

Important Decision of Japanese Supreme Court on **Patent Term Extension Application**

ASAMURA PATENT OFFICE, p.c.
Patent Attorney: Teruo Naganuma
May, 2011

Summary

The Japanese Supreme Court rendered a very important, significant decision (Case No. Hei 21 (Gyo hi) No.326) on April 28, 2011, in which the Supreme Court dismissed an appeal by the Japan Patent Office (JPO) and affirmed a decision of the Japanese Intellectual Property High Court (IP High Court), to cancel a JPO's decision on rejecting a patent term extension application due to the existence of a previously approved drug which is the same in both the active ingredient and the efficacy/effect as a newly approved drug based on which the patent term extension application was filed for a patent covering the newly approved drug. The Supreme Court judged that, if the previously approved drug is not within the scope of any patented claims of the patent, the obtaining of the new approval was necessary for working the patented invention of the patent, and the patent term extension application for the patent therefore should not be rejected due to the existence of the previously approved drug.

According to this decision of the Supreme Court, in Japan, a patent term extension application for a patent covering, for instance, a new drug delivery system for the active ingredient of a previously approved drug will be allowed additionally to the other patent term extension of a basic patent covering the previously approved drug. Thus, this decision would be extremely favorable to new drug makers developing and marketing successively newly improved drugs after the launching of new drugs.

Background

Takeda Chemical Industries, Ltd. (referred to as the Patentee hereunder)

obtained a patent right on a new drug delivery system of the broad scope of a drug as Japanese Patent No. 3,134,187 (the filing date: March 6, 1997; the publication date: November 18, 1997; and the registration date: December 1, 2000) (referred to as the Instant Patent hereunder). The Instant Patent is directed to a controlled-release composition of a drug including morphine, as claimed in claims 1 and 14, as follows:

Claim 1. A controlled-release composition comprising a drug-containing core coated with a coating composition comprising (i) a water-insoluble substance, (ii) a hydrophilic substance selected from a polysaccharide that may have a sulfate group, a polysaccharide having a hydroxyalkyl group or a carboxyalkyl group, methyl cellulose, polyvinylpyrrolidone, polyvinyl alcohol and polyethylene glycol, and (iii) a cross-linked acrylic polymer having an acidic dissociating group and showing pH-dependent swelling.

Claim 14. The controlled-release composition of claim 1, wherein said drug is morphine or a salt thereof.

The Patentee of the Instant Patent received on September 30, 2005 from the Japanese Ministry of Health, Labour and Welfare a marketing approval for "Pacif capsule 30 mg" for use in relieving pain of various types of cancers with moderate to severe pain (referred to as the New Approval hereunder). "Pacif capsule 30 mg" is a controlled-release composition within the scope of claims 1 and 14 of the Instant Patent, and contains morphine hydrochloride as the drug (i.e., an active ingredient).

Based on the New Approval, the Patentee filed a patent term extension application of the Instant Patent on December 16, 2005 (referred to as the Instant Patent Term Extension Application hereunder)..

On the other hand, there had already been a previous approval dated March 14, 2003 for "Opso liquid for oral administration 5 mg/10 mg", which contains morphine hydrochloride as an active ingredient and which is for use in relieving pain of various types of cancers with moderate to severe pain (referred to as the Previous Approval hereunder). That is, the Previous Approval is the same as the New Approval in both the active ingredient and

the efficacy/effect. However, "Opso liquid for oral administration 5 mg/10 mg" is not within the scope of any of the patented claims of the Instant Patent.

The Board of Appeal of the Japan Patent Office (referred to as the JPO's Board of Appeal hereunder) decided on October 21, 2008 to reject the Instant Patent Term Extension Application for the reasons as follows:

Before the New Approval, there had already been the Previous Approval which is the same as the New Approval in both the active ingredient and the efficacy/effect. Therefore, there was not necessity to obtain the New Approval for working the patented invention of the Instant Patent, and the Instant Patent Term Extension Application therefore falls under the reason for rejection of Article 67-3. (1). (i). of the Japanese Patent Law which prescribes that, when it is not deemed that the obtaining of a disposition under Cabinet Order, for which a considerable period time is required as provided in Article 67.(2), was necessary for working the patented invention, the patent term extension application should be rejected.

The Instant Patentee appealed the case to the IP High Court and requested that the decision of the JPO's Board of Appeal be canceled. The IP High Court rendered a decision on May 29, 2009 (Case No. Hei 20 (Gyo ke) No. 10458) to cancel the decision of the JPO's Board of Appeal. The reasonings of the decision of the IP High Court are mainly as follows:

The purport of a patent term extension system resides in compensating a patentee who was unable to work the patented invention despite the patentee's intention and capability to work the invention because the patentee was prohibited from working the invention in the absence of obtaining a disposition.

The eligibility requirement of a patent term extension application under Article 67-3. (1). (i). prescribing that the obtaining of a disposition was necessary for working the patented invention should be examined on the basis of whether or not the patent term extension application satisfies two conditions, i.e., (1) the prohibition of working the invention was removed by obtaining a disposition, and (2) the working is within the scope of the patented invention. In order for the

JPO to reject a patent term extension application, the JPO should bear the burden of proving that the application does not satisfy one or two of the conditions (1) and (2). However, the JPO's Board of Appeal did not prove that the Instant Patent Term Extension Application does not satisfy one or two of the conditions (1) and (2).

Against this decision of the IP High Court, the JPO further appealed the case to the Supreme Court.

Judgment of Supreme Court

The Supreme Court judged that, even in the case that there had already been a previously approved drug which is the same as a newly approved drug in both the active ingredient and the efficacy/effect, if the previously approved drug is not within the scope of any patented claims of a patent which is the subject of a patent term extension application based on the new approval of the newly approved drug, the necessity of obtaining the new approval for working the patented invention of the patent should not be denied due to the existence of the previously approved drug.

The Supreme Court found that the purpose of a patent term extension system is to recovery the period of time in which the patented invention has been unable to be worked for obtaining a disposition under Cabinet Order provided in Article 67.(2) of the Patent Law, and that, even though the previously approved drug is the same as the newly approved drug in both the active ingredient and the efficacy/effect, the patented invention of the patent which is the subject of the patent term extension application has been unable to be worked because the previously approved drug is not within the scope of any patented claims of the patent. Furthermore, the Supreme Court found that, when the previously approved drug is not within the scope of any patented claims of the patent which is the subject of the patent term extension application, this judgment is not influenced by the interpretation of Article 68-2 prescribing the effect of the extended patent right on the approved product and use thereof.

As a consequence, the Supreme Court judged that, because the previously approved drug (i.e., "Opso liquid for oral administration 5 mg/10 mg") of the Previous Approval is not within the scope of any patented claims of the

Instant Patent, the necessity of obtaining the New Approval for working the patented invention of the Instant Patent should not be denied due to the existence of the Previous Approval. Thus, the Supreme Court dismissed the appeal by the JPO and affirmed the decision of the IP High Court, to cancel the JPO's decision on rejecting the Instant Patent Term Extension Application.

Comments

This decision of the Supreme Court is very simple and clear. The Supreme Court judged that, if a previously approved drug is not within the scope of any patented claims of a patent which is the subject of a patent term extension application, the obtaining of a new approval based on which the patent term extension application was filed was necessary for working the patented invention of the patent, and the patent term extension application for the patent should not be rejected due to the existence of the previously approved drug.

The decision of the Supreme Court reversed the current JPO's examination practice on a patent term extension application that a marketing approval for a drug must be the first approval with respect to the active ingredient and the efficacy/effect (i.e., the medical use), and that any subsequent approvals for the same active ingredient and the same medical use which only differ in the dosage form, treatment regime, and the like cannot serve as a basis for an additional extension of the patent term. Thus, the JPO will be required to change the current examination practice on a patent term extension application.

According to this decision, if a new drug maker obtains a patent on, for instance, a new drug delivery system, a pharmaceutical composition characterized by the amount of an active ingredient or the combination of the ingredient with other drug, and the like, the new drug maker would be able to extend the patent term of such patents, independently from or additionally to the extension of the patent term of basic product or medical use patents on the active ingredient. Thus, this decision would be extremely favorable to new drug makers developing and marketing successively newly improved drugs after the launching of new drugs. In contrast, this decision may be problematic to generic drug makers.

Relevant Articles of Japanese Patent Law

Article 67 (Term of patent right)

(1) The term of the patent right shall be 20 years from the filing date of the patent application.

(2) The term of the patent right may be extended, upon application for registration of an extension, by a period not exceeding five years if, because of the necessity of obtaining an approval or other disposition which is governed by provisions in laws intended to ensure safety, etc. in the working of the patented invention, and which is provided for in Cabinet Order as being such that, in view of the object of the relevant disposition, proceedings, etc., a considerable period of time is required for the proper action for the disposition, there was a period in which it was not possible to work the patented invention.

Article 67-3

(1) The examiner shall make a decision that an application for registration of an extension of a patent right is to be refused where it falls under any of the following items:

(i) where it is not deemed that the obtaining of the disposition as provided for in Cabinet Order referred to in Article 67(2) was necessary for the working of the patented invention;

(ii) where the disposition as provided for in Cabinet Order referred to in Article 67(2) was not obtained by the patentee, or a person who has an exclusive license or a registered non-exclusive license on the patent right;

(iii) where the term for which an extension is applied exceeds the period of time during which the patented invention could not be worked;

(iv) where the person applying for an extension is not the patentee concerned;

(v) where the application does not comply with Article 67-2(4).

Article 68-2 (Effect of the term extended patent right)

The effects of the patent right of which the term has been extended [including cases in which the term is deemed to be extended under Article 67-2(5)] shall not extend to acts other than the working of the patented invention concerned in respect of the product (where, in the disposition concerned, any specific use of such product to be used was specified, the product used for such specific use) which was the subject of the disposition as provided for in Cabinet Order referred to in Article 67(2) and as being the ground for the registration of the extension.