JAPAN

ABE & PARTNERS
Osaka

Takanori Abe

and
Michiko Kinoshita

IP High Court gives new ruling on patent term extension

In our article "New patent term extension system in Japan", we discussed the judgments of the IP High Court and the Supreme Court (the *Pacif* case) which became the turning point for the patent term extension system in Japan and the revised Examination Guidelines. This month, we introduce a case where the Grand Panel of the IP High Court provided a new criterion different from the revised Examination Guidelines.

Summary of the case

Genentech, the plaintiff, is the patentee of a patent for an invention titled "vascular endothelial cell growth factor antagonists". Genentech filed an application for the registration of patent term extension in relation to the patent asserting that Genentech obtained an approval of partial changes in manufacturing approval (the disposition), which added a new dosage and administration of its medicine Avastin, whose general name is bevacizumab (the medicine). Regarding the medicine, there was a prior disposition that differs only in dosage and administration (see figure for the differences between the prior disposition and the disposition).

The JPO rejected the application and dismissed an appeal based on the revised Examination Guidelines because the prior disposition already existed for a medicine which had the same general name, effectiveness and efficacy as the medicine. Genentech appealed to the IP High Court seeking to revoke the decision of the JPO. This case is the ninth Grand Panel case of the IP High Court. The presiding judge was Judge Iimura, the then chief judge of IP High Court, who was the presiding judge in the *Pacif* case (the Judgment of May 29 2009, IP High Court).

The medicine which is the subject of the prior disposition

General: bevacizumab
Effectiveness and efficacy: unresectable advanced or recurrent colorectal cancer
Dosage and administration: in combination with other anticancer drugs, adults ordinarily intravenously infused with bevacizumab at a dose of 5 mg/kg (weight) or 10 mg/kg (weight) at administration intervals of at least two weeks.

The medicine which is the subject of the disposition

General: bevacizumab
Effectiveness and efficacy: unresectable advanced or recurrent colorectal cancer
Dosage and administration: in combination with other anticancer drugs, adults ordinarily intravenously infused with bevacizumab at a dose of 7.5 mg/kg (weight) at administration intervals of at least three weeks.

Can patent term extension be granted for this new dosage and administration ?

Judgment of May 30 2014, IP High Court

The Grand Panel of the IP High Court set out two requirements regarding the requirements of Japanese Patent Act Article 67-3(1)(i) which is the same as in the *Pacif* case judgment of IP High Court. It held that in order to refuse an application, it is necessary for an examiner (trial examiner) to selectively demonstrate either [1] "that it cannot be said that a ban was lifted through obtainment of the disposition designated by Cabinet Order" (first requirement) or [2] that "the 'act on which the ban was lifted through obtainment of the disposition designated by Cabinet Order' is not included in the 'acts that fall under the practising of the patented invention'" (second requirement).

The Court provided a new criterion regarding the determination concerning whether the application fulfils the first requirement and held that the scope of the "practising of a patented invention" on which the ban is lifted covers the act of manufacturing, selling, etc a medicine that is identified by ingredient, quantity, dosage, administration, effectiveness and efficacy.

Regarding this case, the Court held that the prior disposition did not lift the ban on the act of using the medicine by the use method that is identified by the dosage and administration which is newly added by the disposition and on the act of manufacturing, selling, etc the medicine on the premise of its use by the aforementioned use method, that said ban was lifted by the disposition, and that it is obvious that the disposition does not fulfil the first requirement. For this reason, the Court revoked the JPO decision.

Furthermore, the Court clearly mentioned in dicta regarding the scope of the extended patent right, especially the meaning of a "product" and a "usage" provided in Article 68-2 of the Patent Act. The Court stated that the patent right whose duration was extended is effective for the scope of the practising of the patented invention that is identified by an "ingredient (not limited to active ingredient)" as an invention pertaining to a "product" and is also identified by "effectiveness and efficacy" and "dosage and administration" as an invention pertaining to a "usage" (it can originally be said to be natural in light of the legislative purpose of the extension registration system that equivalents and products that are evaluated as substantially identical are included).

In addition, the Court stated that the scope of the practising of the patented invention on which the ban is lifted through obtaining a disposition designated by Cabinet Order and the scope of the practising of the patented invention for which the patent right is effective in the cases where the duration of the patent right was extended are not always the same. Where the practising of a patented invention on which the ban was lifted through obtaining a disposition designated by Cabinet Order is included in the scope of the practising of the patented invention for which the relevant patent right whose duration was extended based on a prior disposition is effective, the effect of the extension can become redundant.

Differences between the judgment and the *Pacif* case

The Court set out two requirements regarding requirements prescribed in Article 67-3(1)(i)which are the same as in the *Pacif* case, and provided a new criterion regarding the first requirement which had been unclear. According to Professor Iseki, the meaning of "practising of a patented invention" prescribed in Article 67-3(1)(i) has not been held by the Supreme Court and has been unknown, therefore this judgment is significant for clarifying it.

Regarding the scope of the extended patent right, the *Pacif* case judgment set out three elements of "ingredients", "quantity" and "structure", while this judgment excluded "quantity" and "structure". The reason to exclude "quantity" was that it goes against the purpose of the patent term extension system to permit competing companies to manufacture sell, etc a medicine which differs only in quantity. The reason to exclude "structure" was that "structure" is only for medical equipment and is not regarded as matter to be examined in relation to a medicine.

Significance of the judgment

This judgment approves the granting of registration of patent term extension where an applicant obtains a disposition which differs in dosage and administration from a prior disposition even if its effectiveness and efficacy are the same as that of a prior disposition. For brand-name pharmaceutical companies, it seems to be favourable because the number of cases where patent term extension would be granted for a drug which has characteristics in dosage and administration will be larger than the one judged by the revised Examination Guidelines. However, according to Professor Kato, the scope of the extended patent right could be interpreted more narrowly than before. Therefore it is difficult to conclude whether this judgment is favourable or not to them.

Furthermore, this judgment separates the scope of being granted registration of extension from the scope of extended patent right and approves that the effect of the extension can be redundant. Professor Iseki points out that it may impair foreseeability of the expiration date for generic drug manufacturers.

Regarding the Court's statement that the "ingredient (not limited to active ingredient)" is a factor to decide the scope of the extended patent right, whether the extended patent right covers the medicine which differs only in common ingredients such as excipient or addition agent is a remaining issue.

The scope of this judgment covers only a patent for an ingredient of a medicine and does not cover process patents or patents pertaining to product-by-process claims.

Prospects

This case is appealed to the Supreme Court. In the *Pacif* case, the Supreme Court only mentioned the case when the earlier medicine is not included in the technical scope of the patented invention of the present patent and remained silent regarding the other cases. This case falls within "the other cases". Therefore, it is expected that the Supreme Court provides a new criterion regarding requirements of the rejection prescribed in Article 67-3(i)(i). Furthermore, this IP High Court judgment clearly denied the revised Examination Guidelines; therefore attention should be paid to whether the Examination Guidelines will be revised again in response to the Supreme Court judgment.

On the other hand, regarding the scope of extended patent right prescribed in Article 68-2, it will not be judged in the Supreme Court because the statement of the IP High Court was only dictum. This is left to a future infringement lawsuit.