Date	May 29, 2009	Court	Intellectual Property High Court, Third Division
Case number	2008 (Gyo-Ke) 10458		

A case in which the court ruled that:
– In order for an examiner (trial examiner) to refuse an application for registration of the extension of the duration of a patent right pursuant to Article 67-3, paragraph (1), item (i) of the Patent Act, he/she must prove that (i) the lifting of the prohibition cannot be asserted by reason of having obtained a "disposition designated by Cabinet Order," or (ii) the act for which the prohibition has been lifted by reason of having obtained the "disposition designated by Cabinet Order" is not included in the scope of the act that constitutes the 'working of the patented invention.'
– By referring to Article 68-2 of the Patent Act with regard to the scope of the patent right whose duration is extended, where approval under the Pharmaceutical Affairs Act is required as a "disposition designated by Cabinet Order," the "product" which is the subject of a "disposition designated by Cabinet Order" refers to the "product" as identified by the "ingredients," "dose," and "structure" of the pharmaceutical product that is given such approval.

References:
Article 67-3, paragraph (1), item (i), and Article 68-2 of the Patent Act

Background:
The plaintiff, who holds a patent right for the invention (the "Invention") entitled "Medicine," Patent No. 3677156 (the "Patent"), filed an application for registration of extension of the duration of the patent right (the "Application") on December 16, 2005, by reason of having obtained approval for the pharmaceutical product prescribed in Article 14, paragraph (1) of the Pharmaceutical Affairs Act as set forth in said paragraph on September 30, 2005 (the "Disposition"), but received a decision from the Japan Patent Office (JPO) examiner to refuse that application, dated August 9, 2006. The plaintiff then made a request for a trial against this decision of refusal on September 20, 2006 (Trial against Refusal No. 2006-20940), which was dismissed by the JPO trial examiner on October 21, 2008. The plaintiff filed this suit to seek rescission of the JPO decision of dismissal.

Summary of the JPO decision:
In the trial decision, the JPO ruled that the plaintiff's application should be refused under Article 67-3, paragraph (1), item (i) of the Patent Act, on the following grounds: The pharmaceutical product that is the subject of the Disposition, Pacif Capsules 30mg,

(hereinafter referred to as 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." On the other hand, another pharmaceutical product which contains "morphine hydrochloride" for functioning as a "painkiller for various types of cancers that cause a medium to high level of pain," called "OPSO (oral solution) 5mg/10mg" (hereinafter referred to as the "Earlier Pharmaceutical Product") had been given approval (hereinafter referred to as the "Earlier Disposition") on March 14, 2003, before the Disposition was given, was listed in the National Health Insurance (NHI) Price Standards on June 13, 2003, and was put on sale on June 26, 2003. In view of these facts, a pharmaceutical product which contains "morphine hydrochloride" as its "active ingredient (product)" and has the same effect and efficacy as that of the Pharmaceutical Product had already been given approval prior to the Disposition, and even when the need to obtain a new disposition arose due to the necessity to change the product's features other than the active ingredient or the effect and efficacy, such as the shape of the product, it is not found that it was necessary to obtain a disposition designated by Cabinet Order under Article 67, paragraph (2) of the Patent Act (hereinafter referred to as a "disposition designated by Cabinet Order") for the working of the Invention.

Summary of the court decision:
The court rescinded the JPO decision, holding as follows.
"1. Error in the finding of the applicability of Article 67-3, paragraph (1), item (i) of the Patent Act to this case
(1) Purpose, etc. of Article 67-3, paragraph (1), item (i) of the Patent Act
A. Requirement prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act
The main clause of Article 67-3, paragraph (1) of the Patent Act provides that '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,' followed by item (i) which states, 'where the disposition designated by Cabinet Order under Article 67, paragraph (2) is not deemed to have been necessary to obtain for the working of the patented invention.'
In accordance with these provisions, the requirement (ultimate fact) for making a decision of refusal as prescribed in item (i) of said Article in response to an application for registration of extension of the duration of a patent right is that a 'disposition

designated by Cabinet Order under Article 67, paragraph (2) [note by the court: approval of a pharmaceutical product under Article 14, paragraph (1) of the Pharmaceutical Affairs Act] is not deemed to have been necessary to obtain for the working of the patented invention,' for which the defendant, who is to make such a decision of refusal, should bear the burden of allegation and proof entirely…

B. Purpose of the system of registration of extension of the duration of a patent right

The system of registration of extension of the duration of a patent right has been established under the following circumstances. Where it is necessary to obtain a 'disposition designated by Cabinet Order' under Article 67, paragraph (2) of the Patent Act for the 'working of the patented invention,' the patentee, without such disposition, is unable to work the patented invention even though he/she holds the patent right, which would lead to the situation where the duration of the patent is in effect eroded… Such consequence would be disadvantageous to the patentee in that he/she would not be able to recoup the costs incurred for the efforts in research and development, while also reducing the incentive for those engaged in research and development in general toward carrying out their activities. In order to eliminate such problem on the part of the patentee and increase the incentive toward research and development activities, a new system was established to grant an extension for the duration of a patent right for a period, up to five years, during which the patentee has been unable to work the patented invention."

"Assuming so, …in order for an examiner (trial examiner) to refuse the application for registration of the extension, he/she must prove that (i) the lifting of the prohibition cannot be asserted by reason of having obtained a 'disposition designated by Cabinet Order,' or (ii) the act for which the prohibition has been lifted by reason of having obtained the 'disposition designated by Cabinet Order' is not included in the scope of the act that constitutes the 'working of the patented invention.'"

(2) Applicability to this case

"In this case,…the court finds that the plaintiff has already alleged that (i) the plaintiff obtained the Disposition for the Pharmaceutical Product on September 30, 2005, by which the prohibition on the manufacturing, etc. of the Pharmaceutical Product has been lifted, and (ii) the act for which the prohibition has been lifted by reason of the Disposition involves the act that constitutes the working of the patented invention. In that case, if these allegations already made by the plaintiff are affirmable, it would lead to the conclusion that the requirement for refusing the application for registration of the extension prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act, 'where the disposition designated by Cabinet Order… is not deemed to have been

necessary to obtain for the working of the patented invention,' is not met.
Meanwhile, the Earlier Disposition had been given for the Earlier Pharmaceutical Product on March 14, 2003, before the Disposition was given.
However, there is no dispute between the parties as to the facts that the Earlier Pharmaceutical Product that is the subject of the Earlier Disposition is not included in the technical scope of the Invention and that the person who had obtained the Earlier Disposition is neither the patentee who holds the Patent (the plaintiff) nor an exclusive licensee or registered non-exclusive licensee. In addition, the act of manufacturing, etc. of the Earlier Pharmaceutical Product, for which the prohibition has been lifted by reason of the Earlier Disposition, is not included in the scope of the act of working the Invention. That is to say, although the Earlier Disposition does exist in this case, it is not that the act for which the prohibition has been lifted by reason of having obtained the Earlier Disposition falls within the technical scope of the Invention and therefore falls within the scope of the act of working the Invention.
In consequence, the existence of the Earlier Disposition has no influence on the plaintiff, who holds the patent right for the Invention, in the course of eliminating the state under law where he/she has been unable to work the Invention unless he/she obtains approval under the Pharmaceutical Affairs Act for the pharmaceutical product that is included in the technical scope of the Invention."
(3) Section summary
According to what is examined above, irrespective of whether or not the JPO's holdings in its decision are appropriate as to the scope of the effect of the registration of the extension pertaining to the Earlier Disposition, which is discussed in the next section, the JPO decision made an error as it refused the plaintiff's application pursuant to Article 67-3, paragraph (1), item (i) of the Patent Act, while denying, on the grounds of the existence of the Earlier Disposition, that it was necessary to obtain a disposition designated by Cabinet Order for the working of the Invention, and such error apparently affects the conclusion of the JPO decision.
"2. Error as to the scope of the effect of the registration of extension pertaining to the Earlier Disposition
(1) Purpose of Article 68-2 of the Patent Act
Article 68-2 of the Patent Act provides as follows: 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, paragraph (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, paragraph (2)

which constituted the reason for the registration of extension (where the specific use of the product is prescribed by the disposition, the product used for that use).

This clause stipulates that where the duration of a patent right is extended, that patent right is not effective within the entire scope of the patented invention, but it is effective only in relation to 'the product which was the subject of the disposition designated by Cabinet Order (where the specific use of the product is prescribed by the disposition, the product used for that use).' This is because, where the technical scope of the patented invention that is defined by the statements in the patent claims is broader than the scope for which the prohibition has been lifted by reason of obtaining a 'disposition designated by Cabinet Order,' if the patent right whose duration is extended is treated as being effective beyond the scope where the patentee has been unable to work the patented invention due to the necessity to obtain a 'disposition designated by Cabinet Order' (the scope of the 'product' or 'product and use'), it would go against equity between the patentee and a third party…

(2) 'Product' that is the subject of a 'disposition designated by Cabinet Order' in the case where approval under the Pharmaceutical Affairs Act is required as such disposition

Article 14, paragraph (1) of the Pharmaceutical Affairs Act provides that, 'A person who intends to conduct manufacturing and sale of a pharmaceutical product (…) shall obtain approval from the Minister of Health, Labour and Welfare for manufacturing and sale of each item.' Said Act specifies the matters to be examined as required for granting approval under said paragraph as 'matters concerning the name, ingredients, quantity, structure, usage, dose, method of use, efficacy, effects, performance, side effects and other qualities, effectiveness, and safety' (see Article 14, paragraph (2), item (iii) of said Act; the main clause of Article 14, paragraph (2) of the Pharmaceutical Affairs Act prior to the revision by Act No. 135 of 2004 specified the matters to be examined as the 'name, ingredients, quantity, structure, usage, dose, method of use, efficacy, effects, performance, side effects, etc.'). Article 14, paragraph (9) of the Pharmaceutical Affairs Act further provides that, 'When a person who has obtained approval under paragraph (1) intends to change any of the matters approved for the relevant item (excluding cases where such change is a minor change specified by Ordinance of the Ministry of Health, Labour and Welfare), he/she shall obtain approval from the Minister of Health, Labour and Welfare for such change. In this case, the provisions of paragraph (2) through the preceding paragraph shall apply mutatis mutandis' (the same provisions existed in Article 14, paragraph (7) of the Pharmaceutical Affairs Act prior to the revision by Act No. 135 of 2004). In light of

these provisions, the term 'item' as used in the Pharmaceutical Affairs Act formally refers to each product as identified by the aforementioned features, and approval is to be granted for each such product.

Next, the court examines in details, by referring to Article 68-2 of the Patent Act, the features that define the scope of the patent right whose duration is extended, from a substantial perspective.

Among the features that constitute an item, the 'name' does not affect the objective identity of an item as a pharmaceutical product. As for the 'side effects and other qualities,' 'effectiveness,' and 'safety,' it is not necessary to consider these matters as independent features for identification because, by nature, these features would be identical if items are objectively identical as pharmaceutical products…As for other features, namely, 'usage,' 'dose,' 'method of use,' 'efficacy,' 'effects,' and 'performance,' they do not objectively define the constitution of a 'product' itself, although they may be regarded as its 'use' in the meaning of an 'invention of use.'

Consequently, where approval under the Pharmaceutical Affairs Act is required as a 'disposition designated by Cabinet Order,' the 'product' which is the subject of a 'disposition designated by Cabinet Order' refers to the 'product' as identified by the 'ingredients,' 'dose,' and 'structure' of the pharmaceutical product that is given such approval.

According to the reasoning shown above, where a patented invention relates to a pharmaceutical product, it is appropriate to construe that the patent right whose duration is extended is effective, among the conditions for working the patented invention which are included in its technical scope, only against the working of the patented invention relating to the 'product' as identified by the 'ingredients,' 'dose,' and ' structure' of the pharmaceutical product that is approved under the Pharmaceutical Affairs Act, and against the working of the patented invention relating to the 'product' as identified by the 'use' of such pharmaceutical product (needless to say, in light of the ordinary understanding of the technical scope, any products that are equivalent or regarded as substantially identical to such 'product' are also included).

(3) Court's determination on the defendant's assertions

…

(4) Section summary

For the reasons stated above, there is an error in the JPO decision which determined that the 'product' which is the subject of a 'disposition designated by Cabinet Order,' as set forth in Article 68-2 of the Patent Act, is the 'active ingredient."

* The summary of the judgment of this court on 2008 (Gyo-Ke) 10459 and 10460 is the same as the summary of the judgment of this case as shown above.