Date	May 30, 2014	Court	Intellectual Property High Court, Special Division
Case number	2013 (Gyo-Ke) 10198		

– A case in which, regarding a JPO decision dismissing a request for a trial against an examiner's decision of refusal of an application for the registration of extension of the duration of a patent right on the grounds that the "working of a patented invention," which was made possible by the disposition in question, had already been made possible by a prior disposition and that the disposition in question is thus not deemed to have been necessary to obtain for the working of the Patented Invention, the court ruled that said application is not regarded as falling under the requirement for refusal provided for in Article 67-3, paragraph (1), item (i) of the Patent Act; based on this ruling, the court dismissed the JPO decision.

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

1. Background

The plaintiff is the patentee of a patent (the "Patent") for an invention titled "anti-VEGF antibody." The plaintiff filed an application for the registration of extension of the duration of a patent right (the "Application") in relation to the Patent to seek the registration of extension of the duration of two years, three months and thirty days, asserting that a disposition designated by Cabinet Order (approval under the Pharmaceutical Affairs Act) was necessary to obtain for the working of the invention pertaining to the Patent. However, having received an examiner's decision of refusal, the plaintiff filed a request for a trial against the examiner's decision of refusal (Trial against Examiner’s Decision of Refusal No. 2011-8108). However, the JPO rendered a decision dismissing the request.

This is an action instituted by the plaintiff to seek rescission of the JPO decision.

With regard to the medicine (the "Medicine") which was the subject of the Disposition, approval of manufacturing and sale of the medicine (the "Prior Disposition") had been given in advance of the Disposition. The details of the subject of the Prior Disposition are as follows: the active ingredient is "bevacizumab (transgenic)"; effectiveness and efficacy are stated as "unresectable advanced or recurrent colorectal cancer"; dosage and administration are stated as "In combination with other anticancer drugs, adults are ordinarily intravenously infused with bevacizumab at a dose of 5 mg/kg (weight) or 10 mg/kg (weight) at administration intervals of at least two weeks." The Disposition is approval of a partial change to the matters included in the approval of manufacturing and sale of the medicine. The content of the major change is the

addition of the following dosage and administration: "In combination with other anticancer drugs, adults are ordinarily intravenously infused with bevacizumab at a dose of 7.5 mg/kg (weight) at administration intervals of at least three weeks."

2. Reason for the JPO decision

The reason for the JPO decision dismissing the request is as follows: in making a determination concerning Article 67-3, paragraph (1), item (i) of the Patent Act, it is appropriate to consider the "working of a patented invention" not as the act of manufacturing, selling, etc. a medicine which was the subject of a disposition but as the act of manufacturing, selling, etc. a medicine that is identified by all matters that fall under the matters to identify the invention of the patented invention ("Matters that Fall under Matters to Identify the Invention") out of the matters stated in the written approval of the medicine which was the subject of the disposition; in the case of a patented invention that does not include matters that identify usages as one of the matters to identify the invention, it is appropriate to consider the "working of the patented invention" as the act of manufacturing, selling, etc. a medicine that is identified by all matters that fall under the matters to identify the invention of the patented invention and matters that fall under usages ("Matters to Identify the Invention and Matters that Fall under Usages") out of the matters stated in the written approval of the medicine which was the subject of the disposition; the scope of the Patented Invention that is identified by the "Matters that Fall under Matters to Identify the Invention" or the "Matters to Identify the Invention and Matter that Fall under Usages" of the medicine which was the subject of the Disposition had become workable by the Prior Disposition; therefore, the Disposition is not deemed to have been necessary to obtain for the working of the Patented Invention; consequently, the Application falls under the cases prescribed in Article 67-3, paragraph (1), item (i) of said Act, and the plaintiff cannot obtain the registration of extension of the duration of the patent right.

3. Summary of this judgment

In this judgment, the court determined as follows, and rescinded the JPO decision.

(1) Regarding an error in the determination concerning whether the Application falls under the cases prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act (Ground for Rescission 1)

A. In considering the propriety of the determination in the JPO decision to the effect that the application for the registration of extension of the duration of the patent right should be refused, the conclusion should be drawn by determining whether the requirement set forth in Article 67-3, paragraph (1), item (i) of the Patent Act, which is a basic provision that provides for the requirement for rendering an examiner's decision of

refusal (JPO decision), is fulfilled (the scope for which a patent right whose duration was extended on the grounds of a prior disposition is effective cannot be necessarily regarded as a matter that always directly relates to the question of whether a disposition designated by Cabinet Order was necessary to obtain for the working of the patented invention).

The following are the prerequisites for saying that there is the fact that " the disposition designated by Cabinet Order was necessary to obtain for the working of the patented invention" as set forth in Article 67-3, paragraph (1), item (i) of said Act: [i] A ban was lifted through obtainment of the "disposition designated by Cabinet Order"; [ii] The relevant act on which the ban was lifted by the "disposition designated by Cabinet Order" is included in the acts that fall under the "working of the patented invention." The fulfillment of /these two prerequisites is considered to be necessary.

The aforementioned provision is set as a requirement for an examiner (trial examiner) to refuse an application for the registration of extension as follows: "where the disposition designated by Cabinet Order … is not deemed to have been necessary to obtain for the working of the patented invention." Therefore, in order to refuse the Application, it is necessary for the examiner (trial examiner) to selectively demonstrate either [i] "that it cannot be said that a ban was lifted through obtainment of the disposition designated by Cabinet Order" (first requirement) or [ii] that "the 'act on which the ban was lifted through obtainment of the disposition designated by Cabinet Order' is not included in the 'acts that fall under the working of the patented invention'" (second requirement).

B. A medicine which is the subject of approval under Article 14, paragraph (1) or (9) of the Pharmaceutical Affairs Act is a medicine that is identified by "name, ingredient, quantity, dosage, administration, effectiveness, efficacy, side effects and other qualities, and matters relating to effectiveness and safety." Therefore, the form of the act on which the ban is lifted by the aforementioned approval is the act of manufacturing, selling, etc. the medicine that is identified by the aforementioned matters which were the subjects of the approval.

It is necessary to substantially determine the fulfillment of the aforementioned first requirement provided for in Article 67-3, paragraph (1), item (i) of the Patent Act in light of the purpose of the Patent Act, which established the system for the registration of extension of the duration, instead of determining it by formally applying each element of "name, ingredient, quantity, dosage, administration, effectiveness, efficacy, side effects and other qualities, and matters relating to effectiveness and safety," which are matters to be examined for a medicine.

With regard to a patent for an ingredient of a medicine (excluding process patents and patents pertaining to product-by-process claims, etc.), it is reasonable to understand that the scope of the "working of a patented invention" on which the ban is lifted through obtainment of approval under Article 14, paragraph (1) or (9) of the Pharmaceutical Affairs Act covers the act of manufacturing, selling, etc. a medicine that is identified by the aforementioned matters to be examined, excluding "name" and "side effects and other qualities" and "matters relating to effectiveness and safety" (ingredient, quantity, dosage, administration, effectiveness and efficacy).

C. The ban on the act of using the Medicine by the use method that is identified by the dosage and administration, "In combination with other anticancer drugs, adults are ordinarily intravenously infused with bevacizumab at a dose of 7.5 mg/kg (weight) at administration intervals of at least three weeks," and the act of manufacturing, selling, etc. the Medicine on the premise of its use by the aforementioned use method was not lifted by the Prior Disposition but was lifted by the Disposition for the first time. Therefore, it is obvious that the Disposition does not fulfill the aforementioned first requirement, "it cannot be said that a ban was lifted through obtainment of the disposition designated by Cabinet Order," out of the aforementioned selective requirements for refusing an application for the registration of extension. It is also obvious that the Disposition does not fulfill the aforementioned second requirement, "The 'act on which the ban was lifted through obtainment of the disposition designated by Cabinet Order' is not included in the 'acts that fall under the working of the patented invention,'" out of the aforementioned selective requirements for refusing an application for the registration of extension.

As mentioned above, in this case, it is impossible to say that "it cannot be said that the ban on the act of working of the Patented Invention was lifted through obtainment of the Disposition." Therefore, it cannot be said that the requirement for refusal provided for in Article 67-3, paragraph (1), item (i) of the Patent Act is fulfilled.

(2) Regarding the scope for which a patent right extended under Article 68-2 of the Patent Act is effective

In this judgment, the court considered, for confirmation, the scope for which a patent right extended under Article 68-2 of the Patent Act is effective, and determined that, in light of the purpose of the system for the registration of extension of the duration of a patent right and that of a patent infringement action, it is reasonable to understand that in the case of a patented invention for an ingredient of a medicine, the patent right whose duration was extended pursuant to Article 68-2 of said Act is effective for the scope of the working of the patented invention that is identified by "the ingredients (not

limited to active ingredient)" as an invention pertaining to a "product" and is identified by "effectiveness and efficacy" and "dosage and administration" as an invention pertaining to "usage."