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IP High Court *en banc* Decision for Oxaliplatin Case

The Intellectual Property High Court (IPHC) issued an *en banc* decision (H28 (Ne) 10046) for an Oxaliplatin case on January 20, 2017. The Oxaliplatin case relates to the scope of an extended Japanese patent (i.e., a patent having an extended patent term). The IPHC *en banc* decision is the first decision by the IPHC to discuss the scope of an extended Japanese patent. Thus, the IPHC *en banc* decision will have significance for pharmaceutical and agrichemical patents which can be extended under Japanese Patent Law. The IPHC will prepare and disclose an English translation of this decision on the website of the IPHC in the future. However, at present, the English translation is not yet available. Accordingly, we would like to provide you with a summary of the IPHC *en banc* decision regarding the Oxaliplatin case.

1. Background

Debiopharm International S.A. (Debiopharm) sued Towa Pharmaceutical Co., Ltd. (Towa) at the Tokyo District Court (TDC), the first instance, for patent infringement (H27 (Wa) 12415) based on Japanese Patent No. 3547755 (JP-B-3547755). Debiopharm (plaintiff) asserted that the generic product marketed by Towa (defendant) of the innovator's product (Elplat®) infringes JP-B-3547755, and requested an injunction on the marketing of the generic product. In this litigation, compensation for damages caused by the marketing of the generic product by Towa was not requested by Debiopharm. During the litigation, the original patent term of JP-B-3547755 expired. However, JP-B-3547755 had already been extended before the start of the litigation. Thus, the question was whether the scope of the extended JP-B-3547755 can cover the generic product by Towa. Japanese Patent Law, Article 68bis stipulates, with regard to the scope of an extended Japanese patent, as follows.

> The effects of the patent right of which the term has been extended … shall not extend to acts other than the working of the patented invention concerned with respect to the product (where … any specific use of such a product to be used was specified, the product for such a specific use) …

Accordingly, the scope of an extended Japanese patent is limited by a product (as well as the use of the product) of the patented invention. In the field of pharmaceuticals, the product means an innovator's product. However, it was not very clear in case law in Japan how the scope of an extended Japanese patent is limited. The TDC issued a decision for H27 (Wa) 12415 on March 30, 2016, dismissing the request by Debiopharm. The reason of this decision was that the scope of the extended JP-B-3547755 patent cannot cover the generic product by Towa. The TDC concluded that the scope of an extended patent can cover not only a third party's product which is completely the same as an innovator's product but also a third party's product which is substantially the same as an innovator's product. However, the TDC considered that the generic product by Towa is not substantially the same as the innovator's product (Elplat®).

For more information regarding the first instance decision (H27 (Wa) 12415), please visit the website of the IPHC. The IPHC prepared and disclosed an English translation of the first instance decision on the website thereof. Debiopharm appealed to the IPHC. The IPHC examined this appeal case (H28 (Ne) 10046), and issued a second instance decision on January 20, 2017, as an *en banc* decision. It is rare for the IPHC to issue an *en banc* decision.

2. Conclusion

The IPHC dismissed the appeal by Debiopharm.

3. Summary of Decision

(1) Outline

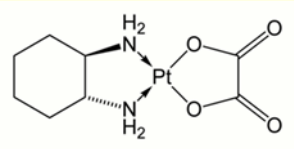
The IPHC affirmed that the scope of an extended Japanese patent can cover not only a third party's product which is completely the same as an innovator's product but also a third party's product which is substantially the same as an innovator's product. Furthermore, the IPHC explained the general rule regarding how "substantially the same" should be examined. Based on the above general rule, the IPHC examined this case, and concluded that the scope of the extended JP-B-3547755 patent cannot cover the generic product by Towa. In other words, the IPHC considered that the generic product by Towa is not substantially the same as the innovator's product. Thus, the IPHC upheld the first instance decision by the TDC. In addition, the IPHC also concluded that the scope of JP-B-3547755 even before patent term extension cannot cover the generic product by Towa either.

(2) Claim 1 of JP-B-3547755

1. A pharmaceutically stable preparation of oxaliplatinum for the administration by the parenteral route, consisting of a solution of oxaliplatinum in water at a concentration of 1 to 5 mg/ml and having a pH of 4.5 to 6, wherein the oxaliplatinum content in the preparation is at least 95% of the initial content and the solution remains clear, colorless and free of precipitate after storage for a pharmaceutically acceptable duration of time.

(3) Innovator's Product

The innovator's product (Elplat®) consists of oxaliplatin and water. In other words, the innovator's product includes only oxaliplatin and water. Oxaliplatin is an anticancer agent represented by the following chemical formula:



(4) Generic Product

The generic product in question of Towa consists of oxaliplatin, water and glycerin. In other words, the generic product includes not only oxaliplatin and water but also glycerin. According to Towa, glycerin is added to reduce the decomposition of oxaliplatin. Towa holds Japanese Patent No. 5314790 which relates to a composition comprising oxaliplatin, water and C3 polyol.

(5) Scope of Extended Patent

The IPHC construed Japanese Patent Law, Article 68[bis], in view of a Japanese Supreme Court Decision regarding the so-called Avastin® Case (H26 (Hi) 356) issued on November 17, 2015, which stated that the scope of an extended Japanese patent should be limited by a product (as well as the use of the product) of the patented invention, and that the "product" (as well as the "use" of the product) should be defined by "ingredient(s)" (成分), "quantity"(分量)[1], "administration"(用法)[2], "dosage"(用量)[3], "efficacy"(効能) and "effects"(効果)[4] if the product is a pharmaceutical product. The English terms for the Japanese terms are selected such that they are consistent with the English translation of the first instance decision prepared by the IPHC. It should be noted that the scope of "ingredient(s)" is not limited to an active pharmaceutical ingredient (API) but also covers an additive other than an API. Thus, according to the IPHC, the principle is that the scope of an extended Japanese patent is limited by the ingredient(s), quantity, administration, dosage, efficacy and effects of an innovator's product.

However, the IPHC commented that, in consideration of equity, even if a third party's product is different from an innovator's product in terms of any one of ingredient(s), quantity, administration, dosage, efficacy and effects, as long as the difference is minor, the third party's product is substantially the same as the innovator's product, and therefore, the third party's product should be within the scope of an extended Japanese patent. In other words, a minor difference in terms of any one of ingredient(s), quantity, administration, dosage, efficacy and effects between an innovator's product and a third party's product is to be ignored. Thus, a third party's product which has only a minor difference from an innovator's product, in terms of any one of ingredient(s), quantity, administration, dosage, efficacy and effects, is considered to be substantially the same as the innovator's product.

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[1] In general, 分量 means unit amount of drug.
[2] In general, 用法 means how to use drug (e.g., three times per day).
[3] In general, 用量 means total amount of drug.
[4] In general, 効能 and 効果 in combination mean target diseases or purpose of drug.

Accordingly, the scope of an extended Japanese patent can cover not only a third party's product which is completely the same as an innovator's product but also a third party's product which is substantially the same as an innovator's product. The IPHC showed a general rule regarding how to find the difference between an innovator's product and a third party's product to be substantially the same. The general rule may be summarized as follows: Whether the difference is minor or not should be determined, based on common technical knowledge of a person skilled in the art, by comparing the technical feature and effects of the innovator's product[5] with those of the generic product in view of the details of the patented invention (e.g., whether the patented invention is directed to a new API or the stability of a known API, dosage forms, and the like) covering the innovator's product.

The IPHC also showed some examples of "substantially the same" as follows.

(i) If a patented invention is directed to a new API, and a generic product includes an additive other than the API, based on well-known or commonly-used technology, in addition to the additive(s) of an innovator's product, these products are substantially the same.

(ii) If a patented invention is directed to the stability of a known API or a dosage form thereof, a generic product includes an additive, based on well-known or commonly-used technology, in addition to the additive(s) of an innovator's product, and the technical feature and effects are identical between these products in view of the details of the patented invention, these products are substantially the same.

(iii) If the difference between an innovator's product and a third party's product has no meaning in terms of numerical values of "quantity", "administration" or "dosage", these products are substantially the same.

(iv) If an innovator's product and a third party's product are different in terms of numerical values of "quantity", as long as they can be regarded as the same in view of "administration" and "dosage" as well, these products are substantially the same.

Lastly, the IPHC commented that the Doctrine of Equivalents ruled by the Japanese Supreme Court in the past cannot be used to determine "substantially the same", because the purpose of Japanese Patent Law, Article 68bis is not broadening the protection of a Japanese patent. However, the IPHC mentioned that file wrapper estoppel can be used to determine what was deliberately excluded from the scope of an extended Japanese patent.

(6) Scope of extended JP-B-3547755 patent

The IPHC applied the above general rule to this case. The IPHC considered, based on the specification of JP-B-3547755, that one of the technical features of the claimed invention of JP-B-3547755 is the absence of any other additive (only oxaliplatin and water are included) in order to stabilize oxaliplatin, and therefore, the technical feature of the innovator's product (Elplat®) is the absence of an additive such as glycerin. On the other hand, the generic product by Towa includes glycerin in addition to oxaliplatin and water. In consideration of the above, the IPHC found that the difference (absence or presence of glycerin) between the innovator's product and the generic product is not minor. In other words, the IPHC did not consider the generic product to be substantially the same as the innovator's product. Accordingly, the IPHC determined that the scope of the extended JP-B-3547755 patent cannot cover the generic product. It should be noted that the IPHC did not discuss the identicalness of effects between the innovator's product and the generic product.

(7) Scope of JP-B-3547755 before patent term extension

The IPHC also discussed the scope of JP-B-3547755 before patent term extension. The IPHC took the file wrapper estoppel (Debiopharm argued before the JPO during prosecution of JP-B-3547755 that the absence of any additive (other than water) is important to stabilize oxaliplatin in water) and the descriptions in the specification of JP-B-3547755 into consideration for this case, and determined that the scope of JP-B-3547755 cannot cover a product including an additive other than water (such as the generic product by Towa including glycerin in addition to water) even before patent term extension.

(8) Possibility of Appeal

Debiopharm may appeal to the Japanese Supreme Court by early March 2017.

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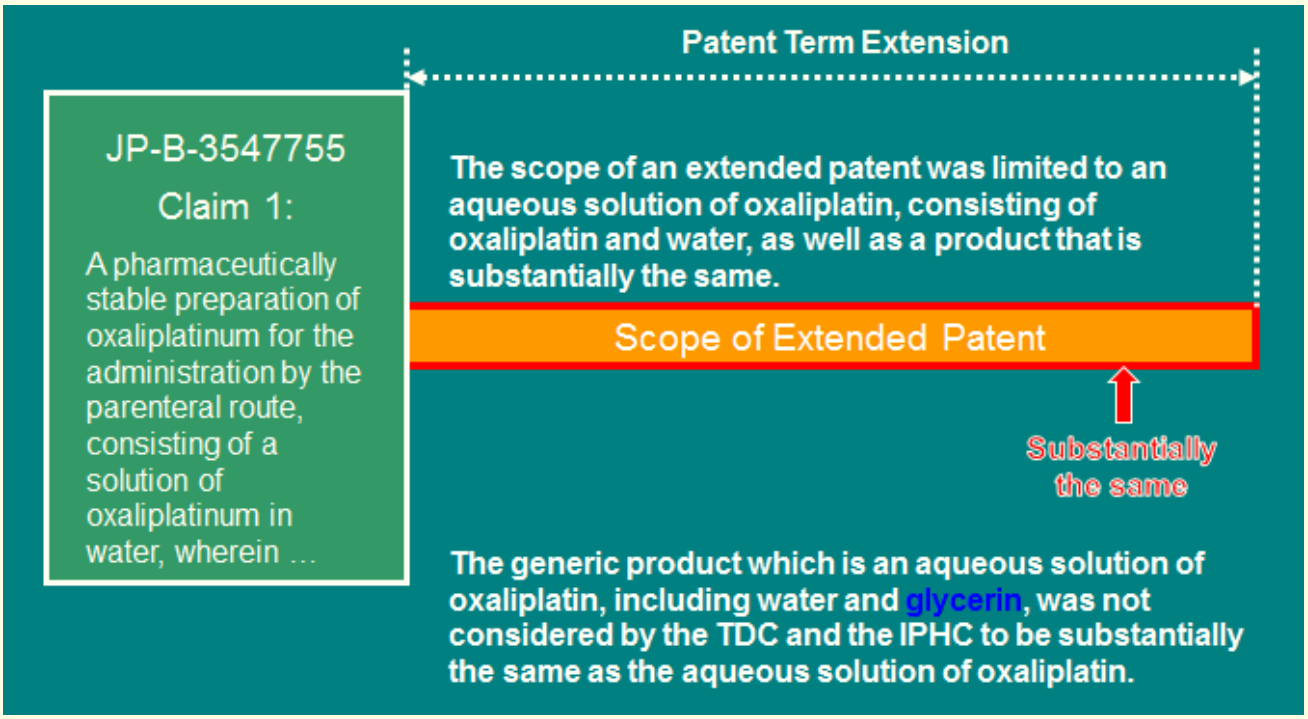
[5] In precise, the "product" defined by the ingredient(s), quantity, administration, dosage, efficacy and effects of an innovator's product

4. Closing

The oxaliplatin case may be similar to above example (ii) shown by the IPHC. However, the technical features of the innovator's product (consisting only of oxaliplatin and water) and the generic product (including oxaliplatin, water and glycerin) were not considered to be identical. Thus, the generic product was not considered to be substantially the same as the innovator's product. In other words, in the oxaliplatin case, the scope of the extended JP-B-3547755 patent was limited to an aqueous solution of oxaliplatin, consisting of oxaliplatin and water, as well as a product that is substantially the same. On the other hand, the generic product in question which includes oxaliplatin, water and glycerin was not considered by the TDC and the IPHC to be substantially the same as the aqueous solution of oxaliplatin. This may be shown by the following diagram.



If this case is appealed to the Japanese Supreme Court, we will report the decision by the Japanese Supreme Court.