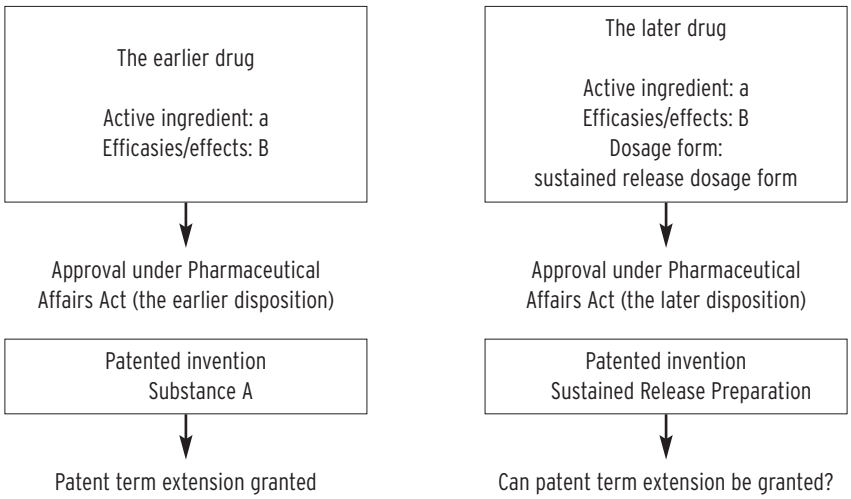
JAPAN

ABE & PARTNERS
Osaka

Takanori Abe

and
Michiko Kinoshita

New patent term extension system



Overview of the system

In Japan, there is a patent term extension system as in the US and Europe. In Europe, SPCs are actively discussed as many lawsuits regarding SPCs are filed and decisions of the the ECJ or the CJEU are rendered. Recently in Japan, judgments of IP High Court and Supreme Court have been rendered and overturned the former practice. As a result of these judgments, the JPO's Examination Guidelines have been revised and the patent term extension system is facing a large turning point. Here we introduce the new patent term extension system in Japan.

It is necessary for drugs or agricultural chemicals to be approved under the Pharmaceutical Affairs Act etc. in order to ensure safety. Therefore, a patentee cannot practise the patented invention until the drug is approved. In order to compensate for the lost patent term, the Japanese Patent Act provides that it can be extended (Article 67(2)).

Article 67-3(1)(i) of the Patent Act provides that an examiner shall reject an application to register an extension of the duration of a patent right if the disposition designated by Cabinet Order under Article 67(2) is not deemed to have been necessary to obtain for the practising of the patented invention. This ground of rejection has been argued in many lawsuits, especially as follows: where a patent term was extended because of an earlier disposition and after that an approval (the later disposition) was granted for a drug which has the same active ingredient and efficacies/effects but has different dosage form and so on, will the extension of the duration of the patent right be granted because of the later disposition? (see above figure)

The problem of former practice

The former practice of the JPO and the former precedents interpreted Article 67-3(1)(i) as follows: a drug which has the same active ingredient and efficacies/effects as an earlier drug falls under the description "where the disposition is not deemed to have been necessary to obtain" and an application for extension of the duration of the patent right should be rejected even though other characteristics of the drug such as dosage form differ from the earlier drug.

However, nowadays pharmaceutical inventions which have features other than active ingredients and efficacies/effects such as drug delivery systems (DDS) are granted patent rights. Therefore, it has been criticised that it is unreasonable to reject the extension of the duration of the patent right for such drugs because they have the same active ingredient and efficacies/effects. It was against the background of this debate that the present case was filed.

Summary of the case

Takeda Pharmaceutical Company Limited owns a patent for an invention regarding DDS. Takeda filed an application to register an extension of the duration of the patent right as it obtained approval for manufacture and sale under the Pharmaceutical Affairs Act (the later disposition) for Pacif Capsule 30mg which uses the patented invention (the later drug).

The JPO rejected the application. The reason was that there had already been an approval (the earlier disposition) for the earlier drug which has the same active ingredient and efficacies/effects as the later drug.

Takeda appealed to the IP High Court seeking to revoke the decision of JPO. The IP High Court and Supreme Court rescinded the JPO decision.

Judgment of IP High Court

In the judgment of May 29 2009, the IP High Court (Judge Iimura, the current chief judge of the IP High Court) held regarding interpretation of Article67-3(1)(i) that in order for an examiner (trial examiner) to reject the application for registration of the extension, he/she must prove that (i) the lifting of the prohibition cannot be asserted by reason of having obtained a "disposition designated by Cabinet Order" or (ii) the act for which the prohibition has been lifted by reason of having obtained the "disposition designated by Cabinet Order" is not included in the scope of the act that constitutes the "practising of the patented invention".

Furthermore, the Court held that even though there was the earlier disposition (in the above figure, an approval for the earlier drug of which active ingredient is "a" and of which efficacies/effects are "B"), the ban on practising the present invention (in above figure, production and sale of the drug of which active ingredient is "a", of which efficacies/effects is "B" and of which dosage form is "sustained release dosage form") was not lifted because the earlier drug (in the above figure, a drug of which active ingredient is "a" and of which efficacies/effects are "B") was not included in the technical scope of the present invention (in the above figure, the patent regarding "sustained release preparation"). This holding means that the ban on practising the present invention was lifted by the later disposition for the first time. Therefore, the present case does not fall under (i) the lifting of the prohibition cannot be asserted by reason of having obtained a "disposition designated by Cabinet

Order". For these reasons, the IP High Court denied that it fell under the ground of rejection in Article 67-3(1)(i).

Furthermore, the IP High Court mentioned in dicta regarding the interpretation of Article 68-2 which provides that the extended patent right shall be effective only against the practice of the product. The Court held that "the product" which decides the range of the effect means the product which was identified by "ingredients", "dose", and "structure" of the approved drug (needless to say, in light of the ordinary understanding of the technical scope, any products that are equivalent or regarded as substantially identical to that "product" are also included).

Judgment of the Supreme Court

In the judgment of April 28 2011, the Supreme Court upheld the decision of the IP High Court. However, the reason was more restrictive. The Supreme Court held as follows;

Even in the case where, prior to the approval for manufacture and sale under Article 14, paragraph (1) of the Pharmaceutical Affairs Act, which gave rise to the need to file an application for registration of extension of the duration of a patent right (the later disposition), another approval for manufacture and sale under said paragraph (the earlier disposition) had been issued with regard to the pharmaceutical product which has the same active ingredient and effect and efficacy as the pharmaceutical product covered by the later disposition, if the earlier pharmaceutical product is not included in the technical scope of the patented invention specified by any of the claims for the patent right pertaining to the application for registration of extension, it is unreasonable to deny that it was necessary to obtain the later disposition for the practising of the patented invention based on that patent right, on the grounds of the existence of the earlier disposition. Therefore, in the present case, it is unreasonable to deny that it was necessary to obtain the later disposition for the practising of the patented invention, on the grounds of the existence of the earlier disposition.

Unlike the IP High Court, the Supreme Court did not mention Article 68-2.

Revision of Examination Guidelines

In response to the Supreme Court decision, the Examination Guidelines were revised on December 28 2011. In the revised Examination Guidelines, the former practice which considers active ingredients and efficacies/effects only has changed and the extension of the duration of the patent right is granted for DDS or other inventions that have features other than active ingredient and efficacies/effects.

Remaining issues

According to the revised Examination Guidelines, the opinion of JPO regarding Article 67-3(1)(i) becomes clear. However, the Supreme Court only mentioned the case when the earlier drug is not included in the technical scope of the patent invention of the present patent. Therefore, the Court's opinion is unclear about when the earlier drug is included in the technical scope of the patented invention of the present patent.

Furthermore, the Supreme Court was silent on Article 68-2 which was specifically mentioned by the IP High Court. Therefore, a uniform opinion regarding the range of the effect of extension is not yet rendered. Further developments are expected.