Issue #43, November 2011

WINDS FROM JAPAN

The Licensing Executives Society Japan

Recent Supreme Court Decision [Hei 20 (Gyo-hi) Nos. 324 to 326] relating to Patent Term Extension System in Japan

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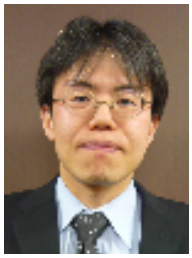

1. Introduction

Under the patent system in Japan, where there is a period during which a patented invention cannot be implemented because a necessary approval or other disposition under the Pharmaceutical Affairs Law or the Agricultural Chemicals Regulation Law has not been obtained, the term of the patent may be extended, upon the filing of an application for registration of a patent term extension (hereinafter referred to as "PTE application"), by a period of up to 5 years (Article 67, Par. 2 of the Japanese patent law, Article 3 of the Patent Law Enforcement Order). The patent term extension system in Japan differs in several respects from the system in the U.S.A. (35 U.S.C. §156) and the system based on the supplementary protection certificate for medicinal products (referred to as SPC) in Europe. In this regard, please refer to YUASA and HARA Intellectual Property News Vol. 28.

In some cases for claiming revocation of an appeal decision of rejection with regard to a PTE application based on a second or subsequent approval for a drug whose active ingredient and efficacy are the same as those of a previously-approved drug, there is a dispute on how to interpret requirements stipulated in Article 67-3, Par. 1, item No. 1 of the Japanese patent law, which stipulates as follows:

Article 67-3, Par. 1

Where an application for the registration of extension of the term of a patent right falls under any of the following items (items (I) to (v)), the examiner shall render a decision to the effect that the application is to be rejected:

(i) where the disposition designated by Cabinet Order under Article 67(2) is not deemed to have been required to be obtained for the working of the patented invention;

(items (ii) to (v) are omitted).

Under the JPO practice, in a case that a drug is previously approved and an active ingredient and efficacy/effect (use) thereof are the same as those of a later-approved drug, a PTE application based on the later approval is rejected based on the previous approval under Article 67-3, Par.1, item No. 1. The JPO applies these criteria to examination of any PTE application, and will reject a PTE application even in a case that a previous approval does not allow a patentee to implement an invention of a patent relating to a subject PTE application based on a later approval.

The Intellectual Property High Court (hereinafter referred to as IPHC) has so far issued decisions supporting such practice of the Japanese Patent Office (hereinafter referred to as the JPO). However, in a judicial decision issued in May 2009, a judgment made by the IPHC included a directive to the JPO to change their practice in examination of PTE applications and also indicated a new interpretation about the scope to be covered by a patent right whose term was extended [the case of claiming revocation of appeal decisions: IPHC, May 29, 2009, Hei 20 (Gyo ke) Nos. 10458 to 10460].

The JPO filed an appeal to the Supreme Court, claiming the revocation of the IPHC decisions. On April 28, 2011, the Supreme Court issued a decision affirming the conclusion of the IPHC decision [Hei 20 (Gyo-hi) Nos. 324 to 326]. In response to the Supreme Court decision, the JPO announced that they are revising the Examination Guideline regarding PTE application.

Hereinafter, summaries of the IPHC decision [Hei 20 (Gyo ke) No. 10460] and the Supreme Court decision [Hei 20 (Gyo-hi) No. 326] will be provided.

2. IPHC decision [case of claiming revocation of appeal decisions: Hei 20 (Gyo ke) No. 10460]

a) Content of the case and the decision by the Japanese Patent Office

Takeda Pharmaceutical Company Limited obtained an approval for "Pacif capsule, 30 mg" (active ingredient: morphine hydrochloride) used in relieving pain of various types of cancers with moderate to severe pain, and filed a PTE application for a patent relating to pharmaceutical formulations (JP No. 3134187). Claim 1 of the subject patent recites as follows.

[Claim 1] A controlled-release composition comprising a core that contains a drug, wherein the core is coated with a coating agent comprising:

(1) a material that is insoluble in water;

(2) a hydrophilic material selected from polysaccharides that may have sulfate group, polysaccharides having hydroxyalkyl or carboxyalkyl,

methyl cellulose, polyvinylpyrrolidone, polyvinyl alcohol, polyethylene glycol; and

(3) crosslinked acrylic acid polymer that has an acidic dissociable group and exhibits pH-dependent swelling.

The JPO pointed out as a reason that the drug (Opso liquid for oral administration: 5 mg/10 mg), which contains morphine hydrochloride as an active ingredient and is used in relieving pain of various types of cancers with moderate to severe pain, had been approved previously, and stated "the drug that contains morphine hydrochloride as an active ingredient (product) and also has the same efficacy/effect (use) as that approved prior to the present disposition, and even if there is found a necessity for obtaining a new disposition because of a required change in dosage form of this drug other than the active ingredient and the efficacy/effect, the disposition (approval under the Pharmaceutical Affairs Law) stipulated in Article 67, Par. 2 of the Japanese patent law is not considered to be necessary in implementation of the present invention, and therefore, this application should be rejected under Article 67-3, Par. 1, item No. 1 of the Japanese patent law." The JPO rejected the application according to existing criteria. In this case, the drug (liquid for oral administration) for which the previous approval was granted does not fall within the scope of the subject patent.

b) Judgment regarding Article 67-3, Par. 1, item No. 1 of the Japanese patent law

In the lawsuit claiming revocation of the appeal decision, with regard to the existing criteria in which requirements set forth in Article 67-3, Par. 1, item No. 1 of the Japanese patent law are interpreted in association with the scope of a patent right after extension of a patent term (Article 68-2 of the Japanese patent law), the IPHC stated that "a point regarding a scope covered by a patent whose term was extended due to a previous disposition does not always directly relate to a point about whether a disposition specified by a cabinet order is required to implement a patented invention. Rather, as in the subject case, in evaluating validity of an appeal decision rejecting a PTE application, it is essential to evaluate whether the application meets the requirement of Article 67-3, Par. 1, item No. 1 of the Japanese patent law, on which the rejection in the examination decision (appeal decision) is based." Therefore, the IPHC revoked the appeal decision due to an erroneous judgment in the appeal decision. The IPHC provided the following grounds in their decision:

"For an examiner (an appeal examiner) to reject the subject application, it is necessary to prove that (1) receipt of 'a disposition specified by a cabinet order' does not result in lifting prohibition, or (2) 'an act for which the prohibition has been cancelled by a disposition specified by a cabinet order' is not included in 'acts corresponding to implementation of the subject patented invention.' In other words, as long as a fact that corresponds to the above-described requirement is not proved in an appeal decision, it is impossible to make a judgment for rejecting the subject PTE application under Article 67-3, Par. 1, item No. 1 of the Japanese patent law."

"It is undisputed among the parties that the drug that is subjected to the previous approval is not included in the scope of the present patented invention, and that a person who received this previous approval is neither a plaintiff who is a patentee of the subject patent, nor an exclusive licensee or a registered non-exclusive licensee. Further, preparation of the previously-approved drug or other relevant acts, the prohibition of which is lifted by the previous approval, do not correspond to implementation of the present invention. In this case, although the precedent disposition exists, there is found no relationship in which an act for which the prohibition is lifted on receipt of the previous approval falls within the scope of the present invention and corresponds to implementation of the subject patented invention. Thus, the existence of the previous approval will not influence revocation of a legal state in which the plaintiff who is the patentee of the present invention could not implement the patented invention without obtaining a predetermined approval under the Pharmaceutical Affairs Law for a drug included in the scope of the patented invention. In implementation of the present patented invention, the existence of the precedent disposition will not constitute a reason for eliminating the necessity of 'a disposition specified by a cabinet order' (in the present case, a predetermined approval under the Pharmaceutical Affairs Law)."

c) Regarding a scope covered by an extended patent right (Article 68-2 of the Japanese patent law)

In the judicial decision, a scope to be covered by an extended patent right on the basis of an approval under the Pharmaceutical Affairs Law was explained as follows by denying criteria established in the existing judicial decisions that the patent covers the scope defined by the same 'active ingredient' and 'efficacy/effect.'

"The Japanese patent law stipulates that, where a patent term is extended, the effect of the patent shall not cover the entire scope of the patented invention but shall cover only 'a product to be subjected to a disposition specified by a cabinet order (the product to which the specific use is applied, where a specific use is determined for the product to be subjected to the disposition concerned).' This is because where the scope of a patented invention defined by the claims of the patent is wider than a scope whose prohibition is lifted by the receipt of 'a disposition specified by a cabinet order,' it shows partiality toward a patentee if the effect of the thus extended patent right covers a broader scope than that in which the patentee could not implement the patented invention due to a necessity for receiving the disposition (scope of 'a product' or 'a product and a use'). Namely, a system of registration of a patent term extension is established to dissolve disadvantages resulting from the loss of an opportunity of implementing a patented invention where, irrespective of the intention and competence of a patentee for implementing a patented invention, the implementation of the patented invention was prevented by the provision of 'law for the purpose of securing the safety and others' stipulated in Article 67, Par. 2 of the Japanese patent law. Therefore, it is against the spirit of the system to deal with the patentee favorably beyond the dissolution of the above-described disadvantage."

Further, it was judged that "a product" stipulated in Article 68-2 of the Japanese patent law should be identified by referring to "component," "quantity" and "structure" of a drug approved under the Pharmaceutical Affairs Law, among matters to be examined under the Pharmaceutical Affairs Law; more specifically, "name, component, quantity, structure, administration, dosage amount, use method, efficacy, effect, performance, side effects, other qualities, matters of effectiveness and safety" (Article 14,

Par. 2, item No. 3 of the Pharmaceutical Affairs Law). It was further stated that "where a patented invention relates to pharmaceuticals, among embodiments included in the scope of the patent, it should be understood that the effect of the thus extended patent right covers only the implementation of the patented invention relating to "a product" specified by "component," "quantity" and "structure" of a drug to which a predetermined approval was given under the Pharmaceutical Affairs Law, and the implementation of the patented invention relating to "a product" specified by "the use" of the drug concerned (As a matter of course, it is natural that the equivalent thereof and a product that is evaluated to be substantially the same are included in view of an ordinary understanding of the scope of the patent.)."

It is noted that in each of Hei 20 (Gyo ke) No. 10458 and Hei 20 (Gyo ke) No. 10459, revocation of an appeal decision was judged on the same grounds as that of the above-described judicial decision.

3. Supreme Court Decision [Hei 20 (Gyo-hi) No. 326]

The Supreme Court affirms the conclusion of the IPHC decision and states in their decision that "since the previously approved drug does not fall within the scope of any claims of the subject patent right, the judgment that the subject approval in this case is recognized as being unnecessary to implement the patented invention on the ground that the previous approval was already obtained is groundless." On the other hand, the Supreme Court also states that the assertions made in the IPHC decision are not acceptable. As a reason for their conclusion, the Supreme Court further states as follows:

"The aim of the patent term extension system is to allow a patentee to recover the term in which a patented invention cannot be implemented because if a necessary disposition of the Patent Law Enforcement Order stipulated in Article 67, Par. 2 of the Japanese patent law. Although the previous approval for the drug of which active ingredient and efficacy/effect are same as the later-approved drug was already obtained, the previously approved drug does not fall within the scope of any claims of the subject patent. In such a case, it is not recognized that the invention recited in any claims of the subject patent as well as the invention corresponding to the later-approved drug can be implemented."

"In a case that the previously approved drug does not fall within the scope of any claims of the patent relating to the PTE application, the conclusion stated above should never depend on the interpretation of the scope covered by the patent wherein the term thereof could be extended based on a previous approval."

4. Influences of the Supreme Court decision

After issuance of the IPHC decisions [Hei 20 (Gyo ke) No. 10458 to No. 10460], examination of PTE applications by the JPO have been conducted on the basis of the existing Examination Guideline. In response to the Supreme Court decision, the JPO announced on May 16, 2011 that they are revising the Examination Guideline for PTE applications and they plan to release the revised guideline in fall, 2011. Further, the JPO announced that they suspend examination of new PTE applications until the revised guideline is released. In light of the Supreme Court decision, a PTE application should never be rejected under Article 67-3, Par. 1, item No. 1 of the Japanese patent law on the ground of a previously approved drug that does not correspond to an invention recited in any claims of the subject patent. It is considered that a PTE application that was not allowed under the former practice (e.g. an application based on a patent relating to a pharmaceutical formulation, drug delivery system and the like) may be allowed under the revised Examination Guideline.

At present, it is unclear how the JPO is to introduce the criteria indicated in the Supreme Court decision into the Examination Guideline. For example, it is possible that the JPO will add criteria in a case that a previously approved drug does not correspond to an invention recited in any claims of a subject patent, and maintain the current practice including the interpretation of the scope of the extended patent. In any event, we recommend filing any PTE application that is considered to be allowable by the deadline, even before the release of the revised guideline.

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Recent amendments to the Patent Act of Japan

By Miyuka NISHI*

The law to amend the Patent Act of Japan was issued on June 8, 2011 and will be effective within a year of the issue date. Since the amendments would have strong impact on patent practice in Japan, this paper would like to show you their key outline as below:

1. Where a Licensed Patent Right Has Been Transferred – Protection of Non-Exclusive Licensees (Art. 99)

Under the current law, where a licensed patent right has been transferred, the transferee can seek injunctive relief and damages against the unregistered non-exclusive licensees. Such results have been criticized as too harsh to the non-exclusive licensees in comparison with the transferee who knew or should have known the existence of non-exclusive license through due diligence before the transfer. In light thereof, the new law abolishes the registration system for non-exclusive license and provides that any non-exclusive license can be claimed against a transferee of the licensed patent right. According to the authority, the transferee will not automatically be regarded as a party to the license agreement and thus will have no contractual rights or obligations unless so agreed with the licensee. Therefore, under the new law, it is more important than before that the transferee (including a M&A buyer) should conduct thorough due diligence on license agreements and arrange in advance an assignment of licensor's rights (e.g., royalty).

2. Where a Patent Application Has Been Filed by Non-Entitled Persons – Protection of True Inventors (Art.
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Under the current law, where a patent application has been filed by non-entitled persons, true inventors or their successors can file an action to invalidate the registered patent, but they cannot seek transfer of such registered patent. It has been criticized as insufficient to protect the true inventors. In light thereof, under the new law, the non-entitled persons should transfer the registered patent to the true proprietors upon their request. In such case, the new law also provides that third parties, to whom the patent rights was assigned or licensed by the non-entitled persons, would be regarded as non-exclusive licensees, who can continue to use the patented technology, but will lose exclusivity. Therefore, under the new law, due diligence on true inventors of patented technology would become more important than before.

3. Where a JPO Panel Decision to Invalidate a Patent Has Been Appealed to IP High Court – Prohibition of Filing with JPO an Action to Amend the Scope of Patent (Art. 126(2))

Under the current law, where a JPO panel decision to invalidate a patent has been appealed to IP High Court, the patentee may simultaneously file with JPO an action to amend the scope of patent within a certain period of time. In such case, IP High Court may just return the case to JPO without review. This procedural inefficiency, going back and forth between JPO and IP High Court, has been criticized as preventing the case promptly settled and imposing on the parties financial burdens. Under the new law, where a JPO panel decision to invalidate a patent has been appealed to IP High Court, the patentee is prohibited from filing with JPO an action to amend the scope of patent. Instead, the new law establishes procedures such that the JPO panel notifies in advance the parties of its invalidation decision so that the patentee is given an opportunity to amend the scope of patent to circumvent the invalidation.

4. Where a Court Judgment in Patent Infringement Lawsuit Became Final and Biding – Limitation of Retrial (Art. 104-4)

Under Japanese patent system, there is a possibility that, after a court ruled for a patentee in the patent infringement lawsuit, a JPO panel may invalidate the patent, and that the said court judgment may be rescinded through retrial on the grounds that "administrative disposition, based on which the judgment … was made, has been modified by a subsequent …administrative disposition" (Art. 338(1) (viii) of the Code of Civil Procedure). This retrial possibility has been criticized as rehashing the settled dispute given that the parties of a patent infringement lawsuit are given the opportunity and authority to make arguments on the validity of the patent under Art. 104-3. In light thereof, the new law restricts the retrial of patent infringement lawsuit for the reason of a subsequent JPO panel decision to invalidate the patent in question.

5. Where an Invention Becomes Publicly Known As a Result of Proprietor's Own Act – Exception to Lack of Novelty of Invention (Art. 30(2))

The current law lists certain cases where an invention is disclosed to the public through its proprietor's own act, and sets out that, in such case, the invention will not lose novelty if a patent application is made for it within 6 months of the disclosure. In order to meet business need, the new law expands the scope of exception and provides that any inventions that have become publicly known as a result of proprietor's own act (except for publication in a patent gazette issued based on filing with JPO or a foreign patent office) will not lose novelty if a patent application is made for it within 6 months of the disclosure.

6. Where a Registered Trademark is Extinguished (e.g., Nullified, Invalidated) – Abolition of One Year Waiting Period for Application to Register the Identical or Similar Trademark (Art. 4(1)(xiii) of the Trademark Act)

The current law refuses an application to register a trademark identical with or similar to the trademark extinguished within one year before the application (Art. 4(1)(xiii)). Although it seems to concern of possible confusion as to the source of goods or services, this concern can be covered by another basis to refuse a trademark application (Art. 4(1) (xv)). Due to the business need to acquire a trademark identical with or similar to the extinguished trademark in timely manner, the new law has removed Article 4(1)(xiii) from the basis to refuse a trademark application.

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Editors' Note

We trust that the articles included in this issue will prove useful in providing you with up-to-date information on a variety of IP issues in Japan.

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