell stabilising agent containing the compound of the inventions described in the specification is a remarkable effect that goes beyond the scope that can be expected by a skilled person based on the state of the art at that time.

An additional remark is made on the examination of the present trial. Whether an invention is easily conceivable should be determined based on whether the invention has an unexpected, remarkable effect in addition to whether there is a motivation for applying a secondary cited invention to a primary cited invention. Then, the parties can allege and prove facts, confirming the conceivability based on a specific cited document and also deny the facts through a secondary JPO decision and a suit against the JPO decision. Assume that a former

judgment became final without alleging or proving the above, and then, at the resumed procedure of the present trial, the parties were allowed to allege and prove that present invention 1, which is not corrected and is the same as in the previous suit, could not have been easily conceived by a skilled person based on the same cited documents 1 and 2 as those in the previous suit. This would cause the case to go back and forth endlessly between the JPO and the court and go against the principle of judicial economy. It raises a problem in light of the purpose of the provision of Article 33(1) of the Administrative Case Litigation Act.

Judgment of August 27 2019, Supreme Court

The Supreme Court (the Third Petty Bench, Presiding Justice Yamasaki) judged as follows and reversed the IP High Court judgment.

According to the above facts, though the other compounds have a histamine release inhibitory effect, which is the same kind of effect as the compound, they have different structures from those of the compound, which are not described in the cited invention 1 nor related to the cited document 2. In addition, cited document 1 and cited document 2 never describe whether the compound has a histamine release inhibitory action from human conjunctival mast cells and to what extent it exhibits the effect in the action. Under such circumstances, it cannot be said that the skilled person could predict the extent of effect of the inventions directly by common knowledge, predicting that as of the priority date the other compounds had the equivalent effect to the compound. In addition, considering that the effects of the inventions are related to the pharmaceutical use of compounds, it cannot be denied that the extent of effect of the inventions is remarkable to go beyond the scope that can be expected by a skilled person, just because the other compounds had been known as of the priority date, having the equivalent effect to the compound but having different structures from the compound.

However, the IP High Court did not clarify specific details of the circumstances to be considered other than the fact that the other compounds were known as of the priority date. In this regard, the court never identified that the extent of effect of the compound can be inferred from that of the other compounds.

The IP High Court denied the invention's unexpected remarkable effect and revoked the present JPO decision just because the other compounds, having the equivalent effect to the compound, were known as of the priority date. In this regard, the court assumed that a skilled person could easily conceive of applying the compound to the use of the inventions. Also, regarding whether the effect of the invention, especially its extent, was unexpected and remarkable, the court failed to fully consider whether a skilled person could not expect as of the priority date the effect to be brought about by the structure of the invention and whether the effect was remarkable to exceed the extent of the effect they could expect from the structure. Based on this, the IP High Court wrongly construed and applied the law rendering the judgment illegal.

Practical tips

Previously, patent cases that the Supreme Court took up have been limited to prominent issues as described in textbooks. The issue in this case is inventive step, one of the most important principles in patent law. However, it is a judgment on an invention's effect, and is therefore more niche. The Supreme Court judged such a niche issue and reversed the judgment of Presiding Judge Takabe (the current chief judge, judge of the 4th division of the IP High Court as of the original instance). This has greater impact than the Supreme Court's judgment on the Grand Panel judgments of the IP High Court, the *Canon Ink Tank* case and the *PBP Claim* case. In the background on the Supreme Court's judgment, there was a concern about the IP High Court's judgment on the issue of what to compare to determine unexpected and remarkable effect. There seemed to also be a concern about an additional remark in the IP High Court judgment that required the JPO and the courts to judge whether there was a remarkable effect in all cases, in addition to whether the invention was easily conceived. Regarding this concern, not only legal scholars, Professor Tamai and Associate Professor Maeda, but also former chief judge of the IP High Court, Mr Imura, and ex-chief judge of the IP High Court, Mr Shimizu, submitted written expert opinions against the IP High Court judgment. The fact that the former and ex-chief judges denied the current chief judge's practice seems to have had a great influence. Attention must be paid to the Supreme Court's attitude including the First and Second Petty Benches, concerning whether the present judgment has a meaning as "a fire signal" that the Supreme Court judges niche issues in future.

According to Associate Professor Maeda, there are three views as to what to compare in examining the unexpected remarkable effects: (1) compare the effect of the cited inventions; (2) compare an effect of the same kind of invention in the state of the art as of filing; and (3) compare a scope of an effect of the claimed invention that the structure of the invention is expected to have. The IP High Court judgment is considered to have taken (2) into account. The Supreme Court is considered to have adopted (3) because the court held that in determining the existence of an unexpected remarkable effect, the court needed to consider whether a skilled person could not expect as of the priority date the effect to be brought about by the structure of the invention and whether the effect was remarkable enough to exceed the extent of the effect they could expect from the structure.

According to the Supreme Court, it is not allowed to deny an unexpected remarkable effect just because the compounds (in this case, other compounds) having structures different from the inventions were known as of the priority date. However, since the Supreme Court held that "the IP High Court never identified that the extent of effect of the compound can be inferred from that of the other compounds", the court allowed to infer an extent of effect to be brought about by a structure of the invention (in this case, the compound) based on an extent of effect of compounds having a different structure from the invention (in this case, other compounds). There is a conflict between "the independent requirement theory" and "the secondary consideration theory" as theoretical explanations that an unexpected remarkable effect is considered in

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judgement of inventive step. The two theories are regarded as differing in whether or not the specification needs to describe the effect and what to compare in determining the unexpected remarkable effect. Though the present case is related to the latter issue, it is difficult to understand clearly from the Supreme Court's judgement which theory is adopted and therefore reach a conclusion on the former issue.

A concern about the judicial economy in the additional remarks underlies the IP High Court judgment. With regard to this, it is stated in the statement of reasons for petition for acceptance of final appeal and the experts' opinions that the true purpose of the IP High Court judgment revoking the trial decision is to have the JPO, conducting the trial after the matter has been remanded, thoroughly implement the "additional remark".

They criticised the fact that, if it is necessary to judge whether there is a remarkable effect in addition to determining whether the structure of the patented invention is easily conceived in all cases, the court has to judge based on imaginary or unconfirmed facts. This causes waste of a great deal of labour for the JPO and the courts, going against examination and trial economy and judicial economy. Although this Supreme Court decision does not directly judge the additional remark, in the decision of acceptance of final appeal, only the 7th reason, "the judgment of the IP High Court should include a judgment contrary to the precedent of the High Court," was excluded because it is not important, and the 9th reason, "additional remark," was not excluded among the reasons for petition for acceptance of final appeal. Therefore it is believed that the Supreme Court decision emphasises the additional remark and has tried to prevent the practice based on the additional remark from spreading due to the IP High Court judgment becoming final. The Supreme Court called for a careful examination even in cases involving several round trips between the JPO and the court as in the present case.

We should closely watch how the Supreme Court will judge in future on Chief Judge Takabe's practice, placing more emphasis on the dispute resolution function of suits against JPO decisions.



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