Japan Supreme Court clarifies requirement of Art. 67-3(1)(i) concerning Patent Term Extension

On November 17, 2015, the Japan Supreme Court rejected the appeal by the Japan Patent Office (JPO), and affirmed the Japan IP High Court judgment *(the JPO vs. Genentech, Inc. : Supreme Court, No. 2014(gyo hi)356)*.

Concerning the requirements for Patent Term Extension (PTE) under Art. 67-3(1)(i) of the Patent Law, the Court rejected the current Examination Guidelines. The Court stated that the requirement of Art. 67-3(1)(i) is determined by "whether it is recognized that the second authorization is covered by the first authorization in terms of examination items directly influencing the substantial identity of the medicine".

1. Background

The cases concern four appeals of the JPO Appellate Board's decisions to reject Genentech's four applications for PTE. The applications for PTE are based on two patents (JP 3398382, JP 3957765) and the second marketing authorization for bevacizumab (Avastin®), an antibody used as an anti-cancer drug. The issue is whether PTE should be approved when an additional marketing authorization concerns only an addition to "Dosage and Administration", while "Indication and Usage" remains unchanged.

	Indication and Usage	Dosage and Administration
1st MA (April 2007)	unresectable, advanced or recurrent colon or rectum cancer	5 mg/kg or 10 mg/kg of bevacizumab to an adult *i.v.* every 2 weeks or more in association with another antineoplastic agent
2nd MA (September 2009)	unresectable, advanced or recurrent colon or rectum cancer	5 mg/kg or 10 mg/kg of bevacizumab to an adult *i.v.* every 2 weeks or more in association with another antineoplastic agent 7.5 mg/kg of bevacizumab to an adult i.v. every 3 weeks or more in association with another antineoplastic agent (Underlined portion was newly authorized and added)

Genentech applied for PTE. After the examiner's rejection, the JPO Appellate Board rejected the application under the current Examination Guidelines again, and Genentech appealed. The IP High Court set aside the decision, and the JPO appealed to the Supreme Court.

2. Grand Panel judgement of IP High Court

Summary of the Grand Panel judgment of the IP High Court *(Genentech, Inc. vs. the JPO: IP High Court, Nos. 2013(gyo ke)10195 to 10198, May 30, 2014)* is shown below, which was also reported in our Japan IP Updates No. 7.

(1) Art. 67-3(1)(i) of the Patent Law

Art. 67-3(1)(i) provides a key requirement for PTE, and recites that an application for PTE shall be rejected when "obtaining an authorization designated by the Cabinet Order under Article 67(2) was necessary in order to work the patented invention".

The IP High Court first construed Art 67-3(1)(i) as including two requirements:

<First requirement>

Prohibition against working the patented invention has not been lifted by the authorization designated by the Cabinet Order; and

<Second requirement>

"The action whose prohibition was lifted by the authorization" is not covered by "the action corresponding to working the patented invention".

Authorization is made under Art. 14(1) or (9) of the Pharmaceutical Affairs Law by examination concerning “name, ingredients, quantity, structure, dosage, administration, operation method, indication, usage, quality including side effects, efficacy and safety” of each medical product. Regarding the first requirement, in cases of medical inventions, the IP High Court determined in consideration of the object of the PTE system, that the scope of "working the patented invention" whose prohibition is lifted, is the action of preparing and selling the medical product specified by “ingredients, quantity, dosage, administration, indication, and usage”.

Regarding the present cases, prohibition for the second authorized product defined by the added Dosage and Administration was not lifted by the first authorization in 2007. Therefore, Art. 67-3(1)(i) does not apply to the present application for PTE, and the rejection by the JPO Appellate Board should be set aside.

(2) Art. 68-2 of the Patent Law

The IP High Court further extended the judgments to comment on the construction of Art. 68-2, which defines the scope of the extended patent’s right by the authorized product and the authorized use. The IP High Court determined that “product” in Art. 68-2 is specified by “ingredients (not limited to active ingredients)”, and that “use” in Art. 68-2 is specified by “Dosage and Administration” and “Indication and Usage”.

3. Supreme Court judgement

At first, the Supreme Court construed the wording of Art. 67-3(1)(i): "obtaining an authorization designated by the Cabinet Order under Article 67(2) was necessary in order to work the patented invention". Then, the Court mentioned that when the second authorization is covered by the first authorization in terms of examination items directly influencing the substantial identity of the medicine, then the second authorization was not necessary. Comparison of the first and second authorizations is sufficient for the requirement, and matters of the patent claim should not be decided. Thus, the current Examination Guidelines are denied. The Court also mentioned that all elements of the authorization including unrelated elements are not necessary.

Regarding the present cases, the second authorization is not covered by the first authorization. Combination therapy of XELOX and bevacizumab could not be marketed by the first authorization, but it can be marketed by the second authorization. Therefore, the Court rejected the appeal by the Japan Patent Office.

< The reporter's Comments>

(1) The Examination Guidelines

Under these circumstances, the JPO must revise the Examination Guidelines again shortly. On the other hand, they may think about revision of the Patent Law, because when the PTE Working Group under the Industrial Structure Council determined the current Examination Guidelines in December 2011, they commented that they will re-examine revision of the Patent Law, etc. after ascertaining the existence of problems, if it is required after the issuance of the current Examination Guidelines.

On the following day November 18, 2015, the JPO announced that they would revise the Examination Guidelines by spring in 2016, and examination of all PTE applications would be suspended until the revision.

(2) The scope of the extended patent's right

The Supreme Court avoided mentioning Art. 68-2, though the IP High Court commented on it. We think this was because Art. 68-2 has ambiguity, and a decision concerning Art. 68-2 was not necessary.

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