



Controversy Over Patent Term Extensions in Japan

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In May 2009 the IP High Court of Japan handed down six related decisions on the conditions under which patent term extensions can be granted. These decisions will have a serious impact on future JPO practice on patent term extensions, because in all six decisions, the IP High Court denied the arguments of the Japanese Patent Office (JPO) and reversed decisions in which the JPO's Board of Appeals rejected requests for patent term extension. However the JPO appealed the case to the Supreme Court.

Patent Term Extensions

The Japanese Patent Law provides that a patent term may be extended up to five years if a patentee is prevented from exploiting a patented invention while obtaining approval under other laws such as the Pharmaceutical Law. The patentee must file an application for patent term extension that is examined by the JPO in much the same manner as a normal patent application. In order to be eligible for a patent term extension, the products which are subject to the approval must fall within the scope of the patent.

Background

In the present case, the patentee had obtained patents on certain pharmaceutical inventions and then applied for and received approval to produce and sell products protected by said patents under the Pharmaceutical Law. The patentee then filed six applications for patent term extension. The applications were rejected by the examiner and then by the Board of Appeals. The patentee appealed the cases to the IP High Court and requested that the decisions by the Board of Appeals be overruled. IP High Court, Cases Hei 20 (Gyo-ke) Nos. 10476, 10477, 10478, 10458, 10459 and 10460.

First issue before the court

The patent applications which later matured to the subject patents were published after examination (post-grant publication) in accordance with the old law under which oppositions were possible (oppositions are no longer possible under the current law). Oppositions were filed against the applications, and the claims were amended in

response to the oppositions before the patent was registered. When filing applications for patent term extension, the patentee submitted only the post-grant publications, and the JPO examined the request for patent term extension based only on these submitted documents. In view of this history, one issue was whether the JPO acted in accordance with the law in having construed the patented invention with reference only to the documents submitted by the patentee, even though the claims therein differ from those in the registered patents.

The second issue was whether it is legal to require that the substance (when a particular intended use is specified for approval, the substance to be used for the particular intended use) which was approved under the Pharmaceutical Law be clearly recited in the claims of the patents for which an extension is requested.

The third issue was whether, when there are two approvals in connection with a patent and a patent term extension has been granted based on the first approval, it is legal to determine the allowability of a second extension for the same patent based on a comparison of the patent scope extended by the first extension and that to be extended by the second extension.

The fourth issue was whether, when a patent term is extended based on an approval under the Pharmaceutical Law, the scope of the extended patent, as far as subsequent patent term extensions are concerned, covers drugs for which the effective ingredients and the efficacy are identical with those approved under the Pharmaceutical Law.

The patentee's arguments

The patentee argued that the JPO erred by construing the patented invention based on the post-grant publication which was subsequently amended before the invention was registered as a patent. The decision of whether to accept a patent term extension needs to be based on a comparison between the drug that was approved and the patented invention.

The JPO found that the drug that was approved needs to be described clearly in the claims to be extended, but there is no



basis for such an assertion. In order for approval to be necessary for the exploitation of a patented invention, it is enough for the production and sale of the accepted drug to fall within the scope of the patent.

The patentee also stated that the drug for which the first approval was issued does not fall within the scope of the patent for which an extension was requested, while the drug for which the second approval was granted does fall within the scope of the patent. The patented invention became exploitable, and the conditions for extension therefore satisfied, only upon receipt of the second approval.

Finally, the patentee argued that approval under the Pharmaceutical Law is provided for a drug as specified in the approval application, and a drug is not a mere combination of "effective ingredients" and "efficacy". Therefore, when a patent term extension is requested, the "substance for which approval (decision) was issued" corresponds to a specific drug. There is no reason whatsoever to interpret the substance as being a combination of an "effective ingredient" and "efficacy".

The JPO's response

The JPO argued that a request for patent term extension is examined based on the documents submitted by the patentee, who is assumed to be well aware of the history of patent examination and approval under the Pharmaceutical Law. The patentee bears the responsibility for proving that the approval was necessary for the exploitation of the patented invention. In spite of this, the patentee submitted only the post-grant publication, and asserted that the approval was necessary for the patent based solely on the post-grant publication.

Therefore, the JPO acted reasonably in relying only on the submitted documents during the examination of the application for patent term extension.

Second, it put forward the argument that, while the scope of a patent must be determined based on the claims, if they only contain an abstract recitation of the invention which is to be covered by the extended patent, it is difficult for those skilled in the art to clearly understand the scope of the extended rights and therefore they would suffer from an unforeseeable disadvantage. In order to avoid this, it is necessary to require that the "drug", that is, the "effective ingredient" that is specified in the approval, be clearly

specified in the patent as a constituent of the invention.

With regard to the present request for patent term extension, the JPO said that there was previous approval for the same "effective ingredient" and "efficacy". Since the previous approval was the first approval as mentioned in the Japanese Patent Law in connection with patent term extensions, the subsequent request for patent term extension must be rejected as not being based on the first approval.

Suppose a "drug" in the Pharmaceutical Law were to be interpreted so as to correspond to a "substance" in the Patent Law. Since the description of the "drug" could, in some cases, be different from the description of a constituent element of the invention according to the Patent Law, it would be difficult to determine whether the approval of the "drug" was necessary for the exploitation of the patented invention. In this way, a "drug" is not suitable for comparison with a "substance", so the terms "substance" and "intended use" in the Patent Law should be interpreted to mean "effective ingredient" and "efficacy", respectively.

Decision by IP High Court

The IP High Court found that the Board of Appeals had erred in the finding of the patented invention and therefore the decision is not valid. In the provision of the Patent Law which provides that an application for patent term extension must be rejected when an approval under the Pharmaceutical Law was unnecessary for the exploitation of the patented invention, it is clear that the term "patented invention" refers to the invention that has been registered as a patent.

Therefore, the JPO erred in construing the patented invention based on the post-grant publication, wherein the invention differs from the patented invention. The JPO's assertion that they are allowed to examine an application for patent term extension based only on the documents submitted by the patentee was rejected because the fact that the examiner and the Board of Appeals did not even check the registry owned by the JPO is unjustifiable. In view of the fact that the decision by the Board of Appeals failed to consider the registered patent, the assertion by the JPO is wrong.

In order to determine whether the approval was necessary for the exploitation of the patented invention, the court looked at the question of whether the production of the drug allowed by the approval falls within the scope of the patent. The Patent Law provides that the exclusive rights provided by an extended



patent do not cover the entire scope of the claims, but only the substance (if a particular use of the substance is specified, the substance to be used for the intended use) which was approved. Even considering this provision and the purpose of the legal system, there is no basis whatsoever to deem that the approved drug must be clearly described in the claims of the patent to be extended. The rejection of a request for extension on such a basis is unreasonable.

Historically, when a patent term is extended based on a first approval, and a second approval is issued, the question of whether the patent term should be extended again has been examined in view of the claim scope extended by the first approval. However, the claim scope extended by the first approval does not necessarily relate to the question of whether the patent term should be extended again. According to the Patent Law, the question whether a patent term should be extended must be determined based on whether the approval was necessary for the exploitation of the patented invention. Therefore, it is necessary and sufficient that the production and sale of a drug has been allowed by the approval and that the production and sale of the drug falls within the scope of the patent. When rejecting an application for the patent term extension, the burden is on the examiner to prove that at least one of these conditions is not met. Putting aside the question of whether the "substance" should be deemed to mean the "effective ingredients", the judgment by the JPO that the approval was not necessary for the exploitation of the patented invention was erroneous in view of the fact that the acts allowed by the first approval do not fall within the scope of the claims while the acts allowed by the second approval do fall within the scope of the claims.

The JPO asserts that the essence of the Pharmaceutical Law resides in the terms "effective ingredients" and "efficacy". However, the Pharmaceutical Law indicates that "name, ingredients, quantity, structure, dose regimen, dosage, usage, efficacy, effects, performance, collateral effects and other qualities, other items relating to efficacy and safety" should be considered when determining approval. It is known that ingredients other than effective ingredients sometimes influence the efficacy and safety of a drug, as do other items such as "quantity", "structure", "dose regimen" and "dosage". In view of this, the JPO's assertion that the essence of the Pharmaceutical Law resides in "effective ingredients" and

"efficacy" is unacceptable by any measure. Furthermore, there is no literal or reasonable basis for the interpretation that the patent scope extended based on approval covers inventions of which the "effective ingredients" and the "efficacy" are the same as the approved substance.

Considerations

The judgment of the IP High Court is very clear, and seems to be reasonable. Therefore, there is no reason to doubt that in the future, extensions will be allowed in circumstances that are the same as the present case.

The present decision eliminated two of the criteria that the JPO previously used in determining whether to allow applications for patent term extensions, and established new standards, so it is likely to have a considerable impact on future applications for patent term extension. According to the new standards established by the IP High Court, it is no longer a requirement for a drug that received approval to be clearly recited in the claims of a patent for which an extension has been requested, and only necessary for the approved drug to be contained within the scope of protection of the patent. Additionally, when there are two applications for extension of the same patent, the question of whether or not there is any overlap between the scope of protection extended by the first extension and the scope of protection extended by the second extension is not decisive, and the requirement is that the drug that received the second approval only became exploitable after having been approved.

Furthermore, since the present decision overruled past judgments of the JPO and High Court regarding the force of patents with extended patent terms, it will also have a significant impact on infringement cases. In other words, the present decision held the view that the scope of protection of an extended patent covers a "substance" defined by "ingredients", "quantity" and "structure" which are the subject of approval of a drug. This judgment narrows the scope of protection as compared with the stance conventionally taken indirectly (i.e. in examinations of applications for patent term extension) by the JPO and IP High Court, under which it was understood that the scope of protection of an extended patent covers drugs having the same "active ingredients" as the drug that received approval. At the present time, there are no precedent cases in which the



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scope of protection of a patent with extended term was directly contested, so the opinion of the court in the present decision is likely to present an important precedent in future cases of patent infringement of patents with extended terms.

Finally, the present decision raises many more questions. For example, there is the problem of patent term extensions of basic inventions based on approval of improvement inventions. In other words, according to the present decision which held that the question of whether or not to allow a patent term extension depends on whether or not the drug which received approval is included within the scope of protection of the patent, when the drug that received approval under the Pharmaceutical Law is an improvement invention of a patented invention, there is the question whether or not to allow extension of the patent term of the basic invention. Even if approval under the Pharmaceutical Law has been obtained for a basic invention, it is clear that further approval will be required to exploit a drug which is an improvement invention, so if the drug which is the subject of the improvement invention is included within the scope of the basic invention, then the requirements for extension of the patent term of the basic patent will be satisfied. The improvement invention¹ may also be an invention that was completed after registration of the patent which is to be extended. In that case, there is some question whether or not it is reasonable to allow extension of the patent term.

¹ *In the present article, an improvement invention means an invention which has all of the features of a previous invention and an additional feature so that the improvement invention is included in the patent scope of the previous invention while the reverse is not true.*