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Contents

DO WE HAVE MORE OPPORTUNITIES TO EXTEND PATENT TERM BASED ON SAME PATENT IN JAPAN?
-Supreme Court decision Case No. Hei 26 (Gyo hi) No. 356 on November 17, 2015

The Supreme Court has denied the 2011 revised guideline for patent term extension.

[Introduction]

The purpose of the patent term extension (hereinafter referred to as "PTE") system in Japan is to recover the period during which a patented invention has been unable to be worked for the necessity of obtaining a marketing approval from the Japanese authority. Thus, the Japanese Patent Law Article 67[ter] (1)(i) stipulates that "where the obtaining of the disposition[1] designated by Cabinet Order under Article 67(2) was unnecessary for the working of the patented invention", an application for registering a patent term extension of the patent shall be rejected.

In the 2011 revised examination guideline for PTE in view of the Japanese Supreme Court decisions dated April 28, 2011 (Case No. Hei 21 (Gyo hi) Nos. 324 to 326), "the working of the patented invention" set forth in Patent Law Article 67 [ter] (1)(i) is construed as acts of selling, manufacturing or the like of a drug product defined by all the matters specified by the details in the written approval corresponding to the elements recited in the patented invention[2]. The JPO examiners have examined PTE applications under this revised guideline since December, 2011.

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[1] An approval of a drug, from which designated extracorporeal diagnostic medicines are excluded, under the Pharmaceutical Affair Law and a registration of agrochemicals, from which fertilizers are excluded, under the Agricultural Chemicals Control Act are designated at present. Regarding regenerative medicines, please refer to Asamura NEWS Vol.09.

[2] Example under the2011 revised examination guideline
[The patented invention] <Claim 1> An analgesic injectable formulation comprising active ingredient A
[the present approval]
Active ingredient : Compound a1 within the scope of active ingredient A
Indication : Analgesia
Dosage form : Injection
Dosage amount : 10mg
[all the matters specified by the details in the written approval corresponding to the elements recited in the patented invention]
Compound a1, analgesia, injection

[Summary of facts]

After the revised guideline was issued, a JPO Appeal Board examined an application for registering a patent term extension of Patent No.3398382 owned by Genentech. The PTE application is based on an marketing approval for Avastin®, which contains bevacizumab, an anti VEGF antibody, as an active ingredient. Prior to the present approval, Genentech obtained another approval for Avastin®. The indication of the 2nd approved drug is the same as that of the 1st approved one, but they are **different from each other in dosage and administration.** The claims of the patent at issue did not recite or define a dosage regime. The 1st approval, the 2nd approval and claim 1 of the patent are outlined below

	Active ingredient	**Indication**	**Dosage and administration**
1st approval	bevacizumab	unresectable, advanced or recurrent colon or rectum cancer	5 or 10 mg/kg of bevacizumab IV on an adult every 2 weeks or more in the combination therapy with other antitumor agent(s)
2nd approval	bevacizumab	unresectable, advanced or recurrent colon or rectum cancer	7.5 mg/kg of bevacizumab IV on an adult every 3 weeks or more in the combination therapy with other antitumor agent(s)
Claim 1 of JP 3398382	hVEGF antagonist which is anti-VEGF antibody	Cancer	(Not defined in claims)

[Summary of Appeal Board Decision and IPHC Grand Panel Decision]

In March, 2014, the JPO Appeal Board rendered a decision of rejection of the PTE application. In the decision, the Appeal Board strictly followed the 2011 revised JPO examination guideline and ruled that the dosage and administration in the written approval should not be taken into account in the examination of the PTE application because these matters are not recited in the claims of the patent. The Appeal Board then held that a drug product defined by all the matters specified by the details in the written approval corresponding to the elements recited in the patented invention, i.e. active ingredient and indication, had been already allowed to be sold or manufactured by the first marketing approval[3], and concluded that the 2nd approval was unnecessary for the working of the patented invention.

Genentech filed a lawsuit to the Intellectual Property High Court (hereinafter referred to as "IPHC") claiming revocation of the Appeal Board decision, and the IPHC Grand Panel rescinded the decision based on the following judgments[4].

i) The IPHC Grand Panel first ruled that to reject a PTE application under Article 67 ter (1)(i), an examiner or Appeal Board is required to prove that (1) a present disposition such as obtaining a marketing approval

[3] For more detailed information, Please refer to Asamura NEWS Vol.09
[4] For more detailed information, please refer to Asamura NEWS Vol.10

for a drug did not remove the prohibition of working of the patented invention (hereinafter referred to as an act at issue); or that (2) the act of which prohibition is removed by the present disposition does not fall under the working of the patented invention. Typically the requirement (1) is understood to be satisfied when a previous disposition has already removed the prohibition of the act at issue. Here the term "the working" includes manufacturing and other acts in the case of a product invention.

ii) "The working of the patented invention", as stipulated in Japanese Patent Law Article 67 ter (1)(i), of which prohibition was removed by an approval under Pharmaceutical Affair Law Articles 14(1) and (9) is interpreted as acts of selling or manufacturing or the other acts of a drug specified by ingredients, quantity, dosage, administration, usage, indications, and efficacy.

iii) As regards the present case, the present approval is for a partial change of the previous approval, and the change is to "intravenously administer 7.5 mg/kg of bevacizumab IV to an adult every 3 weeks or more in the combination therapy with other antitumor agent(s)".The prohibition of acts of using the drug specified by the dosage and administration and the sale and manufacture of the drug for use in these acts had not been removed by the previous approval but for the first time removed by the present approval. Consequently, the above-mentioned requirement (1) is not satisfied. Apparently, the acts of which prohibition is removed by the present approval fall under the working of the patented invention. In fact, both the parties have not disputed this matter. Consequently, the above-mentioned requirement (2) is not satisfied, either. The PTE application shall not be rejected under Patent Law Article 67ter (1)(i), accordingly.

[Overview of Supreme Court Decision]

The JPO held that "the working of the patented invention" set forth in Patent Law Article 67 ^{ter} (1)(i) is construed as acts of selling, manufacturing or the like of a drug product defined by all the matters specified by the details in the written approval corresponding to the elements recited in the claimed invention.

However, in order to reject a PTE application under Article 67 ^{ter} (1)(i), which requires "where the obtaining of the disposition designated by Cabinet Order under Article 67(2) was unnecessary for the working of the patented invention", it must be proved that selling, manufacturing and the like of a drug product allowed by a 1st approval **encompass** those acts of the drug product allowed by a 2nd approval on which the PTE application is based, as a result of comparing both of the approvals. **This judgment must be based only on comparison between the 1st approval and the 2nd approval**, but not be based on all the matters corresponding to the elements recited in the patented invention.

While it is understood that obtaining a marketing approval enables a patentee to manufacture and sell the drug specified by all the approval review matters such as "name, ingredients, quantity, dosage, administration, usage, indications, efficacy, adverse reactions, and other matters related to quality, efficacy and safety" prescribed under Pharmaceuticals and Medical Devices Act, such comparison should be reasonably conducted, in view of types and subject matters of the patented invention at issue, based on **approval review matters directly relating to substantial identity as a drug**, among those approval review matters as described above

With regard to the present case, the patented invention at issue is related to a pharmaceutical composition

for treating cancer, which comprises a therapeutically effective amount of hVEGF antagonist which is anti-VEGF antibody, and hence it is a product invention which is directed to a pharmaceutical active ingredient. Accordingly, the approval review matters directly relating to the substantial identity as the drug are interpreted as "ingredients, quantity, dosage, administration, usage, indications, and efficacy" in the present case. When the 1st approval is compared with the present (2nd) approval on which the PTE application is based, whereas the dosage and administration in the 1st approval is 5 or 10 mg/kg of bevacizumab IV(intravenous drip) on an adult every 2 weeks or more in the combination therapy with other antitumor agent(s), those in the present approval is "7.5 mg/kg of bevacizumab IV(intravenous drip) to an adult every 3 weeks or more in the combination therapy with other antitumor agent(s)". Moreover, the present approval has enabled the combination therapy between XELOX therapy and bevacizumab therapy for the first time.

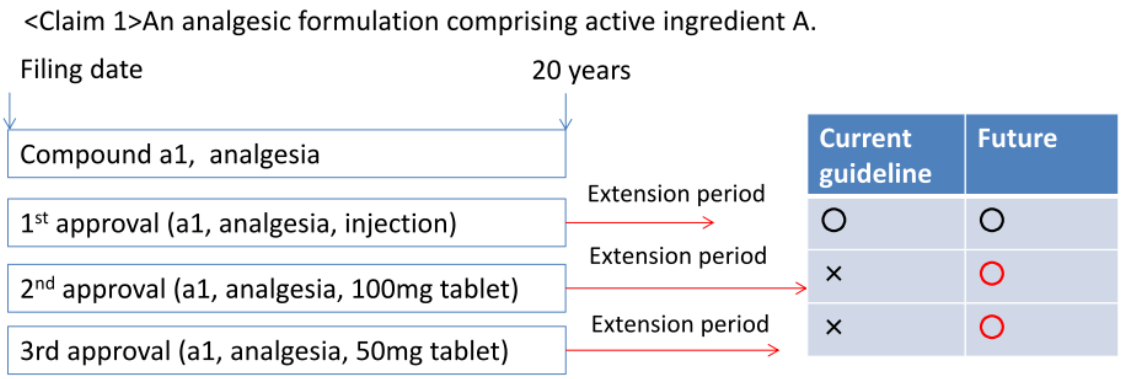
In view of the foregoing, it is not recognized that selling, manufacturing and the like of the drug product allowed by the1st approval encompass those of the drug product allowed by the2nd approval on which the PTE application is based.

As such, the Supreme Court affirmed the preceding IPHC decisions.

[Comments]

The Supreme Court denied the 2011 revised guideline which states that "the working of the patented invention" set forth in Patent Law Article 67 ter (1)(i) is construed as acts of selling, manufacturing or the like of the drug product that defined by the all matters specified by the details in the written approval corresponding to the elements recited in the patented invention. Following this judgment, it was recently announced that the JPO would revise the examination guideline by this spring and stay examination for pending PTE applications which have previous disposition until the new guideline is published.

According to this Supreme Court decision, more opportunities for patent term extensions based on a single patent would be available for patentees. In particular, they will have more opportunities to extend a patent term of a same basic patent directed to an active substance per se, such as a chemical compound, antibodies or the like, and a medical use only specified by an indication. On the other hand, it would be concerned that a scope of the same claim on which multiple extensions are based is fragmented by each of the extensions.



The Supreme Court did not adopt the criteria shown by the IPHC Grand Panel. Instead, it has shown its own criteria that the acts of selling, manufacturing and the like of a drug product allowed by a 1st approval **encompass** those acts of the drug product allowed by a 2nd approval or not.

How should we interpret "the approval review matters directly relating to the substantial identity as the drug in view of types and subject matters of the patented invention? It appears, for example, only change in drug package might not directly relate to the substantial identity as the drug. Accumulation of cases would answer this question.

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