English Translation

Decision of Supreme Court of Japan, 2014(Gyo-Hi)356 (decided on Nov. 17, 2015)

Decided by Supreme Court of Japan, The Third Petty Bench
(Final Appeal against the decision of IP High Court, 2013(Gyo-Ke)10195, decided on May 30, 2014)
Appellant: Commissioner, Japan Patent Office
Respondent: Genentech Incorporated

Principle Text of Judgment:

The appeal is dismissed. The costs of appeal procedure shall be borne by the appellant.

Reasons:

The attorneys of the appellant, Masanori TSUZUKI et. al. show the following reasons for appealing.

1. This is a case of the request by the patentee (the respondent in the final appeal) of Japanese Patent 3,398,382 (hereinafter referred to as "the present patent") to revoke the decision of the Trial Board, JPO that the application for a patent term extension of the present patent shall be rejected.

In this case, there exist an approval (disposition) prior to the present approval (disposition) with respect to a drug or medical device, etc., which is covered by the same patented invention, under a law for controlling the quality, effectiveness and safety of drugs, medical devices, etc. ("The Pharmaceutical Affairs Law", which was revised as "Pharmaceutical and Medical Device Act" (Law No. 84, 2013); hereinafter referred to as "PMD Act") (the approval (disposition) for the drug in the present appeal is hereinafter referred to as "disposition in appeal"), and then, it is disputed whether it was not necessary to obtain the approval for working the invention of the patent subjected to the patent term extension (hereinafter, referred to as "PTE application") in view of the presence of the preceding approval and that the PTE application shall be

rejected under Patent Law, Article 67ter, Item 1, Paragraph 1.

2. The facts confirmed in the original decision are in brief as follows.

(1) The present patent (number of claims: 11), title of the invention: Vascular Endothelial Cell Growth Factor Antagonists, was filed on October 28, 1992 and was granted on February 14, 2003.

The patented invention is concerned with a pharmaceutical composition for treating a cancer which comprises an effective amount of a vascular endothelial cell growth factor antagonist.

(2) The respondent in this final appeal has obtained on September 18, 2009 an approval for manufacturing and selling of a drug (an approval for partial changes) in the tradename "Avastin solution for intravenous infusion 100 mg/4ml", general name: "bevacizumab (genetical recombination)" (hereinafter referred to as "the present drug") under the PMD Act, Article 14, Item 9 (this approval is hereinafter referred to as "the present disposition") (The translator's note: "the present disposition" will means the same disposition as "the disposition in appeal" as defined hereinabove). The present drug comprises as an active ingredient "bevacizumab (genetical recombination)" which corresponds to "anti-VEGF antagonist, hVEGF antagonist" as defined in claim 1 of the present patent and has efficacies/effects of treating "unresectable, advanced and return colorectal cancer" with usage and dosage of "iv infusion in an amount of 7.5 mg/kg(body weight) as bevacizumab per once in adult at an interval of 3 weeks or more in combination of other anti-tumor agent". The manufacturing and selling of the present drug fall within the working of the patented invention of the present patent.

(3) Before the present disposition, an approval of a drug having the same formulation as that of the present drug excepting the usage and dosage are different had been approved under PMD Act, Article 14, Item 9 (hereinafter, it is referred to as "the preceding disposition", and the drug subjected to said preceding disposition is referred to as "the preceding drug"). The preceding drug has the usage and dosage of "iv infusion in an amount of 5 mg/kg(body weight) or 10 mg/kg(body weight) as bevacizumab per once in adult at an interval of 2 weeks or more in combination of other anti-tumor agent". The manufacturing and selling of the preceding drug fall within the working of the patented invention of

the present patent.

(4) The manufacturing and selling of the present drug for the combined therapy of XELOX therapy (administering of the drug by oral administration and intravenous infusion for 2 hours for 3 weeks in one cycle) and bevacizumab therapy has never been permitted according to the preceding disposition (approval), but it has first become workable by the present disposition (approval).

(5) The respondent of the final appeal has filed on December 17, 2009 an application for a patent term extension of the present patent because there was a period of time during which the patented invention could not be worked in view of necessity of obtaining the present disposition, but the application was rejected, and hence, he appealed to the Trial Board, JPO against the decision of rejection.

(6) On March 5, 2013, the Trial Board, JPO has decided to reject the appeal of the applicant, because the working of a patented invention as defined in Patent Law Article 67ter, Item 1, Paragraph 1 means the acts of manufacturing and selling of a drug specified by all matters falling within the matters for specifying the patented invention (i.e. the matters used to specifying the invention by the applicant) among the matters as disclosed in the approval to be subjected to the disposition provided for in Cabinet Order as defined in Patent Law, Article 67, Item 2 (hereinafter, referred to simply as "cabinet order disposition"), and from this viewpoint, it is deemed that the scope of the invention specified by all of the matters to be fallen within the patented invention with respect to the present drug would already been workable by the preceding disposition (approval), and hence, it could not be said that the present disposition (approval) should be obtained for working the patented invention of the present patent. (The above decision of the Trial Board to reject the appeal is hereinafter referred to "the present trial decision")

3. The patent term extension system has been provided for the purpose of recovering a term during which the patented invention could not be worked because of necessity of cabinet order disposition. It is also defined in Patent Law, Article 67ter, Item 1, Paragraph 1 that a PTE application shall be rejected where it is deemed to be unnecessary to obtain a cabinet order disposition for working the panted invention. In

view of the definitions of patent law, where the preceding disposition and the disposition in appeal have been done for manufacturing and selling of a drug, if it is recognized, by comparing the proceeding disposition and the disposition in appeal, that the manufacturing and selling of the drug subjected to the preceding disposition will also include the manufacturing and selling of the drug subjected to the disposition in appeal, it shall be said that the disposition in appeal would not be necessary to obtain for working the patented invention subjected to the PTE application. Thus, for determining whether the disposition in appeal shall be obtained or not for working the patented invention, it shall be compared the preceding disposition and the disposition in appeal, but shall not be determined on the basis of all matters corresponding to the matters specifying the patented invention.

By the way, in an approval for manufacturing and selling of a drug under the provisions of PMD Act, it shall be examined in each drug to be approved with respect to all matters of "name, component, amount, usage, dosage, efficacy, effect, side effect, and other qualities as well as safety" of the drug (cf. PMD Act, Article 14, Item 2, Paragraph 3, head sentence). Besides, from viewpoint of the object of PTE system as mentioned above, it will be not proper to compare both dispositions even for the matters which are not directly relative to the substantial identification as a drug in the light of the kinds and subject matters of the patent to be subjected to the PTE application, because otherwise, it will result in comparing them with respect to even the matters which will hardly be thought to become a bar to work the patented invention in the examination of the acceptability of PTE application. Thus, in order to determine whether the acts of manufacturing and selling of the drug approved by the preceding disposition include or not the acts of manufacturing and selling of the drug approved by the present disposition, it shall be done by comparing both dispositions with respect to the matters which are directly relative to the substantial identification as a drug in the light of the kinds and subject matters of the patented invention of the patent to be subjected to the PTE application, but not by formally comparing them with respect to all of matters to be examined for approval of a drug as mentioned above.

Accordingly, it shall be concluded as follows:

"In case of existing a preceding disposition (i.e. the preceding marketing approval) in addition to the disposition in appeal (i.e. the new marketing approval), the necessity of the marketing approval shall be determined by comparing both of the preceding disposition and the new disposition in appeal with respect to the matters relating directly to the substantial identification of the drugs in the light of the kinds and subject matters of the patent to be subjected to the PTE, and when the acts of manufacturing and selling of the drug approved by the preceding disposition cover the acts of manufacturing and selling of the newly approved drug, it shall be considered that there is no necessity of obtaining the new disposition in appeal in order to work the patented invention subjected to the PTE.

4. The instant case is specifically studied from this viewpoint.

The patented invention of the present patent is concerned with a pharmaceutical composition for treating a cancer which comprises a theraputically effective amount of a vascular endothelial cell growth factor antagonist, i.e. an invention of a medical product. Then, for examination of approval of the medical product in both dispositions, the examination shall be done with respect to the matters relating directly to the substantial identification of the drugs, such as component, amount, usage, dosage, efficacy and effect of the drug. Since the preceding disposition exists, it is compared the present disposition in appeal with said preceding disposition. The drug approved by the preceding disposition has the usage and dosage of "iv infusion in an amount of 5 mg/kg(body weight) or 10 mg/kg(body weight) as bevacizumab per once in adult at an interval of 2 weeks or more in combination of other anti-tumor agent". On the other hand, the present drug has the usage and dosage of "iv infusion in an amount of 7.5 mg/kg(body weight) as bevacizumab per once in adult at an interval of 3 weeks or more in combination of other anti-tumor agent". Then, the manufacturing and selling of the present drug for the combined therapy of XELOX therapy and bevacizumab therapy has never been permitted according to the preceding disposition, but it has first become workable by the present disposition in appeal.

From the above-mentioned situation, it cannot be said that the

acts of manufacturing and selling of the drug approved in the preceding disposition include the acts of manufacturing and selling of the drug approved in the new disposition in appeal.

5. Thus, it is judged to affirm the original decision of IP High Court deciding that the trial decision of the JPO is illegal, since the trial board of JPO wrongly decided that it was not necessary to obtain the approval for manufacturing and selling of the present drug in the disposition in appeal in order to work the patented invention of the patent subjected to the PTE. The argument in the appeal shall not be accepted.

Accordingly, it is judged as mentioned in "Principle Text of Judgment" as above, as a unanimous decision of all of the judges.

(Chief Judge Michiyoshi KIUCHI; Judge Kiyoko OKABE; Judge Takehiko OHTANI; Judge Masaharu ŌHASHI; and Judge Toshimitsu YAMASAKI)