

Pacif Capsule Case
(Conditions of patent term extension)
Supreme Court
Case H21 (Gyohi) No. 326 (April 28, 2011)

FACTS

The patent (Japanese Patent No. 3134187, hereinafter referred to as the “Patent”) involved in the present case is an invention relating to a release control composition that comprises a drug-containing core including a water-insoluble substance, a certain hydrophilic substance, and a certain cross-linked acrylic polymer, and coated with a coating agent.

The Appellee, X (the patentee of the Patent), obtained approval (the “Approval” or “Later Approval”) pursuant to Article 14(1) of the Japanese Pharmaceutical Affairs Law for manufacture and sale of a medical product (the “Medical Product” or “Later Medical Product”) on September 30, 2005.

Prior to the Approval, the third party had gotten approval (“Prior Approval”) pursuant to Article 14(1) of the Pharmaceutical Affairs Law for manufacture and sale for a medical product (the “Prior Medical Product”) which contains the same active ingredient and has the same effects and efficacy as the Medical Product. The Prior Medical Product does not fall within the technical scope of the invention of any of the claims in the Patent.

X filed on December 16, 2005 an application for patent term extension for the Patent on the grounds that there was a period during which the invention of the Patent could not be practiced due to the necessity of receiving the Approval. However, the application was rejected, and X filed an appeal against the decision of rejection.

On October 21, 2008, the JPO issued a decision (the “JPO Decision”) dismissing this appeal on the grounds that the Prior Approval had been issued for the Prior Medical Product containing the same active ingredient and having the same effects and efficacy as the Medical Product before the issue of the Approval, and hence there was no necessity of receiving the Approval upon practicing the invention of the Patent.

X was not satisfied with the JPO Decision and appealed to the IP High Court for cancellation of the JPO Decision. The IP High Court held for X on the grounds that the JPO Decision is erroneous in terms of: (1) the applicability of Article 67-3(1)(i) of the Japanese Patent Law; and (2) the effect and scope of the extended patent right according to the Prior Approval.

The present case is an appeal to the Supreme Court by the JPO against the decision of the IP High Court.

ISSUE

Is the existence of the Prior Approval considered to be sufficient grounds for denying the necessity of receiving Later Approval upon practicing the invention (Article 67-3(1)(i))?

HOLDING

The patent term extension system is intended to restore to the patentee the period during which a patented invention could not be practiced due to the necessity of receiving approval as provided in Article 67(2) of the Patent Law. The Prior Approval has been issued for the Prior Medical Product containing the same active ingredient and having the same effects and efficacy as the Later Medical Product. However, the Prior Medical Product does not fall within the technical scope of the invention of any of the claims in the patent for which the application for patent term extension is filed. Therefore, it is not considered that the invention on which the Later Medical Product is based and the invention of any of the claims in the patent for which the application for patent term extension is filed could be practiced.

Furthermore, when the Prior Medical Product does not fall within the technical scope of the invention of any of the claims in the patent for which the application for patent term extension is filed, the above conclusion cannot be controlled by interpretation of the effect and scope of the patent right (Article 68-2 of the Patent Law) in the case where the patent term could be extended according to the Prior Approval.

Since the Prior Medical Product does not fall within the technical scope of the invention of any of the claims in the Patent, the existence of the Prior Approval is not considered to be sufficient grounds for denying the necessity of receiving the Approval upon practicing the invention of the Patent.

In view of the above, the Supreme Court affirms the decision of the IP High Court that the JPO Decision is erroneous, on the grounds that the existence of the Prior Approval is not a sufficient reason to deny the necessity of receiving the approval for manufacture and sale pursuant to Article 14(1) of the Pharmaceutical Affairs Law upon practicing the invention of the Patent.

Citations:

Article 67-3(1)(i) of the Japanese Patent Law

Where an application for the registration of extension of the duration of a patent right falls pursuant to any of the following items, the examiner shall render the examiner's decision to the effect that the application is to be refused:

(i) where the disposition designated by Cabinet Order pursuant to Article 67(2) is not deemed to have been necessary to obtain for the practicing of the patented invention;

Article 68-2 of the Japanese Patent Law

Where the duration of a patent right is extended (including the case where the duration is deemed to have been extended pursuant to Article 67-2(5)), such patent right shall not be effective against any act other than the working of the patented invention for the product which was the of the disposition designated by Cabinet Order pursuant to Article 67(2) which constituted the reason for the registration of extension (where the specific usage of the product is prescribed by the disposition, the product used for that usage).