# *Japan IP High Court rejects the current Examination Guidelines concerning Patent Term Extension, and indicates its new Guidance*

On May 30, 2014, the Grand Panel of the Japan IP High Court handed down four judgments[1] *(Genentech, Inc. vs. the JPO: IP High Court, Nos. 2013(gyo ke)10195 to 10198)*, as reported in our Japan IP Updates No. 2. The Grand Panel gave new guidance regarding the requirements for Patent Term Extension (PTE) under Art. 67-3(1)(i) of the Patent Law, and rejected the current Examination Guidelines concerning PTE.

## 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<br>7.5 mg/kg of bevacizumab to an adult i.v. every 3 weeks or more in association with another antineoplastic agent<br>(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 practise of the current Examination Guidelines[2] again, and Genentech appealed.

## 2. 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 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 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.

## 3. Rejection of the current Examination Guidelines

The Court stated that the current Examination Guidelines were prepared on their own terms apart from the wording of Art. 67-3(1)(i) and beyond what the Supreme Court decided. Therefore, the Guidelines cannot be accepted.

## 4. Art. 68-2 of the Patent Law

The 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 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".

## *< The reporter's Comments>*

(1) The Examination Guidelines

The JPO may appeal these judgments to the Supreme Court. If these Grand Panel judgments are finalized, then the JPO must revise the Examination Guidelines or the Patent Law, because the Guidelines were rejected.

The current Guidelines were prepared in the PTE Working Group under the Industrial Structure Council in 2011 after the Supreme Court judgment of No. 2009(gyo hi)326 on April 28, 2011. When the PTE Working Group determined the 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 Guidelines.

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

We believe that the comments concerning Art. 68-2 in the judgments may trigger confusion in the pharmaceutical industry. According to the judgments, the scope of the extended patent covers only the originator's medical product restricted by all ingredients. Generic drugs usually contain other excipients, and thus the drugs do not infringe the extended patent under literal infringement.

We will continuously report further developments concerning PTE in Japan, because we believe that change of the PTE practise has a great impact on the pharmaceutical industry.

1) http://www.ip.courts.go.jp/eng/hanrei/g_panel/index.html
2) http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/6.pdf

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