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Date of the judgement

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2011.04.28

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Case Number

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2009(Gyo-Hi)326

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Reporter

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Minshu Vol. 65, No. 3

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Title

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Judgment concerning the case where it is impermissible to refuse an application for registration of extension of the duration of a patent right on the grounds that, prior to the approval for manufacturing and sale under Article 14, paragraph (1) of the Pharmaceutical Affairs Act, which gave rise to the necessity to file the application, another approval for manufacturing and sale under said paragraph had been issued with regard to a pharmaceutical product which has the same active ingredient as well as effect and efficacy as those of the pharmaceutical product covered by the approval pertaining to said application

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Case name

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Case to seek revocation of the trial decision by the Japan Patent Office

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Result

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Judgment of the First Petty Bench, dismissed

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Court of the Second Instance

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Intellectual Property High Court, Judgment of May 29, 2009

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Summary of the judgement

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Even in the case where, prior to the approval for manufacturing and sale under Article 14, paragraph (1) of the Pharmaceutical Affairs Act because of which an application for registration of extension of the duration of a patent right has been filed, another approval for manufacturing and sale under said paragraph had been issued with regard to a pharmaceutical product which has the same active ingredient as well as effect and efficacy as those of the pharmaceutical product covered by the approval pertaining to said application, if the pharmaceutical product covered by the earlier approval is not included in the technical scope of the patented invention specified by any of the claims for the patent right pertaining to the application for registration of extension, it is unreasonable to deny that it was necessary to obtain the approval, which gave rise to the necessity to file said application for registration of extension, for the working of the patented invention based on said patent right, on the grounds of the existence of the earlier approval.

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#### References

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Article 67, paragraph (2), Article 67-3, paragraph (1), item (i), and Article 68-2 of the Patent Act, Article 14, paragraph (1) of the Pharmaceutical Affairs Act

Article 67, paragraph (2) of the Patent Act

Where there is a period during which the patented invention is unable to be worked because approvals prescribed by relevant Acts that are intended to ensure the safety, etc. or any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc., of such a disposition is necessary to obtain for the working of the patented invention, the duration of the patent right may be extended, upon the filing of a request for the registration of extension of the duration, by a period not exceeding 5 years.

Article 67-3, paragraph (1), item (i) of the Patent Act

Where an application for the registration of extension of the duration of a patent right falls under 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 under Article 67(2) is not deemed to have been necessary to obtain for the working of the patented invention;

Article 68-2 of the Patent Act

Where the duration of a patent right is extended (including the case where the duration is deemed to have been extended under 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 subject of the disposition designated by Cabinet Order under 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).

Article 14, paragraph (1) of the Pharmaceutical Affairs Act

A person who intends to manufacture and sell a pharmaceutical product (excluding the pharmaceutical products designated by the Minister of Health, Labour and Welfare by specifying standards, and the pharmaceutical products for in vitro test designated pursuant to the provisions of Article 23-2, paragraph (1)), a quasi-pharmaceutical product (excluding the quasi-pharmaceutical products designated by the Minister of Health, Labour and Welfare by specifying standards), a cosmetic product containing the ingredients designated by the Minister of Health, Labour and Welfare, or a medical device (excluding general medical devices and the controlled medical devices designated pursuant to the provisions of said paragraph) shall obtain approval from the Minister of Health, Labour and Welfare for manufacturing and sale for each product item.

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Main text of the judgement

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The final appeal is dismissed.

The appellant of final appeal shall bear the cost of the final appeal.

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Reasons

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Concerning the reasons for acceptance of final appeal argued by the agents appointed for final appeal, SUDO Noriaki, et al.

1. In this case, the appellee of final appeal, who holds a patent right for Patent No. 3134187 (this patent and patent right shall hereinafter be referred to as the "Patent" and "Patent Right," respectively), seeks revocation of the trial decision issued by the Japan Patent Office (JPO) dismissing the appellee's request for a trial against the examiner's decision to refuse the appellee's application for registration of extension of the duration of the Patent Right.

2. The outline of the facts legally determined by the court of prior instance is as follows.

(1) The Patent (containing 22 claims) was based on the patent application filed on March 6,

1997, for the invention entitled "controlled release composition," and was registered on December 1, 2000.

The invention claimed in the Patent relates to a controlled release composition wherein the core containing medicinal substances is coated by a coating agent that contains a water-insoluble substance, a certain hydrophilic substance, and a certain cross-linked acrylic polymer.

(2) On September 30, 2005, the appellee obtained approval for manufacturing and sale under Article 14, paragraph (1) of the Pharmaceutical Affairs Act (hereinafter referred to as the "Disposition") with regard to the pharmaceutical product called "Pacif Capsules 30mg" (hereinafter referred to as the "Pharmaceutical Product"). The Pharmaceutical Product contains morphine hydrochloride as its active ingredient, and has the effect and efficacy of a painkiller for various types of cancers that cause a medium to high level of pain.

(3) Prior to the Disposition, another approval for manufacturing and sale under Article 14, paragraph (1) of the Pharmaceutical Affairs Act had been issued to another pharmaceutical product called "OPSO (oral solution) 5mg/10mg" which has the same active ingredient as well as effect and efficacy as those of the Pharmaceutical Product (this approval and pharmaceutical product shall hereinafter be referred to as the "Earlier Disposition" and "Earlier Pharmaceutical Product," respectively). The Earlier Pharmaceutical Product is not included in the technical scope of the patented invention specified by any of the claims for the Patent Right.

(4) On December 16, 2005, the appellee filed an application for registration of extension of the duration of the Patent Right, on the grounds that the appellee had been unable to work the patented invention based on the Patent Right during a certain period of time due to the necessity to obtain the Disposition, but the JPO examiner issued a decision to refuse this application. Dissatisfied with this decision, the appellee filed a request for a trial against the examiner's decision of refusal.

(5) On October 21, 2008, the JPO issued a trial decision dismissing the appellee's request for a trial, holding that since the Earlier Disposition had been issued, prior to the Disposition, with regard to the Earlier Pharmaceutical Disposition which has the same active ingredient as well as effect and efficacy as those of the Pharmaceutical Product, it is not found that it was necessary to obtain the Disposition for the working of the patented invention based on the Patent Right (this trial decision by the JPO shall hereinafter be referred to as the "JPO Decision").

3. Even in the case where, prior to the approval for manufacturing and sale under Article 14, paragraph (1) of the Pharmaceutical Affairs Act, which gave rise to the necessity to file an application for registration of extension of the duration of a patent right (this approval shall hereinafter be referred to as the "later disposition"), another approval for manufacturing and sale under said paragraph (hereinafter referred to as the "earlier disposition") had been issued with

regard to the pharmaceutical product which has the same active ingredient as well as effect and efficacy as those of the pharmaceutical product covered by the later disposition (the pharmaceutical product covered by the earlier disposition and that covered by the later disposition shall hereinafter be referred to as the "earlier pharmaceutical product" and "later pharmaceutical product," respectively), if the earlier pharmaceutical product is not included in the technical scope of the patented invention specified by any of the claims for the patent right pertaining to the application for registration of extension, it is unreasonable to deny that it was necessary to obtain the later disposition for the working of the patented invention based on said patent right, on the grounds of the existence of the earlier disposition. The purpose of the system of extension of the duration of a patent right is to reclaim the period of time during which the patentee has been unable to work the patented invention due to the necessity to obtain the disposition designated by Cabinet Order as set forth in Article 67, paragraph (2) of the Patent Act. Just because the earlier disposition had been issued with regard to the earlier pharmaceutical product which has the same active ingredient as well as effect and efficacy as those of the later pharmaceutical product, inasmuch as the earlier pharmaceutical product is not included in the technical scope of the patented invention specified by any of the claims for the patent right pertaining to the application for registration of extension, the existence of the earlier disposition does not mean that the patentee must have been able to work the patented invention based on the patent right pertaining to the application for registration of extension where the later pharmaceutical product constitutes the working of said patented invention, nor does it mean that the patentee must have been able to work the patented invention specified by any of the claims for said patent right. If the earlier pharmaceutical product is not included in the technical scope of the patented invention specified by any of the claims for the patent right pertaining to the application for registration of extension, this conclusion is not affected irrespective of how the scope of the effect of the patent right (Article 68-2 of the Patent Act) is defined in the case where the duration could have been extended because of the existence of the earlier disposition.

Since the Earlier Pharmaceutical Product is not included in the technical scope of the patented invention specified by any of the claims for the Patent Right, it is unreasonable to deny, in this case, that it was necessary to obtain the Disposition for the working of the patented invention, on the grounds of the existence of the Earlier Disposition.

4. For the reasons stated above, the ruling by the court of prior instance can be affirmed as justifiable in that the court found the JPO Decision to be illegal, holding that the existence of the Earlier Disposition cannot be the grounds for denying that it was necessary to obtain approval for manufacturing and sale under Article 14, paragraph (1) of the Pharmaceutical Affairs Act for

the working of the patented invention based on the Patent Right. We cannot accept the arguments for the final appeal.

Therefore, the judgment has been rendered in the form of the main text by the unanimous consent of the Justices.

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Presiding judge

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Justice YOKOTA Tomoyuki

Justice MIYAKAWA Koji

Justice SAKURAI Ryuko

Justice KANETSUKI Seishi

Justice SHIRAKI Yu

(This translation is provisional and subject to revision.)