

## DECISION

The present appeal is dismissed.

The court costs shall be borne by Appellant.

## REASONS

Regarding the Grounds for Appeal by Appellant's Agent Noriaki Sudo *et al.*

1 In the present case, Appellee, the patentee of Japanese Patent No. 3134187 (hereinafter referred to as "Present Patent", the patent rights secured by the Present Patent referred to as "Present Patent Rights"), appealed for cancellation of a decision by the JPO dismissing an appeal against a decision of rejection issued on an application for term extension of the Present Patent Rights.

2 The facts established in the court of first instance can be summarized as follows.

(1) The Present Patent (having 22 claims) was filed in an application entitled "Controlled-Release Composition" on March 6, 1997, and the patent was registered on December 1, 2000.

The invention of the Present Patent relates to a controlled-release composition wherein a drug-containing core is coated with a coating composition containing certain hydrophilic substances and certain crosslinked acrylic polymers.

(2) Appellee received approval under Article 14, Paragraph 1 of the Pharmaceutical Affairs Law (hereinafter referred to as "Present Approval") for manufacture and sales of a pharmaceutical product to be sold under the name "Passif Capsule 30 mg" (hereinafter referred to as "Present Pharmaceutical Product") on September 30, 2005. The Present Pharmaceutical Product has morphine hydrochloride as its active ingredient, and has efficacy and effects for controlling pain in various types of cancer that are accompanied by moderate to severe pain.

(3) Prior to the Present Approval, approval under Article 14, Paragraph 1 of the Pharmaceutical Affairs Law (hereinafter referred to as "Present Prior Approval") had been

granted for manufacture and sales of a pharmaceutical product to be sold under the name “Opso Oral Solution 5 mg, 10 mg” (hereinafter referred to as “Present Prior Pharmaceutical Product”) and having the same active ingredient, efficacy and effects as the Present Pharmaceutical Product. The Present Prior Pharmaceutical Product does not belong within the technical scope of the patent invention according to any of the claims of the Present Patent Rights.

(4) On December 16, 2005, Appellee filed an application for term extension of the Present Patent Rights on the grounds that there was a period during which a patent invention of the Present Patent Rights was not able to be exploited due to the need to obtain the Present Approval. After receiving a decision of rejection, Appellee filed an appeal against the decision of rejection.

(5) On October 21, 2008, the JPO issued a decision (hereinafter referred to as “Present JPO Decision”) dismissing the above appeal on the grounds that the Present Prior Approval had already been issued on the Present Prior Pharmaceutical Product having the same active ingredient, efficacy and effects as the Present Pharmaceutical Product before the Present Approval, and hence there was no need to receive the Present Approval in order to exploit the patent invention under the Present Patent Rights.

3 Even in the case where approval (hereinafter referred to as “Later Approval”) for manufacture and sales under Article 14, Paragraph 1 of the Pharmaceutical Affairs Law on which an application for patent term extension has been based was preceded by approval (hereinafter referred to as “Prior Approval”) for manufacture and sales under the same provisions for a pharmaceutical product (hereinafter referred to as “Prior Pharmaceutical Product”) having the same active ingredient, efficacy and effects as the pharmaceutical product (hereinafter referred to as “Later Pharmaceutical Product”) that was the subject of the Later Approval, if the Prior Pharmaceutical Product does not belong within the technical scope of the patent invention according to any of the claims of the patent which is the subject of the application for patent term extension, then the existence of the Prior Approval cannot be considered to be sufficient grounds for denying that the Later Approval was necessary to exploit the patent invention of that patent. This is because the purpose of the patent term extension system is to compensate for time during which a

patent invention was not able to be exploited due to the need to receive government approval as provided in Article 67, Paragraph 2 of the Japanese Patent Law, and so long as the Prior Pharmaceutical Product does not belong within the technical scope of a patent invention according to any of the claims of the patent that is the subject of an application for patent term extension, the simple fact that a Prior Approval was issued for the Prior Pharmaceutical Product having the same active ingredient, efficacy and effects as the Later Pharmaceutical Product is not sufficient to conclude that the patent invention being exploited by the Prior Pharmaceutical Product in the patent which is the subject of the application for patent term extension, or indeed, any patent invention claimed in the above patent, was able to be exploited. Furthermore, as long as the Prior Pharmaceutical Product does not belong within the technical scope of the patent invention according to any of the claims of the patent which is the subject of the application for patent term extension, the above conclusion cannot be affected by the interpretation of the range of effectiveness of a patent (Japanese Patent Law, Article 68<sup>bis</sup>) when the patent term could have been extended by a prior approval.

Since the Present Prior Pharmaceutical Product does not belong within the technical scope of the patent invention according to any of the claims of the Present Patent Rights, the fact that the Present Prior Approval was issued in the present case is not sufficient to conclude that there was no need to receive the Present Approval in order to exploit that patent invention.

4 In view of the above, we find proper the judgment of the court of first instance overruling the Present JPO Decision on the grounds that the existence of the Present Prior Approval is not sufficient reason to deny that there was a need to receive approval for manufacture and sales under Article 14, Paragraph 1 of the Pharmaceutical Affairs Law in order to exploit the patent invention of the Present Patent Rights. The arguments presented are not persuasive.

As such, by unanimous decision, we find as per the Decision indicated above.

Presiding Justice Tomoyuki Yokota

Justice Koji Miyakawa

Justice	Ryuko Sakurai
Justice	Seishi Kanetsuki
Justice	Yu Shiraki