Judgment rendered on May 30, 2014

2013 (Gyo-Ke) 10197, Case of Seeking Rescission of a JPO Decision

Date of conclusion of oral argument: February 24, 2014

Judgment

Plaintiff: Genentech, Inc.

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Same as above: NAKAHAMA Akiko

Defendant: Commissioner of the Japan Patent Office

Designated representative: IMAMURA Reeko

Same as above: NAITO Shinichi

Same as above: OKUBO Motohiro

Same as above: NAKAJIMA Yoko

Same as above: SERA Satoki

Same as above: HORIUCHI Yoshiko

Main Text

1. The JPO decision rendered regarding Trial against Examiner's Decision of Refusal No. 2011-8107 on March 5, 2013, shall be rescinded.

2. The defendant shall bear the court costs.

Facts and reasons

No. 1 Claims

The same as the main text of this judgment.

No. 2 Assumed facts

1. Progress of procedures at the JPO, etc.

(1) The plaintiff is the patentee of a patent for an invention titled "anti-VEGF antibody" (Patent No. 3957765; number of claims: 32; the application was filed on April 3, 1998; the establishment of the patent right was registered on May 18, 2007; priority claims: April 7, 1997, United States; August 6, 1997, United States (priority country); hereinafter referred to as the "Patent") (Exhibit Ko No. 1).

On December 17, 2009, the plaintiff filed an application for the registration of extension of the duration of a patent right (hereinafter referred to as the "Application") in relation to the Patent (Exhibit Ko No. 2) 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 was necessary

to obtain for the working of the invention pertaining to the Patent. However, having received an examiner's decision of refusal dated January 6, 2011, the plaintiff filed a request for a trial against the examiner's decision of refusal (Trial against Examiner's Decision of Refusal No. 2011-8107) on April 18 of the same year, and made an amendment (Exhibit Ko No. 3) on September 6, 2012. The JPO rendered a decision to the effect that the request is to be dismissed (hereinafter referred to as the "JPO Decision") on March 5, 2013, and a copy of the JPO Decision was delivered to the plaintiff on 15th of the same month.

(2) The content of the disposition (hereinafter referred to as the "Disposition") that constitutes the reason for the registration of extension after the amendment dated September 6, 2012 and the ground for filing the Application are as follows (Exhibits Ko No. 2 and No. 3).

A. Disposition that constitutes the reason for the registration of extension

Approval set forth in Article 14, paragraph (9) of the Pharmaceutical Affairs Act pertaining to a medicine provided for in said paragraph

B. Identification number of the Disposition

Approval No. 21900AMX00910000

C. Subject of the Disposition

Product name: AVASTIN 100 mg/4ml for intravenous infusion

General name: Bevacizumab (transgenic)

(hereinafter the medicine identified by the aforementioned product name or general name is referred to as the "Medicine")

D. Usage identified in relation to the subject of the Disposition

"Intravenous infusion of bevacizumab to adults at a dose of 7.5 mg/kg (weight) in combination with other anticancer drugs for the treatment of unresectable advanced or recurrent colorectal cancer, at administration intervals of at least three weeks"

E. Date of the Disposition

September 18, 2009

F. The fact that the subject of the Disposition designated by Cabinet Order is stated in the scope of claims

The humanized anti-hVEGF antibody stated in Claim 11, etc. is bevacizumab (transgenic), which was the subject of the Disposition (hereinafter omitted).

(3) In relation to the Medicine, the following approval of manufacturing and sale of a medicine (hereinafter referred to as the "Prior Disposition") was given on April 18, 2007. The Disposition is approval of a partial change to the matters included in the approval of manufacturing and sale, which is the Prior Disposition. The major change is the addition of a new dosage and administration to the "Dosage and administration" section (Exhibits Ko No. 13 to No. 16).

A. Grounds for the disposition

Article 14, paragraph (1) of the Pharmaceutical Affairs Act

B. Approval number

21900AMX00910000

C. Effectiveness and efficacy

"Unresectable advanced or recurrent colorectal cancer"

D. Dosage and administration

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.

2. Scope of claims

The scope of claims of the Patent is as follows (hereinafter the inventions claimed in Claims 1 to 32 are referred to as "Patented Invention 1" to "Patented Invention 32" in order and Patented Inventions 1 to 11, 14, 16, 19, 20, 23 and 27 to 32 are collectively referred to as the "Patented Invention") (Exhibit Ko No. 1).

"[Claim 1] A humanized anti-VEGF antibody having a heavy chain variable domain comprising the following hypervariable region amino acid sequences: CDRH1 (GYX_1FTX_2YGMN, wherein X_1 is T or D and X_2 is N or H; SEQ ID NO: 130), CDRH2 (WINTYTGEPTYAADFKR; SEQ ID NO: 2) and CDRH3 ($YPX_1YYGX_2SHWYFDV$, wherein X_1 is Y or H and X_2 is S or T; SEQ ID NO: 131), and a light chain variable domain comprising the following hypervariable region amino acid sequences: CDRL1 (SASQDISNYLN; SEQ ID NO: 4), CDRL2 (FTSSLHS; SEQ ID NO: 5) and CDRL3 (QQYSTVPWT; SEQ ID NO: 6), which combines with human vascular endothelial cell growth factor (VEGF) at a K_d value of no more than about 1×10^{-8}M

[Claim 2] The humanized anti-VEGF antibody stated in Claim 1 which combines with human VEGF at a K_d value of no more than about 5×10^{-9}M

[Claim 3] The humanized anti-VEGF antibody stated in Claim 1 which has an ED_{50} value of no more than about 5nM, which inhibits VEGF-induced proliferation of endothelial cells in vitro

[Claim 4] The humanized anti-VEGF antibody stated in Claim 1 which inhibits VEGF-induced angiogenesis in vivo

[Claim 5] The humanized anti-VEGF antibody of Claim 4 which inhibits at least 50% of tumor growth in an A673 in vivo tumor model, at an antibody dose of 5mg/kg

[Claim 6] The humanized anti-VEGF antibody stated in any of Claims 1 to 5 wherein the aforementioned CDRH1 comprises the amino acid sequence of SEQ ID NO: 1 (GYTFTNYGMN)

[Claim 7] The humanized anti-VEGF antibody stated in any of Claims 1 to 5 wherein the aforementioned CDRH3 comprises the amino acid sequence of SEQ ID NO: 3

(YPHYYGSSHWYFDV)

[Claim 8] The humanized anti-VEGF antibody stated in any of Claims 1 to 7 wherein the aforementioned CDRH1 comprises the amino acid sequence of SEQ ID NO: 1 (GYTFTNYGMN) and the aforementioned CDRH3 comprises the amino acid sequence of SEQ ID NO: 3 (YPHYYGSSHWYFDV)

[Claim 9] The humanized anti-VEGF antibody stated in Claim 8 having a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO: 7

[Claim 10] The humanized anti-VEGF antibody stated in any of Claims 1 to 9 having a light chain variable domain comprising the amino acid sequence of SEQ ID NO: 8

[Claim 11] The humanized anti-VEGF antibody stated in any of Claims 1 to 8 having a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO: 7 and a light chain variable domain comprising the amino acid sequence of SEQ ID NO: 8

[Claim 12] The humanized anti-VEGF antibody stated in any of Claims 1 to 5 wherein CDRH1 comprises the amino acid sequence of SEQ ID NO: 128 (GYDFTHYGMN)

[Claim 13] The humanized anti-VEGF antibody stated in any of Claims 1 to 5 wherein CDRH 3 comprises the amino acid sequence of SEQ ID NO: 129 (YPYYYGTSHWYFDV)

[Claim 14] The humanized anti-VEGF antibody stated in any of Claims 1 to 5 having a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO: 127

[Claim 15] The humanized anti-VEGF antibody stated in any of Claims 1 to 5 having a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO: 118

[Claim 16] The humanized anti-VEGF antibody stated in any of Claims 12 to 15 further having a light chain variable domain comprising the amino acid sequence of SEQ ID NO: 126

[Claim 17] The humanized anti-VEGF antibody stated in any of Claims 12 to 15 further having a light chain variable domain comprising the amino acid sequence of SEQ ID NO: 117

[Claim 18] The humanized anti-VEGF antibody stated in any of Claims 1 to 5 having a light chain variable domain comprising the amino acid sequence of SEQ ID NO: 117 and a heavy chain variable domain comprising the amino acid sequence of SEQ ID NO: 118

[Claim 19] The humanized anti-VEGF antibody stated in any of Claims 1 to 18 which is a full length antibody

[Claim 20] The humanized anti-VEGF antibody of Claim 19 which is a human IgG

[Claim 21] The humanized anti-VEGF antibody stated in any of Claims 1 to 18 which is an antibody fragment

[Claim 22] The antibody fragment of Claim 21 which is a Fab

[Claim 23] A composition comprising the humanized anti-VEGF antibody stated in any of Claims 1 to 22 or a fragment thereof and a pharmaceutically acceptable carrier

[Claim 24] Isolated nucleic acid encoding the antibody of Claim 1

[Claim 25] A vector comprising the nucleic acid of Claim 24

[Claim 26] A host cell comprising the vector of Claim 25

[Claim 27] A process of producing a humanized anti-VEGF antibody comprising culturing the host cell of Claim 26 so that the nucleic acid is expressed

[Claim 28] The process of Claim 27 further comprising recovering the humanized anti-VEGF antibody from the host cell culture

[Claim 29] A pharmaceutical composition comprising the humanized anti-VEGF antibody stated in any of Claims 1 to 22 or a fragment thereof which is to be used for inhibiting VEGF-induced angiogenesis in a mammal, wherein a therapeutically effective amount of the pharmaceutical composition is administered to the mammal and the humanized anti-VEGF antibody combines with human VEGF at a K_d value of no more than about 1×10^{-8}M

[Claim 30] The pharmaceutical composition of Claim 29 wherein the mammal is a human

[Claim 31] The pharmaceutical composition of Claim 29 wherein the mammal has a tumor

[Claim 32] The pharmaceutical composition of Claim 29 wherein the mammal has a retinal disorder

3. Reasons for the JPO Decision

The reasons for the JPO Decision are as stated in a copy of the written JPO Decision attached to this judgment. The gist thereof is as follows.

(1) In making a determination set forth in 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 itself but as the act of manufacturing, selling, etc. a medicine that is identified by all matters that fall under matters to identify the invention of the patented invention (hereinafter referred to as "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.

However, Article 68-2 of said Act provides that where the duration of a patent right is extended, the patent right shall not be effective for any act other than the "working of the patented invention for the product which was the subject of the disposition (where the specific usage of the product is prescribed by the disposition, for the product used for that usage)." The approval of a medicine stipulates matters that fall under such usage. Therefore, in the case of a patented invention for which matters that identify usage are not included in 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 matters to identify the invention of the patented invention and matters that fall under usage (hereinafter referred to as "Matters that Fall Under Matters to Identify the Invention and Usage") out of the matters stated in the written approval of the medicine which was the subject of the disposition.

In addition, it is reasonable to consider matters that fall under usage which are stated in the written approval of a medicine to be the effectiveness and efficacy stated in the written approval, taking into account the necessity of securing the effectiveness of the extended right and the predictability of results by third parties.

If there is a disposition (prior disposition) in relation to a prior medicine that satisfies the "Matters that Fall under Matters to Identify the Invention (and Usage)" of the medicine which was the subject of the disposition, it can be said that the scope identified by the "Matters that Fall under Matters to Identify the Invention (and Usage)" of the medicine which was the subject of the disposition had become workable by the prior disposition. Therefore, there arises a reason for refusal set forth in Article 67-3, paragraph (1), item (i) of said Act.

(2) Regarding Patented Inventions 1 to 11, 14, 16, 19, 20, 23, 27 and 28

Patented Inventions 1 to 11, 14, 16, 19, 20, 23, 27 and 28 are inventions for which matters that identify usage are not included in matters to identify the invention.

A. Regarding Patented Invention 1

The subject of the Disposition is a medicine whose general name is "bevacizumab (transgenic)" and whose effectiveness and efficacy relate to "unresectable advanced or recurrent colorectal cancer." "Bevacizumab (transgenic)" corresponds to the "humanized anti-VEGF antibody having a heavy chain variable domain comprising the following hypervariable region amino acid sequences … and a light chain variable domain comprising the following hypervariable region amino acid sequences …, which combines with human vascular endothelial cell growth factor (VEGF) at a K_d value of no more than about 1×10^{-8}M," which is the matter to identify the invention of Patented Invention 1. In addition, "unresectable advanced or recurrent colorectal cancer," which is effectiveness and efficacy, is a matter that falls under usage.

On the other hand, the subject of the Prior Disposition is a medicine whose general name is "bevacizumab (transgenic)" and whose effectiveness and efficacy relate to "unresectable advanced or recurrent colorectal cancer." It is a medicine that satisfies the "Matters that Fall under Matters to Identify the Invention and Usage" of the medicine which was the subject of the Disposition. In that case, it can be said that the scope of Patented Invention 1 that is identified by the "Matters that Fall under Matters to Identify the Invention and Usage" of the medicine which was the subject of the Disposition had become workable by the Prior Disposition.

B. Regarding Patented Inventions 2 to 11, 14, 16, 19, 20, 23, 27 and 28

Patented Inventions 2 to 11, 14, 16, 19, 20, 23, 27 and 28 all are inventions that further limit Patented Invention 1. The scope of Patented Inventions 2 to 11, 14, 16, 19, 20, 23, 27 and 28 that is identified by the "Matters that Fall under Matters to Identify the Invention and Usage" of the medicine which was the subject of the Disposition is included in or corresponds to the scope

of Patented Invention 1 that is identified by the "Matters that Fall under Matters to Identify the Invention and Usage" of the medicine which was the subject of the Disposition. Therefore, it can be said that said scope had become workable by the Prior Disposition.

(3) Regarding Patented Inventions 29 to 32

Patented Invention 29 is an invention of a medicine whose active ingredient is the "humanized anti-VEGF antibody stated in any of Claims 1 to 22" and whose usage is "to be used for inhibiting VEGF-induced angiogenesis in a mammal." Patented Inventions 30 to 32 are inventions of a medicine that are stated by citing Patented Invention 29.

A. Regarding Patented Invention 29

"Bevacizumab (transgenic)" that is the medicine which was the subject of the Disposition is a matter that corresponds to the "humanized anti-VEGF antibody stated in any of Claims 1 to 22," which is the active ingredient of Patented Invention 29, and "unresectable advanced or recurrent colorectal cancer" that is the effectiveness and efficacy of the medicine which was the subject of the Disposition is a matter that corresponds to "VEGF-induced angiogenesis in a mammal," which is the subject of inhibition in the usage of Patented Invention 29.

On the other hand, the subject of the Prior Disposition is a medicine whose general name is "bevacizumab (transgenic)" and whose effectiveness and efficacy relate to "unresectable advanced or recurrent colorectal cancer," and it is a medicine which satisfies the "Matters that Fall under Matters to Identify the Invention" of the medicine which was the subject of the Disposition. In that case, it can be said that the scope of Patented Invention 29 that is identified by the "Matters that Fall under Matters to Identify the Invention" of the medicine which was the subject of the Disposition had become workable by the Prior Disposition.

B. Regarding Patented Inventions 30 to 32

Patented Inventions 30 to 32 all are inventions that further limit Patented Invention 29. The scope of Patented Inventions 30 to 32 that is identified by the "Matters that Fall under Matters to Identify the Invention" of the medicine which was the subject of the Disposition is included in or corresponds to the scope of Patented Invention 29 that is identified by the "Matters that Fall under Matters to Identify the Invention" of the medicine which was the subject of the Disposition. Therefore, it can be said that said scope had become workable by the Prior Disposition.

(4) As mentioned above, the Disposition is not deemed to have been necessary to obtain for the working of Patented Inventions 1 to 32, and the Application falls under the cases prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act. Therefore, the plaintiff cannot obtain the registration of extension of the duration of the patent right (products pertaining to Patented Inventions 12, 13, 15, 17, 18, 21, 22 and 24 to 26 are not included in the medicine which was the subject of the Disposition; therefore, it cannot be said that the Disposition was necessary to

obtain for the working of these patented inventions).

No. 3 Allegations of the parties concerning grounds for rescission

1. Plaintiff's allegations

(1) 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. Content of the Disposition, etc.

(A) Characteristics of treatment by using anticancer drugs

The active ingredient of the Medicine is a humanized anti-VEGF antibody that is called "bevacizumab," and it falls under the technical scope of Patented Invention 1. In addition, the Medicine falls under the technical scope of the Patented Invention 29.

A drug that clarifies the mechanism of carcinogenesis at the molecular level and targets a specific molecule, such as the medicine of Patented Invention 29, is called molecularly-targeted drug or molecularly-targeted therapeutic drug. For the treatment of cancer, multiple anticancer drugs are often used in combination, and the standard administration regimen has been established according to the anticancer drugs used. Many molecularly-targeted drugs are administered in addition to the established administration regimen. In doing so, it becomes necessary to set the dosage and administration of molecularly-targeted drugs according to each existing treatment method. Therefore, a clinical test is required with respect to each existing treatment method.

For anticancer drugs, the levels of therapeutic dosages and that of dosages that develop side effects are close to each other. For example, the levels of dosages that develop severe side effects exist close to the level of dosages that produce excellent effects. Therefore, their dosages and administration are strictly evaluated as elements having a very important meaning.

(B) Content of the Prior Disposition and that of the Disposition

The dosage and administration subject to the Prior Disposition are as follows: "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." On the other hand, the following dosage and administration were added in the Disposition: "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." The medicine subject to the Prior Disposition and that subject to the Disposition have a commonality in the active ingredient and effectiveness and efficacy.

The Prior Disposition is intended for the combined use of bevacizumab and FOLFOX or FOLFIRI treatment (both of them require a 44 to 46-hour infusion) which has a treatment cycle of two weeks. The dosage in the Prior Disposition, 5 mg/kg (weight), is applied to the cases where cancer has been untreated while the dosage therein, 10 mg/kg (weight) is applied to the

cases where cancer has already been treated. The statement in relation to the administration interval, "at least," is intended to prepare for the cases where it is necessary to wait until a patient recovers from side effects. The Prior Disposition made it possible to give combination treatment of FOLFOX treatment and bevacizumab treatment and combination treatment of FOLFIRI treatment and bevacizumab treatment.

On the other hand, the Disposition is intended for the use of bevacizumab in combination with XELOX treatment which has a treatment cycle of three weeks. For XELOX treatment, the administration interval is long, and 2-hour infusion and administration of an oral medicine alone are required. Therefore, the burden on patients and medical staff members is significantly reduced. The Disposition has its meaning in making it possible to give combination treatment of XELOX treatment and bevacizumab treatment for the first time.

(C) Scope of the ban lifted

As mentioned above, the levels of therapeutic dosages of anticancer drugs and that of dosages that develop side effects are close to each other. Therefore, dosage and administration are far more important for anticancer drugs than for drugs in other areas, and it is thus necessary to strictly set their dosages and administrations. The ban on the administration of bevacizumab at a dosage of 5 mg/kg (weight) or 10 mg/kg (weight) alone was lifted by the Prior Disposition, while the ban on the administration of bevacizumab at a dosage of 7.5 mg/kg (weight) was lifted for the first time by the Disposition. Incidentally, it is not that the dosages covered by the Disposition: dosages of 5 mg/kg (weight) or 10 mg/kg (weight), can be selected voluntarily but are to be determined depending on whether the patient has been treated.

In addition, the administration interval covered by the Prior Disposition is " two weeks or more," while that covered by the Disposition is " three weeks or more." A standard treatment cycle of FOLFOX and FOLFIRI treatments is two weeks, while that of XELOX treatment is three weeks. It can be regarded as a common understanding among persons ordinarily skilled in the art that the administration interval for combination treatment of FOLFOX treatment or FOLFIRI treatment and bevacizumab treatment is in principle two weeks, while that for combination treatment of XELOX treatment and bevacizumab treatment is in principle three weeks unless there are special circumstances, such as side effects.

As mentioned above, FOLFOX and FOLFIRI treatments had the problem of imposing heavy burden on patients in relation to infusions as well as hospitalization and hospital visit(s) therefor because they require long hours of infusion, specifically, infusion for 44 or 46 hours, every two weeks. On the other hand, XELOX treatment requires only 2-hour infusion every three weeks. Other than such infusion, administration of an oral medicine (capecitabine) alone is required. The Disposition made it possible to conduct combined use of XELOX treatment and bevacizumab treatment, and as a result, the burden on patients was significantly reduced, and

the burden on medical staff members was also reduced.

B. Regarding non-fulfillment of the requirement set forth in Article 67-3, paragraph (1), item (i) of the Patent Act

(A) Article 67-3, paragraph (1), item (i) of the Patent Act requires the following for refusing an application for the registration of extension: the application falls under the cases "where the disposition designated by Cabinet Order … is not deemed to have been necessary to obtain for the working of the patented invention."

The Prior Disposition lifted the ban only on the administration of the Medicine according to the dosage and administration approved by the Prior Disposition. On the other hand, the Disposition is the approval set forth in Article 14, paragraph (9) of the Pharmaceutical Affairs Act, and the ban on the working of the Patented Invention according to the dosage and administration added by the Disposition (for example, sale of the Medicine for combination treatment of XELOX treatment and bevacizumab treatment) was lifted for the first time by the Disposition. Therefore, the "disposition designated by Cabinet Order was necessary to obtain" for the working of the Patented Invention. Consequently, the Application does not fall under the cases prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act.

The purpose of the extension registration system is to restore the eroded duration of a patent right in the cases where the patented invention is unable to be worked due to legal regulations even after the obtainment of the patent right. It conforms with the purpose of the extension registration system to restore the duration for which working of part of a patented invention has been banned due to legal regulations. In addition, the scope for which the ban was first lifted through the Disposition falls under the technical scope of the Patented Invention. Consequently, the Application does not fall under the requirement for refusal under said item, "where the disposition designated by Cabinet Order … is not deemed to have been necessary to obtain for the working of the patented invention."

(B) With regard to the "working of the patented invention" set forth in Article 67-3, paragraph (1), item (i) of the Patent Act, the JPO makes the following interpretations: [i] The working of the patented invention in the scope identified by extracting only matters (Matters that Fall under Matters to Identify the Invention) that fall under the matters to identify the invention (constituent features of the patented invention) in the scope of claims out of the matters stated in the written approval of the medicine is the "working of the patented invention"; [ii] However, in the case of a patented invention for which matters that identify usage are not included in matters to identify the invention, the working of the patented invention in the scope identified by all matters that fall under matters to identify the invention of the patented invention and matters that fall under usage (Matters that Fall Under Matters to Identify the Invention and Usage) out of the matters stated in the written approval of the medicine is the "working of the patented

invention."

However, as mentioned below, this interpretation in the JPO Decision has no grounds in the Patent Act and deviates from the text of law. Therefore, it is erroneous.

a. The Pharmaceutical Affairs Act and the Patent Act differs in the purpose, and the matters to be examined prescribed in the Pharmaceutical Affairs Act and the matters to identify an invention under the Patent Act differ from each other. There is no rationality in applying the matters stated in the written approval of a medicine to the matters to identify the invention of a patented invention in a uniform manner despite existence of these differences.

b. According to the interpretation in the JPO Decision, the content of the "working of the patented invention" set forth in Article 67-3, paragraph (1), item (i) of the Patent Act depends on the way that the matters to identify the invention are stated in the scope of claims. For example, if no limitation on dosage and administration is stated in the scope of claims, it means that "voluntary dosages and administrations" are included, and it should be considered that any dosage and administration are included as a technical idea. On the other hand, the JPO identifies the "patented invention" set forth in Article 67-3, paragraph (1), item (i) of the Patent Act based only on the items for which limitations are explicitly stated in the scope of claims, out of all the items subject to examination and approval under the Pharmaceutical Affairs Act. However, there is no reasonable ground for distinguishing between the items for which limitations are explicitly stated in the scope of claims and those for which they are not.

It was from November 1, 2009 onward that the JPO started, in its practice, to treat dosage and administration as having a meaning in the identification of a patented invention. It was not permitted to identify an invention by dosage and administration as of the time when the Patent was registered. Moreover, at the examination stage for the Patent, it was impossible to predict that the interpretation such as the one in the JPO Decision would be adopted in relation to reasons for refusal of an application for the registration of extension of the duration of a patent right. It was also impossible to state matters to identify the invention concerning dosage and administration in the scope of claims.

c. The JPO made the interpretation that, even for a patented invention for which matters that identify "usage" are not included in matters to identify the invention, matters that fall under usage are used to identify the "working of the patented invention" set forth in Article 67-3, paragraph (1), item (i) of the Patent Act. However, there is no ground for adopting an exceptional treatment only in relation to "usage." The JPO cites Article 68-2 of said Act as a reason for the exceptional treatment for "usage." However, said provision relates to the effect of a patent right in cases where the duration of the patent right is extended, and does not stipulate a reason for refusal of an application for the registration of extension. Article 68-2 of said Act has no relation to the interpretation of the reason for refusal provided for in Article 67-3, paragraph

(1), item (i) of said Act.

C. Regarding the registration of extension in the cases where a clinical test is required for obtaining approval

Even if the registration of extension is not permitted for each approval granted under the Pharmaceutical Affairs Act, the registration of extension should be permitted in the cases where a clinical test is required for obtaining approval.

A clinical test requires long periods of time, and consequently, it takes a long time to obtain approval under the Pharmaceutical Affairs Act. As materials concerning the results of a clinical test are required in filing the application for approval set forth in Article 14, paragraph (1) or (9) of said Act, it should be considered that the registration of extension is permitted if there is a period during which the patented invention was unable to be worked.

In the current practice, a clinical test is also required for obtaining the approval set forth in paragraph (9) of said Article in relation to a medicine of a new dosage, and the Disposition also falls under the "approval set forth in Article 14, paragraph (1) or (9) of said Act that requires materials concerning the results of a clinical test in filing an application therefor." Therefore, a clinical test was necessary for obtaining the Disposition. Taking the aforementioned actual conditions into account, the Application does not fall under the cases prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act, and the registration of extension should be permitted.

(2) Error in the interpretation of the scope for which the registration of extension pertaining to a prior disposition is effective as prescribed in Article 68-2 of the Patent Act (Ground for Rescission 2)

As mentioned above, the propriety of an examiner's decision of refusal of an application for the registration of extension of the duration of a patent right should be determined solely based on whether the application falls under the cases prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act, i.e., "where the disposition designated by Cabinet Order as set forth in Article 67, paragraph (2) of said Act is not deemed to have been necessary to obtain for the working of the patented invention.

Even if there is room to take into account the provisions of Article 68-2 of said Act in determining the propriety of an examiner's decision of refusal set forth in Article 67-3, paragraph (1), item (i) of said Act, "dosage and administration," which are the matters to be examined under the Pharmaceutical Affairs Act, should be considered as being included in the "usage" of "(where the specific usage of the product is prescribed by the disposition, the product used for that usage)" as prescribed in Article 68-2 of the Patent Act, as mentioned below.

That is, said Article provides that where the duration of a patent right is extended, the patent right shall not be effective for any act other than the working of the patented invention for the product which was the subject of the disposition designated by Cabinet Order (where the

specific usage of the product is prescribed by the disposition, the product used for that usage).

The JPO makes the interpretation that "effectiveness and efficacy" alone in the matters to be examined under the Pharmaceutical Affairs Act correspond to "usage," and, based on this interpretation, identifies the "usage" of the invention of medicine as a disease (cancer) which is the subject of treatment.

However, there is no ground for the interpretation that "effectiveness and efficacy," which are the matters to be examined under the Pharmaceutical Affairs Act, alone are "usage."

"Usage" means "a way of use, how to use and place of use." Therefore, it should be considered as not being limited to "effectiveness and efficacy" but also as including "dosage and administration."

Under the Pharmaceutical Affairs Act, "dosage and administration" are emphasized to the same degree as "effectiveness and efficacy." For example, dosage and administration fall under the items that should be taken into account in determining whether a medicine falls under a new medicine in the same way as active ingredients and effectiveness and efficacy. Moreover, out of the items to be examined for approval of manufacturing and sale of a medicine under the Pharmaceutical Affairs Act, examination items concerning methods of use are "effectiveness and efficacy" and "dosage and administration." There is no reason that "usage" is limited to "effectiveness and efficacy."

There is no reasonable ground for extracting "effectiveness and efficacy" alone and taking no account of "dosage and administration" despite the fact that "dosage and administration" have great significance in this manner. Dosage and administration have become increasingly important in the JPO's practice due to the progress of research and development in the medical field. Therefore, the conventional Examination Guidelines were revised. In examinations on and after November 1, 2009, the JPO has adopted the practice wherein an invention of a medicine that specifies dosage and administration is examined as an invention of a product and is patented in the same way as an invention of a medicine that specifies a disease which is the subject of treatment.

As mentioned above, even if there is room to take into account the provisions of Article 68-2 of the Patent Act in determining whether there is a reason for refusal set forth in Article 67-3, paragraph (1), item (i) of said Act, the term, "usage," in parentheses in said Article should be considered as not being limited to "effectiveness and efficacy" under the Pharmaceutical Affairs Act but as including "dosage and administration." Therefore, the JPO Decision contains an error in its determination.

(3) Summary

As mentioned above, the JPO Decision contains an error in its determination to the effect that the Disposition is not deemed to have been necessary to obtain for the working of the

Patented Invention, and that the plaintiff cannot obtain the registration of extension of the duration of the patent right as the Application falls under the cases prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act because the Patented Invention includes no matter to identify the invention that corresponds to "dosage and administration."
Moreover, the JPO Decision also contains an error in its interpretation of the scope for which the registration of extension pertaining to a prior disposition is effective as prescribed in Article 68-2 of said Act.

2. Defendant's counterarguments

(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. Regarding the content of the Disposition, etc.

(A) The plaintiff alleges that the working of Patented Inventions 1 and 29 in the combination treatment of XELOX treatment and bevacizumab treatment became possible for the first time by the Disposition.

However, as mentioned below, the plaintiff's allegation is unreasonable.

Patented Invention 1 is an invention of a substance whose technical idea is the finding of a new and useful humanized anti-VEGF antibody. Patented Invention 29 is a use invention whose technical idea is the finding of a new usage wherein the aforementioned humanized anti-VEGF antibody is applicable to the inhibition of VEGF-induced angiogenesis in a mammal. Even if the manufacturing and sale of a medicine that is used according to the dosage and administration that were added by the Disposition became possible for the first time by the Disposition and combination treatment with XELOX treatment thereby became possible, it is not sufficient to say that the working of Patented Inventions 1 and 29 based on the aforementioned technical ideas became possible for the first time by the Disposition.

Acts on which the ban is lifted by a disposition under the Pharmaceutical Affairs Act are decided with respect to each disposition under the Pharmaceutical Affairs Act. On the other hand, the unit of a patented invention is a technical idea expressed by the matters to identify the invention. Therefore, even if a ban was lifted on any act by the Disposition, it is impossible to say that Patented Inventions 1 and 29 became workable for the first time by reducing Patented Inventions 1 and 29 to a specific medicine which was the subject of the Disposition independently of their technical ideas.

The plaintiff confuses the working of Patented Inventions 1 and 29 with the act of manufacturing, selling, etc. a medicine that is used according to the dosage and administration added by the Disposition, which is independent of the technical ideas of Patented Inventions 1 and 29. Therefore, the plaintiff's allegation is unreasonable.

It is reasonable to understand that the "working of the patented invention" in Article 67-3, paragraph (1), item (i) of the Patent Act is 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 for which matters that identify "usage" are not included in matters to identify the invention, it is reasonable 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 usage (Matters that Fall under Matters to Identify the Invention and Usage) out of the matters stated in the written approval of the medicine which was the subject of the disposition. It is also reasonable to consider matters that fall under usage as the "effectiveness and efficacy" stated in the written approval of the medicine.

In this case, the working of Patented Invention 29 in the form of a pharmaceutical composition containing "bevacizumab (transgenic)" (this corresponds to the "humanized anti-VEGF antibody stated in any of Claims 1 to 22" which is one of the matters to identify the invention) that is to be used for inhibiting "unresectable advanced or recurrent colorectal cancer" (this corresponds to "VEGF-induced angiogenesis in a mammal" which is one of the matters to identify the invention), and the working of Patented Invention 1 in the form of "bevacizumab (transgenic: this corresponds to the entirety of the matters to identify the invention in Claim 1)" which is used in relation to "unresectable advanced or recurrent colorectal cancer" (a matter that falls under usage) had become possible by the Prior Disposition.

(B) With regard to the "working of the patented invention" set forth in Article 67-3, paragraph (1), item (i) of the Patent Act, the JPO made the following interpretations: [i] The working of the patented invention in the scope identified by extraction of only matters that fall under the matters to identify the invention out of the matters stated in the written approval of the medicine is the "working of the patented invention"; [ii] However, in the case of a patented invention for which matters that identify usage are not included in matters to identify the invention, the working of the patented invention in the scope identified by all matters that fall under the matters to identify the invention of the patented invention and matters that fall under usage (Matters that Fall Under Matters to Identify the Invention and Usage) out of the matters stated in the written approval of the medicine is the "working of the patented invention." These interpretations in the JPO Decision are reasonable as mentioned below.

a. In the case of a patented invention for which matters that identify usage are included in matters to identify the invention (in the case of [i] above)

(a) An approved medicine is a product that is identified by many matters stated in a written approval. On the other hand, a patented invention is a creation of a technical idea expressed by matters to identify the invention, and is not a specific product itself. In that case, the following interpretation in the JPO Decision is reasonable in light of the provisions of Article 70, paragraph (1), Article 36, paragraph (5) and Article 2, paragraph (1) of the Patent Act: The "working of the patented invention" in Article 67-3, paragraph (1), item (i) of said Act is 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 the patented invention) out of the matters stated in the written approval of the medicine which was the subject of the disposition.

The system of extension of the duration of a patent right is consistently a system that is provided for in the Patent Act. In addition, not only the Pharmaceutical Affairs Act but also the Agricultural Chemicals Control Act (other laws may be added in the future) relate to the disposition designated by Cabinet Order. Therefore, it is sufficiently reasonable to interpret the "working of the patented invention" not based on the Pharmaceutical Affairs Act but based on the definition of the technical scope of a patented invention (Article 70, paragraph (1)), the provisions on the matters required to be stated in the scope of claims (Article 36, paragraph (5)) and the definition of an invention (Article 2, paragraph (1)) in the Patent Act. It is reasonable to understand the "working of the patented invention" by having the matters stated in the written approval of a medicine correspond to the matters to identify the invention of the patented invention in a specific case.

(b) The fact that the scope of claims includes no matters to identify the invention concerning dosage and administration means that dosage and administration are matters that have no relation to the technical idea of the Patented Invention. Consequently, it is reasonable to interpret the working of the Patented Invention without taking into account dosage and administration.

Patented Invention 29 is an invention that is recognized as having novelty and inventive step based on a technical idea: the finding of a new usage wherein the humanized anti-VEGF antibody of Claim 1 is applicable to the inhibition of VEGF-induced angiogenesis in a mammal. At the examination stage, it was not necessary to state dosage and administration in the scope of claims in order to have the examiner recognize the novelty of the invention. Moreover, it was originally impossible to state the dosage and administration that would enable combination treatment with XELOX treatment, which is not stated in the description, in the scope of claims. Therefore, the plaintiff did not miss the opportunity for the registration of extension of the duration due to a change in the JPO's examination practice.

b. In the case of a patented invention for which matters that identify usage are not included in

matters to identify the invention (in the case of [ii] above)

Article 68-2 of the Patent Act provides that where the duration of a patent right is extended, if the specific usage of the product is prescribed by the disposition, the patent right shall not be effective for any act other than the working of the patented invention for the product used for that usage. The approval of manufacturing of a medicine falls under the "cases where the specific usage of the product is prescribed," and the extended patent right is effective only on the "medicine used for the approved usage." With regard to an invention of a substance, it is reasonable to interpret, in consideration of the scope for which a patent right is effective in the case the duration thereof is extended, that the "working of the patented invention" set forth in Article 67-3, paragraph (1), item (i) of said Act is the working of the patented invention in the scope identified by all matters that fall under the matters to identify the invention of the patented invention and matters that fall under usage (Matters that Fall Under Matters to Identify the Invention and Usage) out of the matters stated in the written approval of the medicine which was the subject of the disposition.

B. Regarding the registration of extension in the cases where a clinical test is required for obtaining approval

The plaintiff alleges that the registration of extension should be permitted if there was a period during which a patented invention is unable to be worked due to the necessity of obtaining materials concerning the results of a clinical test in filing an application for approval set forth in Article 14, paragraph (1) or (9) of the Pharmaceutical Affairs Act because a clinical test requires long periods of time and it consequently takes a long time before obtaining approval under the Pharmaceutical Affairs Act.

However, it is impossible to make an interpretation that the registration of extension is permitted as long as a relevant disposition is one that "requires considerable time for the proper execution of the disposition in light of the purpose, procedures, etc. of such a disposition" as provided for in Article 67, paragraph (2) of the Patent Act. Therefore, the plaintiff's allegation is unreasonable.

(2) Regarding an error in the interpretation of the scope for which the registration of extension pertaining to the prior disposition is effective as prescribed in Article 68-2 of the Patent Act (Ground for Rescission 2)

A. As mentioned above, in determining whether a disposition was necessary to obtain for the working of a patented invention in relation to a patent for a substance by interpreting Article 68-2 of the Patent Act and Article 67-3, paragraph (1), item (i) of said Act in a consistent manner, it is reasonable to interpret, in consideration of the scope for which a patent right is effective in the case where the duration thereof is extended, that the working of the patented invention in the scope identified by all matters that fall under the matters to identify the

invention of the patented invention and matters that fall under usage (Matters that Fall Under Matters to Identify the Invention and Usage) out of the matters stated in the written approval of the medicine is the "working of the patented invention" set forth in said item.

It is reasonable to consider that where the registration of extension is permitted for a patent for a medicinal usage, the extended patent right is effective on the act of working the patented invention in that form. In the case of a patent for a substance, it is necessary to interpret "usage" in Article 68-2 of said Act as "effectiveness and efficacy" in order to prevent the effect of the extended patent right from becoming narrower than that in the case of a patent for a medicinal usage.

In such case, if matters that fall under "usage" are considered as "effectiveness and efficacy" and "dosage and administration," a patent right pertaining to a patent for a substance whose duration was extended based on a relevant disposition is effective only in a narrow scope that is limited within the scope of the approved specific "effectiveness and efficacy" and "dosage and administration." Consequently, the patentee who has obtained the patent for a substance is unable to secure the effectiveness of the right. Moreover, even if the period of extension of the duration is limited up to five years, extension of the duration of a patent right may go against a third party's expectation concerning the time of expiration of the patent right and harm the interest of the third party in some cases.

According to the above, regarding a patent for a substance, it is reasonable to consider matters that fall under "usage" as the "effectiveness and efficacy" stated in the written approval of the medicine, on the basis of the understanding that the "working of the patented invention" set forth in Article 67-3, paragraph (1), item (i) of said Act is 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 usage (Matters that Fall Under Matters to Identify the Invention and Usage) out of the matters stated in the written approval of the medicine which was the subject of the disposition. Therefore, the interpretation in the JPO Decision is reasonable.

B. Even if dosage and administration are treated as concepts that are as important as effectiveness and efficacy under the Pharmaceutical Affairs Act, they do not affect the interpretation of the working of a patented invention in which dosage and administration constitute no technical idea, in light of the fact that the Patent Act and the Pharmaceutical Affairs Act differ in purpose.

An invention of a medicine (an invention of a product) that specifies dosage and administration has come to be recognized as having novelty in examinations on and after November 1, 2009. In such a case, the specification of the dosage and administration constitutes a difference from publicly known medicines. However, this has nothing to do with whether the

patent right pertaining to the Patented Invention, whose technical idea is the finding of a new usage wherein a humanized anti-VEGF antibody is applicable to the treatment of cancer, satisfies the requirement for the registration of extension of the duration.

No. 4 Court decision

This court determines that the JPO Decision contains the following errors.

The JPO determined as outlined below: [i] The medicine which is the subject of approval and the Patented Invention differ from each other because the former is identified by the matters stated in the written approval while the latter is a creation of a technical idea expressed by the "matters to identify the invention"; [ii] Therefore, in determining whether the Application falls under the cases prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act, the "working of the patented invention" should not be considered as the act of manufacturing, selling, etc. the medicine which was the subject of the Disposition itself but as the act of manufacturing, selling, etc. the 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; [iii] However, Article 68-2 of said Act provides that where the duration of a patent right is extended, the patent right shall not be effective for any act other than the "working of the patented invention for the product which was the subject of the disposition (where the specific usage of the product is prescribed by the disposition, for the product used for that usage)" while the approval of a medicine stipulates matters that fall under usage; therefore, in the case of a patented invention for which matters that identify usage are not included in matters to identify the invention, the "working of the patented invention" should be considered 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 usage (Matters that Fall Under Matters to Identify the Invention and Usage) out of the matters stated in the written approval of the medicine which was the subject of the disposition; [iv] If there is a disposition (prior disposition) in relation to a prior medicine that satisfies the "Matters that Fall under Matters to Identify the Invention (and Usage)" of the medicine which was the subject of the disposition, it should be said that the scope of the patented invention identified by the "Matters that Fall under Matters to Identify the Invention (and Usage)" of the medicine which was the subject of the disposition had become workable by the prior disposition; therefore, the Application is refused pursuant to Article 67-3, paragraph (1), item (i) of said Act.

However, the aforementioned determination in the JPO Decision contains errors. The grounds therefor are as follows

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)

(1) Purpose of the system for the registration of extension of the duration of a patented invention

Article 67, paragraph (1) of the Patent Act provides for the duration of a patent right as 20 years from the filing date of a patent application. At the same time, paragraph (2) of said Article provides that where there is a period during which the patented invention is unable to be worked because a disposition designated by Cabinet Order is necessary to obtain for the working of the patented invention, the duration of the patent right may be extended by a period not exceeding 5 years, thereby having established the system for the registration of extension of the duration of a patent right.

The purpose of establishing the system for the registration of extension of the duration of a patent right is as follows.

That is, where it is necessary to obtain a "disposition designated by Cabinet Order" as set forth in Article 67, paragraph (2) of said Act for the "working of the patented invention," the patentee is unable to work the patented invention even if he/she has the patent right. This substantially causes the erosion of the term of the patent (however, even during such period, the patentee never ceases to have the exclusive "right to work the patented invention as a business," and the patentee is not precluded from claiming an injunction or damages against a third party in relation to the third party's act of working the patented invention without permission of the patentee; therefore, regarding the content of the disadvantages incurred by the patentee, attention is paid only to the point that the patentee was unable to work the patented invention, out of all the effects of the patent right). Then, this results in creating disadvantages for the patentee such as becoming unable to recover the costs required for research and development. In addition, it causes developers and researchers to lose incentives for research and development. For resolving such inconvenience and enhancing incentives for research and development, the system made it possible to extend the duration of a patent right for the period during which a patented invention was unable to be worked, with limits that are not to exceed 5 years.

Approval under the Pharmaceutical Affairs Act and registration under the Agricultural Chemicals Control Act, which are designated by Cabinet Order, fall under permissions in terms of academic research. The act of manufacturing, selling, etc. is generally and abstractly banned, and it is permitted to commit said act only after receiving an individual, specific disposition based on each administrative law. Therefore, the legal situation where the act of manufacturing, selling, etc. is banned will continue unless the patentee tries to obtain such permission. However, the Patent Act provides that the entire period (leaving aside the 5-year limit) during which a patented invention was unable to be worked, including the period during which the patentee did not try to obtain permission, shall not be considered as the basis for the calculation of the

extension of the duration and that only the period during which a patented invention was unable to be worked despite the patentee's intension and ability to work the patented invention, that is, the period required to obtain the relevant "disposition designated by Cabinet Order," shall be subject to extension of the duration. This point is also obvious in light of a judicial precedent (see the judgment of the Second Petty Bench of the Supreme Court; 1998 (Gyo-Hi) 43; October 22, 1999; Minshu, Vol. 53, No. 7, at 1270) to the effect that the "period during which the patented invention is unable to be worked" should be considered as meaning the period from the day of start of a test required to obtain a "disposition designated by Cabinet Order" or the day of registration of the establishment of a patent right, whichever is later, to the day before the day on which the disposition becomes effective through arrival of the relevant "disposition designated by Cabinet Order" to the applicant.

In this manner, the system for the registration of extension of the duration of a patent right can be regarded as a system that tries to eliminate the disadvantage incurred by a patentee who was unable to work a patented invention even with his/her intention and ability to work the patented invention by taking measures to extend the duration of the patent right in relation to the act of working the patented invention on which the ban was lifted through obtainment of a "disposition designated by Cabinet Order" for the period required to obtain [the/said] "disposition designated by Cabinet Order."

(2) Regarding the requirement for an examiner's decision of refusal on the grounds of Article 67-3, paragraph (1), item (i) of the Patent Act

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 a patent right should be refused, the conclusion should be drawn by determining whether said application fulfills 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 an examiner's decision (JPO Decision) to the effect that the application is to be refused (the scope for which the patent right whose duration was extended for the reason of a prior disposition is effective cannot be regarded as a matter that necessarily always directly relates to the question of whether it was necessary to obtain a disposition designated by Cabinet Order for the working of the patented invention).

Considering the provisions of Article 67-3, paragraph (1), item (i) of said Act in light of the aforementioned purpose of the system for the registration of extension of the duration of a patent right, the following serve as the prerequisites for saying that there is the fact that "a disposition designated by Cabinet Order was necessary to obtain for the working of the patented invention": [i] A ban was lifted through obtainment of the "disposition designated by Cabinet Order" (for example, it can be neither evaluated nor determined that the ban has already been lifted through obtainment of a prior disposition); [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" (for example, in the case of an invention of a product, the act of producing, etc. the product). The fulfillment of these two prerequisites is considered to be necessary.

On the premise of the aforementioned points, the issue is organized as follows. Article 67-3, paragraph (1), item (i) of said Act provides the following requirement for an examiner (trial examiner) to refuse an application for the registration of extension: "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 such an application, it is necessary for an 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) (incidentally, in light of the provisions of Article 67-2, paragraph (1), item (iv) of said Act and paragraph (2) of said Article, it is considered that the existence and content of a "disposition designated by Cabinet Order" should be made clear by the applicant from the perspective of ensuring the smooth operation of examination and other practices and the principle of equity).

Summing up the above, it should be said that it is impossible to draw a conclusion to the effect that an application for the registration of extension should be refused on the grounds of Article 67-3, paragraph (1), item (i) of said Act unless an examiner (trial examiner) demonstrates that there is a fact that falls under either of the aforementioned requirements.

(3) Regarding approval of manufacturing, sale, etc. of a medicine

Article 14, paragraph (1) of the Pharmaceutical Affairs Act provides that a person who intends to manufacture and sell a medicine, quasi-pharmaceutical product, certain cosmetics or medical equipment shall obtain approval of the Minister of Health, Labour and Welfare for each product in relation to the manufacturing and sale thereof. Paragraph (9) of said Article provides that where a person who has obtained the approval set forth in paragraph (1) of said Article intends to change part of the approved matters in relation to a relevant product, he/she shall obtain approval of the Minister of Health, Labour and Welfare in relation to the change. The approval set forth in paragraph (1) of said Article and the approval set forth in paragraph (9) of said Article concerning medicine fall under the disposition designated by Cabinet Order as set forth in Article 67, paragraph (2) of the Patent Act (Article 3 of the Order for Enforcement of the Patent Act).

It is necessary to obtain approval for the manufacturing and sale of a medicine, quasi-pharmaceutical product, cosmetic and medical equipment under Article 14, paragraph (1)

or (9) of the Pharmaceutical Affairs Act with respect to each product. In obtaining such approval, the "name, ingredient, quantity, structure, dosage, administration, use method, effectiveness, efficacy, performance, side effects and other quality, and matters relating to effectiveness and safety" of the relevant medicine, etc. are to be examined (paragraph (2), item (iii) of said Article). Paragraph (2), item (iii) of said Article cites the aforementioned matters as the subjects of examination. However, these matters cover all medicines, quasi-pharmaceutical products, cosmetics and medical equipment. Out of the aforementioned matters to be examined, "structure, use method and performance" are only for medical equipment and are not regarded as matters to be examined in relation to a medicine (see paragraph (8), items (i) and (ii) of said Article and Article 14-4, paragraph (1), item (i)). In that case, a medicine which becomes the subject of the approval under Article 14, paragraph (1) or (9) of said Act is a medicine that is identified by its "name, ingredient, quantity, dosage, administration, effectiveness, efficacy, side effects and other qualities, and matters relating to effectiveness and safety." Therefore, the act on which the ban is lifted by the aforementioned approval is the act of manufacturing, selling, etc. a medicine that is identified by the aforementioned matters which were the subjects of the approval.

(4) Regarding the determination concerning whether the Application fulfills the requirement prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act

As mentioned above, Article 67-3, paragraph (1), item (i) of the Patent Act provides the following requirement for refusing an application for the registration of extension of the duration of a patent right: "where the disposition designated by Cabinet Order … is not deemed to have been necessary to obtain for the working of the patented invention." In relation to this requirement, the fulfillment of the first requirement mentioned in [i] above, "it cannot be said that a ban was lifted through obtainment of the disposition designated by Cabinet Order," must not be determined 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 the matters to be examined for a medicine, but it must be substantially determined in light of the purpose of the Patent Act that established the system for the registration of extension of the duration.

Considering a patent of an ingredient of a medicine (excluding process patents and patents pertaining to product-by-process claims, etc.; the same applies hereinafter) from the aforementioned perspective, out of the elements that constitute a product, "name" does not affect objective identity as a medicine. Therefore, it is not considered as an element for determining whether a ban was lifted. In addition, "side effects and other qualities" and "matters relating to effectiveness and safety" cannot be usually regarded as matters directly relating to substantial identity as a medicine. Therefore, they are considered as not being required elements for determining whether a ban was lifted.

According to the above, regarding a patent of an ingredient of a medicine, 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).

(5) Regarding this case

The Patented Invention is an invention of an ingredient of a medicine, and the Prior Disposition has been made in relation to the act of manufacturing, selling, etc. said medicine. Therefore, the relationship between the scope for which the ban is determined to have been lifted by the Prior Disposition and the scope for which the ban is determined to have been lifted by the Disposition is considered in light of the perspective mentioned in (4) above.

As mentioned above, the Prior Disposition is an approval of manufacturing and sale of a medicine that was given under Article 14, paragraph (1) of the Pharmaceutical Affaires Act on April 18, 2007. The subject of the Prior Disposition is as follows: The product name is "AVASTIN 100 mg/4ml for intravenous infusion," the active ingredient is "bevacizumab (transgenic)," the effectiveness or efficacy is "unresectable advanced or recurrent colorectal cancer" and the dosage and administration are as follows: "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 an approval of a partial change to the matters included in the approval of manufacturing and sale of a medicine under paragraph (9) of said Article. The major change is the addition of the following dosage and administration to the dosage and administration approved by the Prior Disposition: "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."

The Prior Disposition did not lift 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 on the act of manufacturing, selling, etc. the Medicine on the premise of its use by the aforementioned use method. Said ban was lifted by the Disposition. Therefore, it is obvious that the Disposition does not fulfill the requirement that "it cannot be said that a ban was lifted through obtainment of the disposition designated by Cabinet Order" (the aforementioned first requirement), out of the aforementioned selective requirements for refusing an application for the registration of extension.

Moreover, the parties agree that the act of using the Medicine by the use method that is identified by the aforementioned dosage and administration and the act of manufacturing, selling, etc. the Medicine on the premise of its use by the aforementioned use method, on which the ban was lifted by the Disposition, fall under the act of working the Patented Invention. It is thus also obvious that the Disposition does not fulfill the requirement 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'" (the aforementioned second requirement) out of the aforementioned selective requirements for refusing an application for the registration of extension.

According to the above, in this case, it is not possible to state that "it cannot be said that the ban on the act of working 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.

(6) Regarding the defendant's allegation

A. In this regard, the defendant alleges as follows: [i] The medicine which is the subject of approval and the Patented Invention differ from each other because the former is identified by the matters stated in the written approval while the latter is a creation of a technical idea expressed by the "matters to identify the invention" and is in units of a technical idea; [ii] As the unit of a patented invention is a technical idea expressed by the matters to identify the invention, even if a ban was lifted on any act by the Disposition, it is impossible to say that the Patented Invention became workable for the first time by reducing the Patented Invention to a specific medicine which was the subject of the Disposition independently of the technical idea; [iii] Therefore, it is reasonable to consider the "working of the patented invention" in Article 67-3, paragraph (1), item (i) of the Patent Act 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 for which matters that identify "usage" are not included in matters to identify the invention, it is reasonable 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 usage (Matters that Fall under Matters to Identify the Invention and Usage) out of the matters stated in the aforementioned written approval, and it is also reasonable to consider matters that fall under usage as the "effectiveness and efficacy" stated in the aforementioned written approval.

B. However, the aforementioned reasons [i] and [ii] alleged by the defendant cannot serve as sufficient grounds for drawing the conclusion as alleged by the defendant. Moreover, the

conclusion mentioned in [iii] above as alleged by the defendant goes against the purpose and text of the provisions of Article 67-3, paragraph (1), item (i) of the Patent Act, and it is thus unacceptable.

(A) As mentioned in detail in (1) above, the system for the registration of extension of the duration of a patent right was established for the purpose of resolving the inconvenience that, where the disposition as prescribed in Article 67, paragraph (2) of the Patent Act is necessary to obtain for the "working of the patented invention," the patentee is unable to work the patented invention even if he/she has the patent right. The requirement set forth in Article 67-3, paragraph (1), item (i) of said Act was established to resolve this issue.

Where the act of manufacturing, selling, etc. on which the ban was lifted by a relevant disposition (the same applies to a prior disposition) is not included in the act of working the patented invention, said disposition does not at all affect the working of the patented invention. Therefore, it can be said that it is impossible to say that the disposition was necessary to obtain for the working of the patented invention. However, where the act of manufacturing, selling, etc. on which the ban was lifted by the relevant disposition is included in the act of working the patented invention, it becomes essential to consider the fulfillment of the first requirement out of the aforementioned selective requirements for refusing an application for the registration of extension provided for in said item.

(B) In this regard, the defendant alleges as follows: In the case of a patented invention for which matters that identify "usage" are included in matters to identify the invention, it is reasonable to consider the "working of the patented invention" in Article 67-3, paragraph (1), item (i) of the Patent Act 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; while, in the case of a patented invention for which matters that identify "usage" are not included in matters to identify the invention, it is reasonable to consider said "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 usage (Matters that Fall under Matters to Identify the Invention and Usage) out of the matters stated in the aforementioned written approval; it is also reasonable to consider matters that fall under "usage" as the "effectiveness and efficacy" stated in the aforementioned written approval.

The defendant's allegation is understood as meaning that the ban on manufacturing, selling, etc. was lifted by the disposition in relation to the scope that is identified only by the matters stated in the written approval of the medicine which was the subject of the disposition (including the prior disposition) that overlap with the matters to identify the invention of the

patented invention or by those matters and effectiveness and efficacy. However, this allegation is unacceptable as explained below.

a. The defendant's allegation is considered as being based on the premise that matters that are not stated as the constituent features (matters to identify the invention) in the scope of claims should be treated as matters that have no relation to the technical idea of the patented invention. However, constituent features (matters to identify the invention) in the scope of claims are selected and stated by the applicant for the purpose of defining the technical scope (scope of exclusive right) of the patented invention. Matters that are not stated as constituent features (matters to identify the invention) mean that the technical idea of the patented invention can be established in a broad scope without being limited by constituent features (matters to identify the invention). Consequently, the broad technical scope of the patented invention becomes the subject of the exclusive right. However, this does not immediately mean that matters that are not stated as constituent features (matters to identify the invention) have no relation to the technical idea of the patented invention.

b. As mentioned in (1) above, the system for the registration of extension of the duration of a patent right was established under the Patent Act for the purpose of eliminating disadvantages such as being unable to recover the costs required for research and development, and enhancing incentives for research and development. For the purpose of realizing such, the Patent Acts provides for the following as the requirement for refusal: "where the disposition designated by Cabinet Order … is not deemed to have been necessary to obtain for the working of the patented invention." Thereby, the Patent Act clarifies the content which an examiner (trial examiner) needs to demonstrate in order to refuse an application for the registration of extension.

Even limiting such disposition to a disposition for a medicine under Article 14, paragraph (1) or (9) of the Pharmaceutical Affairs Act, it is obvious from the provisions of Article 14, paragraph (1) or (9) of said Act that acts on which the ban is lifted by such a disposition are limited to the act of manufacturing, selling, etc. a medicine that is identified by "ingredient, quantity, dosage, administration, effectiveness and efficacy" stated in a written approval, as instructed above, and are not the entirety of the acts of manufacturing, selling, etc. a medicine that is identified by the matters to identify the invention of the patented invention or by those matters and matters that fall under effectiveness and efficacy that exceed those acts.

Looking at this case, the Prior Disposition lifted 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 5 mg/kg (weight) or 10 mg/kg (weight) at administration intervals of at least two weeks) approved by the Prior Disposition and on the act of manufacturing, selling, etc. the Medicine on the premise of its use by said use method. On the other hand, the Disposition lifted the ban on each

of the aforementioned acts in relation to 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), which was added by the Disposition. The Disposition made it possible to sell, etc. the Medicine for combination treatment of XELOX treatment and bevacizumab treatment for the first time (for a medicine, approval is given only after it is confirmed through a clinical test for a considerable period of time that the working of the patented invention according to a specific dosage and administration has few side effects and is highly safe (Exhibit Ko No. 25); it is thus obvious that the ban on the working of the patented invention according to a dosage and administration that differs from said specific dosage and administration, which was the subject to examination for the approval, has not been lifted). Consequently, for the Patented Invention, the ban was lifted for the aforementioned scope for the first time by the Disposition. Therefore, it is obvious that the Application does not fall under the cases prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act.

In light of such purpose of the extension registration system and the text of the provisions on the requirement, the following allegation by the defendant is unacceptable: The "working of the patented invention" in said item should be considered as the act of manufacturing, selling, etc. a medicine that is identified not by the specific content of the approval of manufacturing, sale, etc. of the medicine but only by the matters stated in the written approval of the medicine that overlap with the matters to identify the invention of the patented invention or by those matters and effectiveness and efficacy.

c. As mentioned above, the following defendant's allegation is unacceptable: It is deemed that the ban was also lifted by a disposition designated by Cabinet Oder in relation to the act of working the patented invention on which the ban was not lifted by said disposition designated by Cabinet Order. It is thus erroneous to refuse the application for the registration of extension of the duration of the patent right based on this allegation.

(7) Regarding changes in the practice relating to an examiner's decision of refusal pertaining to extension of the duration of a patent right

There have been changes in the practice relating to the fulfillment of the requirement for refusal set forth in Article 67-3, paragraph (1), item (i) of the Patent Act. The outline thereof is as follows.

A. Practice based on the Examination Guidelines before the revision on December 28, 2011

(A) The practice relating to an examiner's decision of refusal provided for in Article 67-3, paragraph (1), item (i) of the Patent Act under the Examination Guidelines concerning an examiner's decision of refusal before the revision (hereinafter referred to as the "Old Examination Guidelines") was as follows.

Regarding the requirement prescribed in Article 67-3, paragraph (1), item (i) of said Act, "where the disposition designated by Cabinet Order as set forth in Article 67, paragraph (2) is not deemed to have been necessary to obtain for the working of the patented invention," the following practice had been adopted: "In light of legislative purpose, the essence of regulatory laws, such as the Pharmaceutical Affairs Act, is to regulate the manufacturing, sale, etc. of a specific product (or a product used for a specific usage). Therefore, "product" (or "product" and "usage") is the most important matter out of many matters identified by a disposition. Where there are multiple dispositions whose subject product is the same (where a usage is identified in dispositions, dispositions whose subject product and usage are the same), the patented invention became workable in relation to the product (or the product used for that usage) by obtaining the first disposition from those dispositions. Therefore, subsequent dispositions are not deemed to have been necessary to obtain for the working of the patented invention. Where approvals have been given for medicines that are identical with each other in terms of the active ingredient (product) and effectiveness and efficacy (usage) but differ from each other only in the manufacturing process, tablet form, etc., the registration of extension is permitted based only on the first approval from those approvals."

(B) It is considered that the practice that does not conform to the provisions of Article 67-3, paragraph (1), item (i) of the Patent Act had been adopted under the Old Examination Guidelines as no consideration was given to the perspective that manufacturing, sale, etc. based on a prior disposition is not included in the technical scope of the relevant patented invention (the aforementioned second requirement).

B. Judgment of the Intellectual Property High Court; 2008 (Gyo-Ke) 10460; May 29, 2009

(A) The aforementioned judgment was rendered on the following case: An application for the registration of extension of the duration of a patent right was filed on the grounds that the approval pertaining to a medicine provided for in Article 14, paragraph (1) of the Pharmaceutical Affairs Act was necessary to obtain for the medicine, "Pacif Capsules 30mg," for the working of the patented invention relating to a controlled release composition; in response, the JPO maintained, in its decision, the conclusion of the examination to the effect that the medicine whose active ingredient (product) is "morphine hydrochloride" and which has the same effectiveness and efficacy (usage) has already been approved before said disposition and that even if it becomes necessary to obtain a new disposition due to the need to change the tablet form or other matters concerning the medicine other than the active ingredient and effectiveness and efficacy, the disposition designated by Cabinet Order as set forth in Article 67, paragraph (2) is not deemed to have been necessary to obtain for the working of the aforementioned invention; and the legitimacy of the JPO Decision became the issue.

(B) The aforementioned judgment held the following two points. First, the judgment indicated

that the requirement (fact required) for rendering an examiner's decision of refusal prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act in relation to an application for the registration of extension of the duration of a patent right is "where the disposition designated by Cabinet Order as set forth in Article 67, paragraph (2) is not deemed to have been necessary to obtain for the working of the patented invention" and that the JPO that renders an examiner's decision of refusal should bear the burden of assertion and of proof. Then, the court ruled that, in specific cases, a medicine that was the subject of a prior disposition is not included in the technical scope of the aforementioned patented invention, and the act of manufacturing, etc. the medicine on which the ban was lifted by the prior disposition does not fall under the act of working the aforementioned patented invention. Based on this ruling, the court rescinded the JPO Decision.

C. Judgment of the First Petty Bench of the Supreme Court; 2009 (Gyo-Hi) 326; April 28, 2011; Minshu, Vol. 65, No. 3, at 1654

In the aforementioned judgment, the court dismissed the final appeal filed by the Commissioner of the JPO for the following reasons.

In the aforementioned Supreme Court judgment, the court held that even if approval of manufacturing and sale (prior disposition) under Article 14, paragraph (1) of the Pharmaceutical Affairs Act has been given for a medicine whose active ingredient and effectiveness and efficacy are the same as those of a medicine which was the subject of a subsequent disposition prior to approval (subsequent disposition) of manufacturing and sale under said paragraph that constituted a reason for filing an application for the registration of extension of the duration of a patent right, when the medicine which was the subject of the prior disposition does not fall under the technical scope of the patented invention claimed in any claim of the patent right pertaining to the application for the registration of extension, it cannot be said that the subsequent disposition is not deemed to have been necessary to obtain for the working of the patented invention covered by the patent right on the grounds of the existence of the prior disposition.

D. Revision of the Old Examination Guidelines

(A) On December 28, 2011, the JPO revised the practice relating to an examiner's decision of refusal provided for in Article 67-3, paragraph (1), item (i) of the Patent Act as follows, in response to the aforementioned Supreme Court judgment.

A patented invention is a creation of a technical idea expressed by the "matters to identify the invention" (matters which the applicant recognizes as necessary to identify the invention for which a patent is sought). Therefore, in making a determination set forth in Article 67-3, paragraph (1), item (i) of said Act, the "working of the patented invention" should not be considered as the act of manufacturing, selling, etc. a medicine which was the subject of the

disposition itself 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 for which matters that identify usage are not included in matters to identify the invention, the "working of a patented invention" should be considered as the act of manufacturing, selling, etc. a medicine that is identified by all matters that fall under matters to identify the invention of the patented invention and matters that fall under usage (Matters that Fall Under Matters to Identify the Invention and Usage) out of the matters stated in the written approval of the medicine which was the subject of the disposition.

On that basis, where there is a prior disposition in relation to a prior medicine that satisfies the "Matters that Fall under Matters to Identify the Invention (and usage)" of the medicine which was the subject of the disposition, it can be said that the scope of the patented invention that is identified by the "Matters that Fall under Matters to Identify the Invention (and usage)" of the medicine which was the subject of the disposition had become workable by the prior disposition. Therefore, a reason for refusal arises.

(B) However, in the aforementioned Supreme Court judgment and the Intellectual Property High Court judgment, both courts just referred to the relationship with the "technical scope of the patented invention" in the process of drawing a conclusion that an application for the registration of extension based on a subsequent disposition does not fall under the requirement for refusal prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act, in response to the determination in the JPO Decision to the effect that even where the medicine which was the subject of the prior disposition does not fall under the technical scope of the patented invention covered by the patent right pertaining to the application for the registration of extension, the registration of extension based on the subsequent disposition is not permitted if the medicine which was the subject of the prior disposition and the medicine which was the subject of the subsequent disposition are identical with each other in terms of the active ingredient and effectiveness and efficacy. The aforementioned revision of the Examination Guidelines by the JPO was made from an independent standpoint beyond the holding in the aforementioned Supreme Court judgment. As mentioned above, the revision is apart from the text of the provisions of said item, and is unacceptable.

(8) Summary

As mentioned above, the JPO Decision contains an error in its determination to the effect that the Application falls under the cases prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act and the extension of the duration of the patent right cannot be registered. Consequently, the JPO Decision should be rescinded without the need for a ruling on other

issues.

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

The JPO Decision contains an error in its determination to the effect that the Application falls under the cases prescribed in Article 67-3, paragraph (1), item (i) of the Patent Act. Therefore, the JPO Decision is determined to be illegal without the need for a ruling on other issues. Moreover, the scope for which the extended patent right is effective under Article 68-2 of said Act is originally the issue that should be determined in a patent infringement action. However, just to make sure, this issue is considered as follows.

(1) Regarding the purpose of Article 68-2 of the Patent Act

Article 68-2 of the Patent Act provides that "Where the duration of a patent right is extended (including the cases where the duration is deemed to have been extended under Article 67-2, paragraph (5)), such patent right shall not be effective for any act other than the working of the patented invention for the product which was the subject of the disposition designated by Cabinet Order as set forth in Article 67, paragraph (2), which constituted the reason for the registration of extension (where the specific usage of the product is prescribed by the disposition, for the product used for that usage)."

The aforementioned provisions provide that where the duration of a patent right is extended, the patent right is effective not for the entire scope of the patented invention but only for the "product which was the subject of the disposition designated by Cabinet Order (where the specific usage of the product is prescribed by the disposition, for the product used for that usage)."

(2) Regarding the scope of the act of working a patented invention for the "product which was the subject of the disposition designated by Cabinet Order" and "usage" as set forth in Article 68-2 of the Patent Act

A. Where the "disposition designated by Cabinet Order" is an approval pertaining to a medicine as prescribed in the Pharmaceutical Affairs Act, the scope of the act of working the patented invention for the product (product and usage) which was the subject of approval under the Pharmaceutical Affairs Act, for which the patent right whose duration was extended is effective, is regarded as a matter that should be considered in a patent infringement action, as mentioned above. However, this issue is considered for convenience to the related extent.

B. Article 14, paragraph (1) of the Pharmaceutical Affairs Act provides that "A person who intends to manufacture and sell a medicine … shall obtain approval of the Minister of Health, Labour and Welfare for each product in relation to the manufacturing and sale thereof. The matters which becomes the subject of examination necessary for obtaining approval of a medicine pertaining to said paragraph are provided for as "name, ingredient, quantity, dosage,

administration, effectiveness, efficacy, side effects and other qualities, and matters relating to effectiveness and safety" (Article 14, paragraphs (2) and (9) of said Act). According to this, where the "disposition designated by Cabinet Order" is an approval pertaining to a medicine as prescribed in the Pharmaceutical Affairs Act, "effectiveness and efficacy" are always included in the matters to be examined, and they are included in "usage." Therefore, said approval is considered as falling under the cases "where the specific usage of the product is prescribed by the disposition" as prescribed in parentheses in Article 68-2 of the Patent Act.

C. The interpretation of the "product and usage which were the subjects of the disposition designated by Cabinet Order" in relation to a medicine which was the subject of approval under the Pharmaceutical Affairs Act is the issue of identifying the matters based on which the scope for which the patent right whose duration was extended pursuant to Article 68-2 of the Patent Act is effective. Therefore, this should be reasonably interpreted after taking into account the purpose of the system for the registration of extension of the duration of a patent right (the purpose of the system is that where there is a period during which the patentee was unable to work the patented invention even with his/her intension and ability to work the patented invention due to the necessity to obtain a disposition designated by Cabinet Order, extension of the duration of the patent right is permitted for a period not exceeding 5 years) and the equity between the patentee and third parties. Incidentally, there are various medicine-related patents, and it is thus difficult to discuss them in a uniform manner. Consequently, the following holding concerning the effect of a patent right for which extension of the duration was registered concerns a patented invention pertaining to an ingredient of a medicine.

(A) Regarding the "product which was the subject of the disposition designated by Cabinet Order" as prescribed in Article 68-2 of the Patent Act

Out of the aforementioned matters to be examined as prescribed in Article 14, paragraph (2), item (iii) of the Pharmaceutical Affairs Act, "name" does not affect objective identity as a medicine, and it does not become a matter that identifies the structure of a medicine. Therefore, it is not considered as an element that limits the effect of an extended patent right.

"Ingredient (not limited to active ingredient)" is a matter that objectively identifies the structure of a medicine, and is an important element among the aforementioned matters to be examined. Therefore, it becomes an element that limits the effect of an extended patent right.

"Quantity" means the quantity of ingredients, etc. included in a unit of a medicine, such as a tablet or a pack. Therefore, it can be an element that objectively identifies the structure of a medicine. However, it goes against the purpose of the establishment of the extension registration system to permit competing companies to manufacture, sell, etc. a medicine whose dosage and administration are substantially the same as those of a medicine for which the patentee obtained approval through a clinical test, etc. and which differs only in quantity from a medicine for

which the patentee obtained approval, after the expiration of the original duration of the patent. Consequently, quantity cannot be regarded as becoming an element that limits the effect of an extended patent right.

"Side effects and other quality, and matters relating to effectiveness and safety" are also usually not regarded as matters that directly relate to substantial identity as a medicine. Therefore, they can also not be considered as elements that limit the effect of an extended patent right.

(B) Regarding "usage" as prescribed in Article 68-2 of the Patent Act

In light of the example of use of the term "usage" in relation to a medicine, "effectiveness and efficacy" which are included in the aforementioned matters to be examined fall under the "usage" of the relevant medicine. Therefore, they become elements that limit the effect of an extended patent right.

In relation to medicines, "dosage and administration" which are included in the aforementioned matters to be examined relate to a method of using a medicine for a patient. However, for medicines, a clinical test intended to confirm the safety of side effects with respect to each specific dosage and administration is essential. Therefore, a considerable period of time is required before obtainment of approval. There is the situation where the patentee is precluded from working the patented invention during that period. "Dosage and administration" are among the important matters to be examined out of all matters to be examined for approval under the Pharmaceutical Affairs Act (Exhibit Ko No. 25). In addition, there are the cases where "dosage and administration" are decided on the premise of "combined use of the medicine with other anticancer drugs," such as the cases subject to the Prior Disposition and the Disposition. In light of these facts, it is reasonable to understand that "dosage and administration" are also included in "usage" and become elements that limit the effect of an extended patent right.

(C) As mentioned above, in light of the purpose of the system for the registration of extension of the duration of a patent right and the purpose of the system for a patent infringement action, in the case of a patented invention of an ingredient of a medicine, it is reasonable to conclude that the patent right whose duration was extended pursuant to Article 68-2 of the Patent Act is effective for the scope of the working of the patented invention that is identified by "ingredient (not limited to active ingredient)" as an invention pertaining to a "product" and is also identified by "effectiveness and efficacy" and "dosage and administration" as an invention pertaining to a "usage" (it can originally be said to be natural in light of the legislative purpose of the extension registration system that equivalents and products that are evaluated as substantially identical are included).

D. Based on the aforementioned understanding, the scope of the working of the patented invention on which the ban is lifted through obtainment of a disposition designated by Cabinet

Order and the scope of the working of the patented invention for which the patent right is effective in the cases where the duration of the patent right was extended are not always the same. However, it should be said that there is no unreasonableness in the inconsistency between these scopes as long as the scope for which the patent right whose duration was extended for the reason of a prior disposition is effective does not directly relate to the question of whether a disposition designated by Cabinet Order was necessary to obtain for the working of the patented invention. Incidentally, where the working of a patented invention on which the ban was lifted through obtainment of a disposition designated by Cabinet Order is included in the scope of the working of the patented invention for which the relevant patent right whose duration was extended based on a prior disposition is effective, the effect of the extension can arise redundantly. Where the period extended by a subsequent disposition is longer than the period extended by a prior disposition, the duration of the relevant patent right is extended for the corresponding period. However, taking into account that the working of the relevant patented invention had been banned in part during said period, the above understanding is not at all unreasonable.

3. Conclusion

On these grounds, there is reason for the grounds for rescission alleged by the plaintiff. Therefore, the JPO Decision shall be rescinded. The judgment shall be rendered in the form of the main text.

Intellectual Property High Court, Special Division

Presiding judge: IIMURA Toshiaki

Judge: SHITARA Ryuichi

Judge: TOMITA Yoshinori

Judge: SHIMIZU Misao

Judge: YAGI Kimiko