Date	January 20, 2017	Court	Intellectual Property High Court Special Division
Case number	2016 (Ne) 10046		

– A case in which the court dismissed a claim for an injunction against the manufacture, sale or otherwise handling of preparations based on a patent right whose duration was extended on the grounds that said patent right is not effective against the preparations.

– A case in which the court found that [i] the patented invention pertaining to a patent right whose duration was extended is not only effective against the "product" (medicine) specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by the Cabinet Order disposition but also against those that are substantially identical with such products as medicines; and [ii] even if the abovementioned structures prescribed by the Cabinet Order disposition contain any part different from the product manufactured, etc. by the other party (the "subject product"), if such part only represents a slight difference or formal difference as a whole, the subject product is included in the products which are substantially identical with those that are subject to the Cabinet Order disposition as a medicine and falls within the scope against which the patent right whose duration was extended is effective.

– With respect to a patented invention of a product for the ingredients of medicines, limited to the case where there is any one or more difference concerning the "ingredients" prescribed by the Cabinet Order disposition, or quantitative difference in the "quantity" or in the "dosage or administration" but no other difference, the determination on whether or not such difference is a slight difference or formal difference as a whole should be made based on the common general technical knowledge of persons ordinarily skilled in the art by making a comparative examination on the identicalness of the technical features and function and effect of the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by the Cabinet Order disposition and those of the subject product, based on and in relation to the content of the patented invention.

– In the abovementioned limited case, the difference between the subject product and the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by the Cabinet Order disposition is a slight difference or formal difference as a whole and the subject product is included in the products that are substantially identical with those that are subject to the Cabinet Order disposition as medicines, in the following cases: [i] a case where, in relation to a patented invention which is characterized only by the active ingredients of a medicine and for which the

extension of duration of the patent right was registered, a different ingredient is partially added, converted, etc. in the subject product, with respect to an "ingredient" other than the active ingredients, based on well-known or commonly used art as of the time of the filing of an application for the Cabinet Order disposition; [ii] a case where, in relation to a patented invention for the stability or dosage form, etc. of a medicine pertaining to publicly known active ingredients, a different ingredient is partially added, converted, etc. in the subject product based on well-known or commonly used art as of the time of the filing of an application for the Cabinet Order disposition, the subject product and the product subject to the Cabinet Order disposition are recognized as being identical with each other in the technical features and function and effect in light of the content of the patented invention; [iii] a case where there is only a quantitatively meaningless difference between the subject product and the product subject to the Cabinet Order disposition in terms of the "quantity" or "dosage or administration" prescribed by the Cabinet Order disposition; and [iv] a case where the subject product and the product subject to the Cabinet Order disposition differ in terms of the "quantity" prescribed by the Cabinet Order disposition but are recognized as identical in consideration of the "dosage and administration."

– A case in which the court found that in the case where there are special circumstances such that the subject product was intentionally excluded from the scope against which the patent right whose duration was extended is effective in the procedures of filing an application for the registration of extension of duration, the subject product would not be found to be substantially identical with the relevant product under Article 68-2 of the Patent Act.

References: Article 100, paragraphs (1) and (2) and Article 68-2 of the Patent Act

Number of related rights, etc.: Patent No. 3547755

Summary of the Judgment

1. Background, etc.

In this case, the appellant (plaintiff in the first instance), who holds the patent right in question ("Patent Right") for an invention titled "pharmaceutically stable preparation of oxaliplatinum," claimed against the appellee (defendant in the first instance) an injunction against the production, etc. of the preparations manufactured and sold by the appellee (defendant in the first instance; such preparations shall hereinafter be referred to as the "Products of the Defendant in the First Instance") based on the following allegations: [i] the Products of the Defendant in the First Instance fall within

the technical scope of the invention stated in Claim 1 ("Invention") of the description ("Description") attached to the written application of the patent in question; and [ii] the Patent Right for which the extension of the duration was registered is effective against the act of producing, assigning or offering for assignment ("production, etc.") the Products of the Defendant in the First Instance by the defendant in the first instance.

Since the duration of the Patent Right has been extended, in the first instance, the scope to which the Patent Right whose duration was extended is effective, in other words, whether or not the Patent Right is effective against the production, etc. of the Products of the Defendant in the First Instance came into issue. In the judgment in prior instance, the court dismissed all of the claims made by the plaintiff in the first instance by finding that the Patent Right is not effective against the Products of the Defendant in the First Instance and thus the plaintiff in the first instance, who was dissatisfied with such judgment, filed an appeal ("Appeal").

2. Details of this judgment

In this judgment, the court first explained the fact that a patent right for which the extension of the duration was registered is not only effective against products that are identical with the products subject to the Cabinet Order disposition but also against those that are substantially identical with the latter, and the specific scope of products to be construed as being substantially identical with the product subject to the Cabinet Order disposition. Following this, the court determined that the Products of the Defendant in the First Instance cannot be found to be substantially identical with the products subject to the Cabinet Order dispositions in this case based on the technical features of the Invention identified from the scope of claims and description of the patent. The court also identified the technical scope of the Invention based on the scope of claims and description of the patent as well as the written opinion submitted in the process of the application, and determined that the Products of the Defendant in the First Instance do not fall within the technical scope of the Invention. Based on these findings and determinations, the court found that the judgment in prior instance which dismissed the claims made by the plaintiff in the first instance is appropriate and thereby dismissed the Appeal.

The outline of the determinations made in this judgment is as follows.

(1) Regarding the scope against which the patent right whose duration was extended based on Article 68-2 of the Patent Act (hereinafter simply referred to as the "Act") is

effective

A. Article 68-2 of the Act provides that "Where the duration of a patent right is extended (including the case where the duration is deemed to have been extended under Article 67-2, paragraph (5)), such patent right shall not be effective against any act other than the working of the patented invention for the product which was the subject of the disposition designated by Cabinet Order under 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, the product used for that usage)."

B. The elements of the "product which was the subject of the disposition designated by Cabinet Order" and "usage" of the medicines which were subject to the disposition of approval under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices specify the scope against which the patent right whose duration was extended is effective. Thus, these elements should be interpreted in a reasonable manner by taking into consideration the purpose of the system of the registration of extension of duration of a patent right (if there is a period during which the patentee is unable to work a patented invention in order to obtain a disposition designated by Cabinet Order though he/she had the intention and ability to work the patented invention, the duration may be extended by a period not exceeding five years) and impartiality between patentees and third parties.

C. The matters subject of the examination necessary to obtain an approval for a medicine are the "name, ingredients, quantity, dosage, administration, efficacy, effects, side effects and other quality, effectiveness and safety related matters" of the medicine, and an approval is obtained for each "item" specified by these elements. Therefore, these elements formally serve as standards for defining the "product" and "usage."

Yet, in light of the purpose of the system of the registration of extension of duration of a patent right, it is not reasonable if the effect of a patent right is limited even where there is a difference in a matter for examination that is not directly related to substantial identity as a medicine. Moreover, in light of the fact that, with respect to a patented invention of a product concerning ingredients of medicines as in this case, the examination matters that are directly related to the substantial identity as medicines are "ingredients, quantity, dosage, administration, efficacy, and effects" (judgment of the Third Petty Bend of the Supreme Court of November 17, 2015 [Minshu Vol. 69, No. 7 at 1912, Bevacizumab Case]), it is appropriate to specify the "product" and "usage" within the scope of such elements and to define the scope against which the patent right whose duration was extended is effective.

In addition, the elements of "ingredients and quantity" affect objective identity as a

"product" itself but cannot fall under "usage" in terms of the nature thereof. Therefore, it is reasonable to consider them as matters to specify the "product." On the other hand, the elements of "dosage, administration, efficacy and effect" do not affect objective identity as a "product" itself but can fall under "usage," and thus it is appropriate to regard them as elements that specify the "usage."

Based on the abovementioned findings, it is appropriate to construe that, in the case of a patented invention of a product for the ingredient of a medicine, the patent right whose duration was extended is effective against the "working of the patented invention" for the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by a specific Cabinet Order disposition.

D. However, if anyone could easily escape the patentee's exercise of rights, such as claiming an injunction, unless the subject product and the product subject to the Cabinet Order disposition are identical with each other in all of the aforementioned matters for examination prescribed by the Cabinet Order disposition as a result of formal comparison between them, this would not only go against the purpose of the system of the registration of extension of duration of a patent right to enable the patentee to restore the period during which he/she could not work the patented invention due to the need to obtain a Cabinet Order disposition, but would also be against the principle of impartiality. Based on such standpoint, it should be said that a patent right whose duration was extended is not only effective against the "product" (medicine) specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by the Cabinet Order disposition but against those that are substantially identical with the first-mentioned product as medicines, and third parties should expect this.

Accordingly, even if there is a part that differs from the subject product in the abovementioned structures prescribed by the Cabinet Order disposition, if said part is merely a slight difference or formal difference as a whole, it is reasonable to understand that the subject product is included in the products that are substantially identical with those subject to the Cabinet Order disposition and falls within the scope against which the patent right whose duration was extended is effective.

E. In addition, limited to the case where there is any one or more difference concerning the "ingredients" prescribed by the Cabinet Order disposition, or quantitative difference in the "quantity" or in the "dosage or administration" so prescribed, with respect to a patented invention of a product for the ingredient of a medicine, but no other difference, the determination on whether or not such difference is a slight

difference or formal difference as a whole should be made based on the common general technical knowledge of persons ordinarily skilled in the art by making a comparative examination on the identicalness of the technical features and function and effect of the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by the Cabinet Order disposition and those of the subject product based on and in relation to the content of the patented invention (including whether or not the patented invention is an invention that is characterized only by the active ingredient of the medicine, whether or not it is an invention for the stability or dosage form, etc. of the active ingredient of the medicine on the premise of the existence of the active ingredient, or what is the content of the technical features and function and effect of the invention; the same shall apply hereinafter).

In the abovementioned limited case, the type of cases where the subject product is included in the products that are substantially identical with the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by the Cabinet Order disposition as medicines, is as follows.

Specifically, it should be said that the difference between the subject product and the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by the Cabinet Order disposition is a slight difference or formal difference as a whole and the subject product is included in the products that are substantially identical with those subject to the Cabinet Order disposition as medicines, in the following cases: [i] a case where, in relation to a patented invention which is characterized only by the active ingredients of a medicine and for which the extension of duration of the patent right was registered, a different ingredient is partially added, converted, etc. in the subject product, with respect to an "ingredient" other than the active ingredients, based on well-known or commonly used art as of the time of the filing of an application for the Cabinet Order disposition; [ii] a case where, in relation to a patented invention for the stability or dosage form, etc. of a medicine pertaining to publicly known active ingredients, a different ingredient is partially added, converted, etc. in the subject product based on well-known or commonly used art as of the time of the filing of an application for the Cabinet Order disposition, the subject product and the product subject to the Cabinet Order disposition are recognized as being identical with each other in terms of the technical features and function and effect in light of the content of the patented invention; [iii] a case where there is only a quantitatively meaningless difference between the subject product and the product subject to the Cabinet Order disposition in terms of the "quantity" or "dosage or administration"

prescribed by the Cabinet Order disposition; and [iv] a case where the subject product and the product subject to the Cabinet Order disposition differ in terms of the "quantity" prescribed by the Cabinet Order disposition but are recognized identical in consideration of the "dosage and administration" (the cases mentioned in [i], [iii] and [iv] above are those in which the subject product is virtually and presumptively recognized as being identical with the product subject to the Cabinet Order disposition in the technical features and function and effect).

In contrast, such logic shall not apply in the case where there is a difference between the subject product and the product subject to the Cabinet Order disposition in the "dosage, administration, efficacy, and effects" related to medicines in the case other than the abovementioned limited cases. This is because, for example, where a difference other than a quantitative difference arises in "dosage and administration" due to a difference in dosage form (e.g. spray and injection), it is necessary to examine the difference from multiple points of view according to the specific content of the difference. In addition, if "efficacy, and effects" differ between the subject product and the product subject to the Cabinet Order disposition due to a difference in the subject diseases, it is considered important to examine the difference from medical perspectives, such as the similarity of diseases.

F. In determining the scope of substantial identity referred to in Article 68-2 of the Act, the five requirements for finding infringement under the doctrine of equivalents specified in the judgment of the Third Petty Bench of the Supreme Court of February 24, 1998 (Minshu Vol. 52, No. 1 at 113, Ball Spline Bearing Case, judgment of the Supreme Court) cannot be applied or analogically applied.

G. Yet, based on the idea of general estoppel, in the case where there are special circumstances such that the subject product was intentionally excluded from the scope against which the patent right for which the extension of duration was registered is effective in the procedures for filing an application for the registration of extension of duration of the patent right, it is construed that the subject product would not be found to be included in the products substantially identical with the relevant product under Article 68-2 of the Act.

H. Article 68-2 of the Act provides for a system intended to relieve a patentee who was unable to substantially exercise his/her patent right by allowing the extension of duration of a patent right but not a system intended to enlarge the technical scope of a patented invention. Therefore, in order to find infringement of a patent right whose duration was extended, it is a matter of course that allegations must be made or proof must be shown for the fact that the subject product falls within the technical scope of

the patented invention (including the case of infringement under the doctrine of equivalents). This is also obvious from the fact that Article 68-2 of the Act prescribes that a patent right whose duration was extended "shall not be effective against any act other than the working of the patented invention" for the product which was the subject of a Cabinet Order disposition.

(2) Consideration for this case

A. Whether or not the Products of the Defendant in the First Instance are identical with the products subject to the dispositions in question ("Dispositions")

Since the Patent Right for which the extension of duration was registered is effective against the scope of "working of the patented invention" for the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by the Cabinet Order disposition, based on a literal interpretation, the "ingredients" under the Dispositions only contain oxaliplatin and injectable water and no other ingredients.

In contrast, the "ingredients" of the Products of the Defendant in the First Instance contain concentrated glycerin, as an additive, in an amount equivalent to that of oxaliplatin in addition to oxaliplatin and injectable water, and such concentrated glycerin is used as a stabilizer.

As such, there is no choice but to find that the product subject to the Dispositions and the Products of the Defendant in the First Instance at least differ in terms of their "ingredients" based on a literal interpretation. Thus, it shall be determined whether or not the two products are substantially identical under Article 68-2 of the Act based on a finding that the abovementioned difference is a slight difference or formal difference as a whole.

B. Whether or not the Products of the Defendant in the First Instance are included in the products that are substantially identical with the products subject to the Dispositions

According to the statements in the Description, oxaliplatinum is a publicly known cytostatic antineoplastic agent which can be used to treat various types of cancer and the Invention is created for the purpose of obtaining an aqueous solution of oxaliplatinum that shows a chemical purity and therapeutic activity equivalent to the lyophilisate of oxaliplatinum (the Invention falls under the category of patented invention prescribed in [ii] mentioned in (1)E. above). In the Description, it is stated that the purpose of the Invention can be achieved by using "an aqueous solution of oxaliplatinum that is free of any acidic or alkaline agent, buffer or other additive," in addition to specifying the concentration and pH of the active ingredients to fall within a limited scope. Moreover, the Description is also found to have contained a statement

which reads "This preparation is free of any other ingredients and should, in principle, not contain more than about 2% of impurities."

Based on such statements, it is found that, in the Invention, the fact that the aqueous solution of oxaliplatinum does not contain any additive constitutes one of the technical features of the Invention, in addition to the act of specifying the concentration and pH of the active ingredients to fall within a limited scope.

Based on these findings, the abovementioned difference concerning the "ingredients" found between the products subject to the Dispositions and the Products of the Defendant in the First Instance (i.e. the difference such that the products subject to the Dispositions are aqueous solutions consisting solely of oxaliplatinum and injectable water, while the Products of the Defendant in the First Instance are those wherein concentrated glycerin is added in an amount equivalent to that of oxaliplatinum to oxaliplatinum and injectable water) cannot be found to be a slight difference or formal difference as a whole in light of the abovementioned technical features of the Invention. Therefore, the Products of the Defendants in the First Instance cannot be found to be included in the products that are substantially identical with the products subject to the Dispositions.

Therefore, without the need to make determinations on other points such as the identicalness of the function and effect, the Products of the Defendant in the First Instance cannot be found to fall within the scope against which the Patent Right for which the extension of duration was registered is effective as products created by an act substantially identical with the working of the Invention for the "products" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" that were subject to the Dispositions.

C. Whether or not the Products of the Defendant in the First Instance fall within the technical scope of the Invention

Taking into consideration the statements in the Description and those in the written opinion submitted in the process of the application, the problem to be solved by the Invention is to obtain an injection solution of oxaliplatinum, which is pharmaceutically stable for an acceptable period in accordance with the approved standard, shows a chemical purity and therapeutic activity equivalent to those obtained from the lyophilisate of oxaliplatinum and can be used without any change, with respect to the publicly known active ingredient, "oxaliplatinum." Moreover, the Invention has presented, as the means to solve such problem, the dissolution of oxaliplatinum in water at a concentration in the range from 1 to 5mg/ml and at a pH in the range from 4.5 to 6. Furthermore, the Invention has also presented, as an equivalent means to

solve the problem, the element that "the relevant aqueous solution is free of any acidic or alkaline agent, buffer or other additive."

Therefore, there is no choice but to construe that the phrase which reads "consisting of an aqueous solution of oxaliplatinum" contained in the statements in the scope of claims of the Invention means that the Invention is an aqueous solution which consists solely of oxaliplatinum and water and contains no other additive, etc.

In contrast, the Products of the Defendant in the First Instance contain, in addition to oxaliplatinum and injectable water, concentrated glycerin of the same quantity as oxaliplatinum as an ingredient other than the active ingredients and thus, without the need to make determination on the other structures, it should be said that the Products of the Defendant in the First Instance do not fall within the technical scope of the Invention.

D. As described above, the Patent Right for which the extension of duration was registered is not effective against the Products of the Defendant in the First Instance.

End

Judgment rendered on January 20, 2017

2016 (Ne) 10046, Appeal Case of Seeking Injunction against Patent Infringement (Court of prior instance: Tokyo District Court; 2015 (Wa) 12414)

Date of conclusion of oral argument: November 25, 2016

Judgment

Appellant: Debiopharm International S.A.

Counsel attorney: OHNO Seiji

Same as above: OHNO Hiroyuki

Same as above: KIMURA Hiroyuki

Counsel subagent attorney: TADA Hirofumi

Counsel patent attorney: MATSUTOYA Yuko

Appellee: Towa Pharmaceutical Co., Ltd.

Counsel attorney: YOSHIZAWA Takao

Same as above: KAWADA Atsushi

Counsel patent attorney: KONNO Akio

Same as above: INAMI Minoru

Patent attorney as an assistant in court: ITO Takeyasu

Main Text

1. This appeal shall be dismissed.

2. The appellant shall bear the cost of the appeal.

3. The additional period for filing a final appeal against this judgment and a petition for acceptance of final appeal shall be specified as 30 days.

Facts and reasons

No. 1 Objects of the appeal

1. The judgment of prior instance shall be revoked.

2. The appellee shall neither produce, nor assign, nor offer for assignment the preparations stated in 1 to 3 of the Appellee's Product List attached to this judgment.

3. The appellee shall dispose of the preparations stated in 1 to 3 of the Appellee's Product List attached to this judgment.

4. The appellee shall bear the court costs for both the first and second instances.

No. 2 Outline of the case (hereinafter abbreviations are as in the judgment of prior instance unless otherwise noted)

1. The appellant (plaintiff in the first instance; hereinafter referred to as the "Appellant"), who is the patentee of Patent No. 3547755 (the "Patent"), alleges that the preparations stated in the Appellee's Product List attached to this judgment (hereinafter each of them is referred to as "Appellee's Product 1," etc. according to the number stated in said list, and these preparations

are collectively referred to as "Appellee's Products"), which are manufactured and sold by the appellee (defendant in the first instance; hereinafter referred to as the "Appellee") fall within the technical scope of the invention (the "Invention") claimed in Claim 1 of the scope of claims in the description attached to the application for the Patent (the "Description") and that the patent right in question (the "Patent Right") for which the registration of extension of duration was obtained is effective against the production, assignment, and offering for assignment ("production, etc.") by the Appellee of the Appellee's Products. Based on this allegation, the Appellant filed this action against the Appellee to seek an injunction against the production, etc. of the Appellee's Products and disposal thereof.

The duration of the Patent Right was extended, and in the first instance, the parties disputed the scope against which the Patent Right whose duration was extended is effective, that is, whether or not the Patent Right is effective against the production, etc. of the Appellee's Products. The court of prior instance ruled that the Patent Right is not effective against the production, etc. of the Appellee's Products and dismissed all of the Appellant's claims. Therefore, the Appellant filed an appeal against the judgment of prior instance.

2. Facts on which the decision is premised (facts on which the parties agree or facts that can be easily determined based on the evidence described in the judgment and the entire import of the oral argument)

(1) Parties

The Appellant is a Swiss corporation engaging in the business of manufacturing, selling, exporting, and otherwise handling medicines, etc. The Appellee is a stock company engaging in the business of manufacturing, selling and purchasing, exporting, importing, and otherwise handling medicines, etc.

(2) The Patent Right and the registration of extension of duration thereof

The Appellant is the patentee of the Patent with the following content. The Appellant filed applications for the registration of extension of duration of the Patent Right as described in the "Application No. (Filing date)," "Period of extension," and "Date of registration of extension" columns in the Registrations of Extensions of Durations attached to this judgment, and received the registrations of the extensions (the "Registrations of Extensions"). The dispositions which constituted a reason for Registrations of Extensions 1 to 7 as recorded in the registry of the Patent (the "Dispositions") are as described in the "Description of the dispositions designated by Cabinet Order under Article 67, paragraph (2) of the Patent Act" column in said attachment (Exhibits Ko 1 and 2).

Incidentally, the period of extension pertaining to Registration of Extension 2 is up to "November 21," and the relevant duration already expired on July 28, 2016.

Patent number: Patent No. 3547755

Date of registration: April 23, 2004
Application number: Patent Application No. 1996-507159
(International application number: PCT/IB1995/000614)
Filing date: August 7, 1995
Priority claim number: 2462/94-6
Priority date: August 8, 1994
Priority country: Swiss Confederation
Title of the invention: Pharmaceutically stable preparation of oxaliplatinum
(3) Invention
A. The statement in Claim 1 in the scope of claims in the Description is as follows.

"A pharmaceutically stable preparation of oxaliplatinum for the administration by the parenteral route, consisting of an aqueous solution of oxaliplatinum at a concentration of 1 to 5 mg/ml and having a pH of 4.5 to 6, and after storage for a pharmaceutically acceptable duration of time, with the oxaliplatinum content in the preparation being at least 95% of the initial content and the solution remaining clear, colorless and free of any precipitate."

B. The Invention is segmented into the following constituent features.
[G] A pharmaceutically stable preparation of oxaliplatinum
[F] for the administration by the parenteral route,
[C] consisting of an aqueous solution of oxaliplatinum
[A] at a concentration of 1 to 5 mg/ml and
[B] having a pH of 4.5 to 6, and
[D] after storage for a pharmaceutically acceptable duration of time, with the oxaliplatinum content in the preparation being at least 95% of the initial content and
[E] the solution remaining clear, colorless and free of any precipitate.
(4) Appellee's act
A. The Appellee first obtained approvals for the manufacturing and sale of a medicine from the Minister of Health, Labour and Welfare on August 15, 2014 for Appellee's Products 1 and 2, as generic medicines of "Elplat I.V. Infusion Solution 50 mg" ("Elplat 50") and "Elplat I.V. Infusion Solution 100 mg" ("Elplat 100"), both of which are manufactured and sold by Yakult Honsha Co., Ltd. ("Yakult Honsha"), which was granted the exclusive license for the Patent Right, as preparations of oxaliplatin (synonym for oxaliplatinum). After that, upon listing in the National Health Insurance Drug Price Standard on December 12 of the same year, the Appellee started selling these medicines on the same day (Exhibit Ko 6).

In addition, the Appellee also subsequently obtained an approval for the manufacturing and sale of a medicine from the Minister of Health, Labour and Welfare for Appellee's Product 3, as a generic medicine of "Elplat I.V. Infusion Solution 200 mg" ("Elplat 200"; hereinafter it,

together with Elplat 50 and Elplat 100, are collectively referred to as "Elplat I.V. Infusion Solutions" or merely "Elplat Solutions"), which is manufactured and sold by Yakult Honsha as a preparation of oxaliplatin (Exhibit Ko. 5).

Incidentally, Elplat 50 is a medicine subject to Dispositions 1, 3, and 5, Elplat 100 is a medicine subject to Dispositions 2, 4, and 6, and Elplat 200 is a medicine subject to Disposition 7.

B. The composition and nature, efficacy and effects, and dosage and administration of Appellee's Products are as follows, respectively (Exhibit Ko 5). The efficacy and effects and dosage and administration of the Appellee's Products are identical with those of Elplat I.V. Infusion Solutions (the parties agree on this point).

In addition, the Appellee's Products have the structure that fulfills Constituent Features [A], [B], [E], and [F] of the Invention (entire import of the oral argument).

(A) Composition and nature

	Appellee's Product 1	Appellee's Product 2	Appellee's Product 3
Content per vial	10 mL	20 mL	40 mL
Active ingredient per vial	Oxaliplatin … 50 mg	Oxaliplatin … 100 mg	Oxaliplatin … 200 mg
Additive	Concentrated glycerin … 50 mg	Concentrated glycerin … 100 mg	Concentrated glycerin … 200 mg
Nature	Colorless and clear liquid		
pH	4.0 to 7.0		
Osmotic pressure ratio	Approx. 0.23 (ratio to normal saline solution)		

Incidentally, the additive (concentrated glycerin) is used as a stabilizer in all of the Appellee's Products (Exhibit Ko 39).

(B) Efficacy and effects

Unresectable advanced or recurrent colorectal cancer

Postoperative adjuvant chemotherapy for colon cancer

Unresectable pancreas cancer

(C) Dosage and administration

"1. Method A or B is used for the purpose of treatment of unresectable advanced or recurrent colorectal cancer and postoperative adjuvant chemotherapy for colon cancer while Method A is used for the purpose of treatment of unresectable pancreas cancer. Incidentally, the dosage is reduced as appropriate depending on the patient's condition.

Method A: In combination with other anticancer drugs, the medicine is ordinarily intravenously

administered to an adult as oxaliplatin at a dose of 85 mg/m^2 (body surface area) for two hours once a day at administration intervals of at least 13 days. This is considered as one cycle, and the administration is repeated.

Method B: In combination with other anticancer drugs, the medicine is ordinarily intravenously administered to an adult as oxaliplatin at a dose of 130 mg/m^2 (body surface area) for two hours once a day at administration intervals of at least 20 days. This is considered as one cycle, and the administration is repeated.

2. The medicine is infused into 5% glucose injection solution, and thereby, it is brought into a solution of 250 to 500 mL and is intravenously administered."

3. Issues

The issues of this case are the following four points, and each of them corresponds to Issues 1 to 4, which are described in 3. (line 5 to line 12 of page 6 of the judgment of prior instance) in "No. 2 Outline of the case" in the "Facts and reasons" section of the judgment of prior instance.

(1) Whether or not the Appellant's Products fall within the technical scope of the Invention (fulfillment of Constituent Features [C], [D], and [G]) (Issue 1)

(2) Whether or not the Patent Right for which extension of duration was registered is effective against the production, etc. of the Appellee's Products (Issue 2)

(3) Whether or not the patent for the Invention is recognized as one that should be invalidated by a trial for patent invalidation (lack of novelty or an inventive step by citing Exhibit Otsu 5 or 9 as the primarily cited document) (Issue 3)

(4) Whether or not the Registrations of Extensions are recognized as those that should be invalidated by a trial for invalidation of the registration of extension of duration (Issue 4)

No. 3 Allegations of the parties

As mentioned below, the allegations of the parties are as described in "No. 3 Allegations of the parties concerning the issues" (line 13 of page 6 to line 2 of page 20 of the judgment of prior instance) in the "Facts and reasons" section in the judgment of prior instance though the parties made additional allegations regarding Issue 2 in this instance, respectively. Therefore, the relevant part is cited.

1. Additional allegations of the Appellant in this instance (Regarding Issue 2)

(1) Regarding the scope against which a patent right for which extension of duration was registered is effective

Regarding equivalents or substantially identical products (hereinafter they are collectively referred to as "substantially identical products, etc.") against which a patent right for which extension of duration was registered is effective, the court of prior instance interpreted a "product" subject to a disposition as a product for which a difference from the substantially identical products, etc. is a mere addition, deletion, conversion, etc. of well-known or

commonly used art and does not produce any new effect. Based on this interpretation, the court of prior instance held as follows: The Appellee's Products do not fall under substantially identical products, etc. because concentrated glycerin used in the Appellee's Products is not an addition, etc. of well-known or commonly used art but produces a new effect, and the Patent Right for which extension of duration was registered is not effective against the Appellee's Products.

However, as long as substantially identical products, etc. should be considered based on the purpose of the system of the registration of extension of duration of a patent right, what should be questioned is "whether or not an approval was obtained completely based on the outcome that was obtained as a result of the impossibility of working a patented invention for the purpose of obtaining a disposition for the original medicine, without independently conducting any test, etc. prescribed by laws and regulations for ensuring safety, etc. thereon." A generic medicine that differs from the original medicine in additives, like the Appellee's Products, should also be interpreted as naturally falling under substantially identical products, etc. if it is manufactured and sold after obtaining an approval completely based on an outcome, such as confirmation of safety, which was obtained as a result of the impossibility of working a patented invention for the purpose of obtaining a disposition for the original medicine, without independently conducting any test, etc. prescribed in laws and regulations for ensuring safety, etc. thereon. Therefore, the judgment of prior instance clearly contains an error in its interpretation of substantially identical products, etc.

Even if substantially identical products, etc. are interpreted as those for which a difference from the "product" subject to a disposition is an addition, deletion, conversion, etc. of well-known or commonly used art and does not produce any new effect, the Appellee's Products obviously fall under substantially identical products, etc. because concentrated glycerin used in the Appellee's Products is listed in Japanese Pharmaceutical Excipients Directory (Exhibit Ko 34) and only produces the effect of a stabilizer as described in said directory within the scope of the administration route and maximum amount of use described in said directory.

(2) Generic medicines and additives

A. Positioning of the Appellee's Products which are generic medicines

In determining whether or not the Appellee's Products fall under the "substantially identical products, etc." of the Invention, it is necessary to understand the accurate positioning of the Appellee's Products, which are generic medicines, under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Pharmaceuticals and Medical Devices Act), which is one of the "Acts that are intended to ensure the safety, etc." referred to in Article 67, paragraph (2) of the Patent Act (hereinafter merely referred to as the "Act" when citing provisions).

In this regard, a generic medicine is a preparation whose manufacturing and sale is approved after the expiration of a substance patent or a use patent for the original medicine, which was approved after being confirmed as having a new active ingredient and a new efficacy, effect, etc. through a clinical test, etc., by way of verifying the facts that it is a preparation that contains the same active ingredients as those of the original medicine and administered by the same route as the original medicine, that it is a medicine which is in principle identical with the original medicine in efficacy and effects as well as dosage and administration, and that it is equivalent to the original medicine from a therapeutic perspective by a bioequivalence test, etc. (Article 14 of the Pharmaceuticals and Medical Devices Act).

Moreover, a generic medicine is approved after being confirmed to be equivalent to the original medicine from a therapeutic perspective completely based on the outcome of the approval of the original medicine under the Pharmaceuticals and Medical Devices Act, which falls under the "approvals prescribed by relevant Acts that are intended to ensure the safety, etc. or any other disposition designated by Cabinet Order as requiring considerable time for the proper execution of the disposition in light of the purpose, procedures, etc. of such a disposition" referred to in Article 67, paragraph (2) of the Act. Regarding this point, there is no difference between generic medicines whose ingredients are completely identical with those of the original medicines and generic medicines which differ from the original medicines in additives, including the Appellee's Products.

In this regard, the Ministry of Health, Labour and Welfare explains as follows: "Test items that are necessary to confirm the effectiveness and safety of a medicine are roughly divided into two kinds, 'tests for active ingredients' and 'tests for medicines which have been made into preparations.' At the time of an examination for approval of the original medicine, the effectiveness and safety of the major ingredient (active ingredient) and preparation of the medicine are confirmed by toxicity tests, pharmacological tests, and clinical tests called clinical trials, etc. On the other hand, a generic medicine is identical with the original medicine in the major ingredient though it differs therefrom in additives. Therefore, the effectiveness and safety of the major ingredient have already been confirmed based on such 'tests for active ingredients' and post-market surveillance data for the original medicine. If it is confirmed that a generic medicine containing the same quantity of the same active ingredient as the original medicine indicates the same blood concentration change as the original medicine, the generic medicine is confirmed to have the same intensity of action and effect as a medicine as the original medicine, and the generic medicine can be determined to be equivalent to the original medicine in terms of therapeutic effect, that is, effectiveness and safety for human beings. The test to make such determination is a bioequivalence test" (Exhibit Ko 30; page 6 of the Ministry of Health, Labour and Welfare's brochure titled "*Jenerikkuiyakuhin eno gimon ni kotaemasu*" (Answers to

questions about generic medicines)). The Ministry of Health, Labour and Welfare made clear that a generic medicine which differs from the original medicine in additives, like the Appellee's Products, is also one for which an approval for manufacturing and sale is given completely based on the confirmation of safety of the original medicine, in the same manner as a generic medicine whose ingredients are identical with those of the original medicine.

Incidentally, the Appellee's Products are exempted even from a bioequivalence test as they fall under "preparations for intravenous injection which are in the form of an aqueous solution at the time of use" (Exhibit Ko 31, page 19 of the attachment to PFSB/ELD Notification 0229 No. 10). Therefore, the Appellee's Products were approved by the Ministry of Health, Labour and Welfare even without submitting any data on bioequivalence, not to mention any data on effectiveness and safety, and were approved completely based on the safety of Elplat I.V. Infusion Solutions, which are the original medicines of Yakult Honsha that is the exclusive licensee of the Invention.

B. Additives which are permitted to be used in generic medicines

A generic medicine is approved completely based on the results of tests for ensuring safety of the original medicine, and additives used therein are strictly regulated.

That is, the Ministry of Health, Labour and Welfare provides as follows: "Additives are substances contained in a preparation other than active ingredients, and are used for the purpose of increasing the usefulness of active ingredients and the preparation, making it easy to formulate a preparation, stabilizing quality, or improving usability, etc. Appropriate additives can be added to a preparation as needed. However, additives used should be those that show no pharmacological action and are harmless at the dose of its preparation. In addition, additives must not prevent the therapeutic effect of active ingredients" (Exhibit Ko 32, Japanese Pharmacopoeia 16th edition [Public Notice of the Ministry of Health, Labour and Welfare No. 65 of March 24, 2011]).

In response to these provisions, the following practice is adopted: "Use examples are available for pharmaceutical additives used in Japan that are listed in 'Japanese Pharmaceutical Excipients Directory,' and such pharmaceutical additives are treated as those for which usage, the amount of use, etc. have been confirmed. The use of such pharmaceutical additives is permitted without need of submitting special data as long as they are used within the scope of 'administration routes' and 'maximum amount of use' described for each individual additive in said directory. The pharmaceutical additives listed in Japanese Pharmaceutical Excipients Directory and their administration routes and the maximum amount of use are based on a list which was prepared based on the results of the survey on the actual conditions of use of pharmaceutical additives conducted by the Ministry of Health, Labour and Welfare, and they are publicly indicated. … As mentioned above, pharmaceutical additives that can be used in Japan

are ordinarily those that are listed in 'Japanese Pharmaceutical Excipients Directory' and are also within the scope of the administration routes and the maximum amount of use described in said directory" (Exhibit Ko 33; Japan Generic Medicines Association, "*Iyakuhintenkazai ni tsuite*" (Regarding pharmaceutical additives), page 1). That is, in actual practice, it is necessary for a person to acquire data on safety, etc. by him/herself to obtain an approval in order to use an additive that has not been used in the past, such as one that is not listed in Japanese Pharmaceutical Excipients Directory (Exhibit Ko 34) or an additive that has been used in the past without complying with the usage, administration route, and maximum amount of use that have been recognized as use examples (Exhibits Ko 37-1 and 37-2).

Concentrated glycerin that is used as an additive in the Appellee's Products is described as a "stabilizer, etc." in terms of [Usage] and as being administered at the dose of up to "12.5 g" per day in the case of "intravenous infusion" in terms of [Administration route/maximum amount of use] in Japanese Pharmaceutical Excipients Directory (Exhibit Ko 34).

In the Appellee's Products, concentrated glycerin is also used as a stabilizer and is added within the scope of [Administration route/maximum amount of use] described in said directory (the maximum amount of use is 220 mg if the maximum dosage per day [130 mg/m^2] is administered to a person having a standard body surface area [1.695 m^2]). In addition, as mentioned above, concentrated glycerin must not have any pharmacological action in the Appellee's Products.

As mentioned above, the Appellee's Products were approved as generic medicines, and concentrated glycerin used as an additive is used in compliance with the usage, administration route, and maximum amount of use described in Japanese Pharmaceutical Excipients Directory (Exhibit Ko 34), which is a list prepared based on the results of the survey on the actual conditions of use of pharmaceutical additives conducted by the Ministry of Health, Labour and Welfare. The Appellee's Products were nothing more than an application of well-known or commonly used art at least at the time when preparation for the manufacturing, sale, etc. of the Appellee's Products as generic medicines was commenced.

Incidentally, Japanese Pharmaceutical Excipients Directory (Exhibit Ko 34) is a book which is extremely widely known among pharmaceutical manufacturers to the extent that no such person can be assumed as not knowing the content of the book. It is obvious that using an additive described therein in compliance with the usage, administration route, and maximum amount of use described therein can be considered as well-known or commonly used art.

(3) Scope of substantially identical products, etc.

It is obvious from court precedents that the patent right for which extension of duration was registered as referred to in Article 68-2 of the Act is effective not only against medicines whose ingredients, efficacy, effects, dosage, and administration are the same as those of the medicine

subject to the patent right but also against medicines which are evaluated as the substantially identical products, etc. of the medicine subject to the patent right (judgment of the Intellectual Property High Court of May 29, 2009 [hereinafter referred to as the "Intellectual Property High Court Judgment on the Pacif Capsule Case"]; judgment of the Special Division of the Intellectual Property High Court of May 30, 2014 [hereinafter referred to as the "Intellectual Property High Court Judgment on the Bevacizumab Case"]).

The scope of substantially identical products, etc. should be considered based on the legislative intent of the system of the registration of extension of duration. This point is as held in the Intellectual Property High Court Judgment on the Bevacizumab Case: "The interpretation of the 'product and usage subject to a disposition designated by Cabinet Order' for a medicine subject to an approval under the Pharmaceutical Affairs Act is a question of how to specify the scope against which a patent right whose duration was extended pursuant to Article 68-2 of the Patent Act is effective. Therefore, such product and usage should be reasonably interpreted in consideration of the purpose of the system of the registration of extension of duration of a patent right (if there is a period during which the patentee is unable to work a patented invention in order to obtain a disposition designated by Cabinet Order though he/she had the intention and ability to work the patented invention, the duration may be extended by a period not exceeding five years) and impartiality between patentees and third parties."

From such perspective, under the Pharmaceuticals and Medical Devices Act, which is one of the "Acts that are intended to ensure the safety, etc." referred to in Article 67, paragraph (2) of the Act, it is reasonable to interpret that not only a generic medicine whose ingredients are the same as those of the original medicine but also a generic medicine which differs from the original medicine only in additives falls under substantially identical products, etc. and that the patent right for which extension of duration was registered is effective against it, because the latter is manufactured and sold after obtaining an approval completely based on the outcome that was obtained as a result of the impossibility of working a patented invention for the purpose of obtaining a disposition for the original medicine, without independently conducting any test, etc. prescribed by laws and regulations for ensuring safety, etc. thereon. It is a reasonable interpretation, taking into account the purpose of the system of the registration of extension of the duration of a patent right and impartiality between patentees and third parties.

It obviously goes against impartiality to permit a person who manufactures and sells a generic medicine which differs from the original medicine in additives, like the Appellee, to make a duplicitous allegation that the generic medicine does not fall under the substantially identical products, etc. of the original medicine because a different additive is used in the generic medicine at the scene of a patent right infringement action despite the fact that he/she obtained an approval for the generic medicine without conducting any test, etc. prescribed by

laws and regulations for ensuring safety, etc. thereon at the scene of obtaining an approval under the Pharmaceuticals and Medical Devices Act by alleging that the generic medicine is substantially identical with the original medicine.

The court of prior instance ruled as follows: "taking into account the purpose of the system of the registration of extension of duration of a patent right, [i.e., permitting extension of patent term … it is reasonable to understand that if it [said subject item] falls under equivalents of … or products that are evaluated as being substantially identical with the "product (used for that usage)" subject to said Cabinet Order Disposition (for example, in the cases where said difference is recognized as a mere addition, deletion, conversion, etc. of well-known or commonly used art and as not producing any new effect in light of the type and subject of the patented invention pertaining to the patent right whose duration was extended …) … the patent right whose duration was extended is also effective against the working of said subject item" (lines 8 to 21 of page 23 of the judgment of prior instance). Thereby, the court of prior instance interpreted that the substantially identical products, etc. against which the patent right for which extension of duration was registered is effective are those for which a difference from the "product" subject to a disposition is a mere addition, deletion, conversion, etc. of well-known or commonly used art and does not produce any new effect.

However, as long as substantially identical products, etc. should be considered based on the purpose of the system of the registration of extension of duration of a patent right, what should be questioned is whether or not an approval was obtained completely based on the outcome that was obtained as a result of the impossibility of working a patented invention for the purpose of obtaining a disposition for the original medicine, without independently conducting any test, etc. prescribed by laws and regulations for ensuring safety, etc. thereon. The court of prior instance questioned the technical evaluation of a difference from the products subject to the dispositions and considered it in light of the ordinary understanding of the technical scope while ruling that substantially identical products, etc. should be considered based on the purpose of the system of the registration of extension of duration of a patent. Therefore, the judgment of prior instance is obviously unreasonable.

As mentioned above, whether or not a generic medicine falls under substantially identical products, etc. should be interpreted based on whether or not an approval for the generic medicine was obtained completely based on the outcome that was obtained as a result of the impossibility of working a patented invention for the purpose of obtaining a disposition for the original medicine, without independently conducting any test, etc. prescribed by laws and regulations for ensuring safety, etc. thereon. Such interpretation also conforms to the legal systems of other countries (United States, South Korea, etc.) concerning the effect of a patent right for which extension of duration was registered, and it is very reasonable.

(4) Regarding the point that the patent right after the registration of extension of duration is also effective even based on the interpretation adopted in the judgment of prior instance

Even based on the interpretation that substantially identical products, etc. are those for which a difference from the "product" subject to a disposition (in this case, Elplat Solutions which are the original medicines of Yakult Honsha, which is the exclusive licensee of the Invention) is a mere addition, deletion, conversion, etc. of well-known or commonly used art and does not produce any new effect, as mentioned in the judgment of prior instance, it is obvious that the Patent Right after the registration of extension of duration is effective against the Appellee's Products.

A. As already mentioned, the Appellee's Products and Elplat Solutions, which are the original medicines, differ in that concentrated glycerin is used as an additive in the Appellee's Products. However, said difference is nothing more than an application of well-known or commonly used art at least at the time when preparation for manufacturing, sale, etc. of the Appellee's Products as generic medicines was commenced. The addition of the concentrated glycerin as a stabilizer also does not produce any new effect. Therefore, the Appellee's Products obviously fall under the substantially identical products, etc. of Elplat Solutions even in accordance with the judgment of prior instance.

On the other hand, the court of prior instance ruled as follows: "there is no sufficient evidence to recognize that addition of concentrated glycerin of the same quantity as oxaliplatin to an aqueous solution of oxaliplatin fell under a mere addition, etc. of well-known or commonly used art as of the time when a test necessary to obtain a Cabinet Order Disposition for the Defendant's Products [Appellee's Products] was commenced. Rather, it can be considered that a new effect in terms of restraining the natural decomposition of oxaliplatin is produced by the glycerin that is added to an aqueous solution of oxaliplatin" (lines 1 to 7 of page 31 of the judgment of prior instance). Based on this ruling, the court of prior instance held that the Appellee's Products fall under the substantially identical products, etc.

However, as mentioned above, the Appellee's Products were exempted from a test that is necessary to obtain a disposition designated by Cabinet Order ("Cabinet Order disposition"), and the time when preparation for manufacturing, sale, etc. of the Appellee's Products was commenced should be considered as the time when the Appellee obtained approvals for the Appellee's Products as generic medicines. The Appellee's Products are those prepared by merely adding concentrated glycerin in compliance with the usage, administration route, and maximum amount of use as described in Japanese Pharmaceutical Excipients Directory (Exhibit Ko 34), which is a list prepared based on the results of the survey on the actual conditions of use of pharmaceutical additives conducted by the Ministry of Health, Labour and Welfare, and it is obvious that said addition is a mere addition of well-known or commonly used art and does not

produce any new effect.

The aforementioned finding and determination in the judgment of prior instance are unreasonable decisions that go against the Ministry of Health, Labour and Welfare's public notice as follows: "Additives are substances contained in a preparation other than active ingredients, and are used for the purpose of increasing the usefulness of active ingredients and the preparation, making it easy to formulate a preparation, stabilizing quality, or improving usability, etc. Appropriate additives can be added to a preparation as needed. However, additives used should be those that show no pharmacological action and are harmless at the dose of its preparation. In addition, additives must not prevent the therapeutic effect of active ingredients" (Exhibit Ko 32).

In the approval procedure under the Pharmaceuticals and Medical Devices Act, the Appellee obtained approvals without submitting any data, etc. concerning concentrated glycerin by alleging that concentrated glycerin is "listed in Japanese Pharmaceutical Excipients Directory and is also within the scope of the administration route and maximum amount of use described in said directory." On the other hand, the Appellee alleged, at the scene of a patent right infringement action, that using concentrated glycerin as an additive does not fall under an addition, etc. of well-known or commonly used art but produces a new effect. It is obvious that acceptance of such duplicitous allegation goes against impartiality.

B. The Appellant conducted a test comparing the Appellee's Products and Elplat Solutions to see the effect of restraining the natural decomposition of oxaliplatin.

The test results are as indicated in the Test Results attached to this judgment.

Here, lower limit difference [i] indicates the value obtained by deducting the lower limit at the start of the test from the lower limit after long-term storage, while upper limit difference [ii] indicates the value obtained by deducting the upper limit at the start of the test from the upper limit after long-term storage (the test results for the Appellee's Products are based on the interview form [Exhibit Ko 39] prepared by the Appellee).

It can be said that the natural decomposition of oxaliplatin is restrained more as lower limit difference [i] is smaller and upper limit difference [ii] is smaller. It can be confirmed from the test results that lower limit difference [i] for the Appellee's Products is not smaller than that for Elplat Solutions and that upper limit difference [ii] for the Appellee's Products is also not smaller than that for Elplat Solutions.

Incidentally, even comparing the Appellee's Products with other generic medicines in the same manner, there was also no significant difference between them.

Therefore, comparing the Appellee's Products with Elplat Solutions, there is no difference between them in the effect of restraining the natural decomposition of oxaliplatin, which is to be caused by glycerin contained in the Appellee's Products. Therefore, even based on these test

results, the finding in the judgment of prior instance that this point "can be deemed to indicate that a new effect is produced" is considered as an obvious error of fact.

C. Concentrated glycerin which is used as an additive in the Appellee's Products is used in compliance with the usage, administration route, and maximum amount of use as described in Japanese Pharmaceutical Excipients Directory (Exhibit Ko 34), and said use is nothing more than an application of well-known or commonly used art, as mentioned above.

In addition to this, making glycerin (glycerol) contained in an aqueous solution of oxaliplatin in varying quantities is a practice which has been generally conducted in the past (Exhibits Ko 40-1 to 40-4). In this regard, addition of concentrated glycerin to an aqueous solution of oxaliplatin can also be considered as nothing more than well-known or commonly used art.

(5) Regarding the point that the Appellee's Products fall within the technical scope of the Invention (supplementation of a counterargument against the Appellee's allegation)

As mentioned later, the Appellee alleges that the Invention is a preparation consisting solely of water and oxaliplatin which is free of any additive and other ingredient and is an invention that excludes the existence of any additive, etc.

However, this point is an issue that has already been settled in the judgment (rendered on March 9, 2016) on another action to seek rescission of a JPO decision (Intellectual Property High Court; 2015 (Gyo-Ke) 10105; hereinafter referred to as "Another Action"). It is obvious that the Appellee's Products containing an additive fall within the technical scope of the Invention.

Moreover, the content of the written opinion in question (Exhibit Otsu 13; the "Written Opinion") questioned by the Appellee is nothing more than an explanation of the invention described in the Description, and it is not an allegation of the point of being "free of any acidic or alkaline agent, buffer or other additive," as a reason for the Invention not falling under Article 29, paragraph (2) of the Act, in order to show a difference from the cited document.

2. Additional allegations of the Appellee in this instance (Regarding Issue 2)

(1) Regarding the scope against which the patent right for which extension of duration was registered is effective

The allegation of the Appellant is erroneous as mentioned below.

First, the Invention is a preparation consisting solely of water and oxaliplatin which is free of any additive or other ingredient (Exhibit Ko 2; lines 43 to 46 of page 2 and lines 2 and 3 of page 3), and it is an invention that excludes the existence of any additive, etc.

On the other hand, it is obvious that the Appellee's Products do not fall within the technical scope of the Invention because they contain concentrated glycerin of the same quantity as oxaliplatin as an additive.

Therefore, the Appellee's Products originally do not fall within the technical scope of the Invention, and are not those that are completely based on the "outcome, such as confirmation of safety, which was obtained as a result of the impossibility of working a patented invention for the purpose of obtaining a disposition for the original medicine."

Secondly, whether or not a product falls under substantially identical products, etc. is supposed to be an issue wherein substantial identity is discussed in relation to the "product subject to the patented invention" for which duration was extended (the act of working the patented invention in relation to the product subject to the disposition) in terms of determining whether or not the product falls within the technical scope of the patented invention for which duration was extended under the Patent Act. However, the Appellant mixes up the approval system for medicines with the patent system and discusses this issue by using whether or not the generic medicine is based on the outcome, such as confirmation of safety of the original medicine, in the approval system for medicines as a ground for determination (the Appellant is trying to discuss dependence on the original medicine in terms of the approval system as if it is the same as dependence on the invention). The Appellant's allegation is erroneous in this point.

Thirdly, the Appellant alleges as if the Invention is one that should be protected as a basic patent for oxaliplatin in terms of the effectiveness and safety of its major ingredient, by discussing the approval system for medicines, and also alleges that the Appellee's Products have been approved completely based on the outcome of the approvals for the Appellant's medicines. Based on this allegation, the Appellant concludes that the Appellee's Products should be interpreted as the substantially identical products, etc. of the Appellant's medicines.

However, the medical effect and basic safety of oxaliplatin had already been established at the time of the filing of the patent application in question, and the Invention was not patented owing to the medical effect of oxaliplatin. The allegation of the Appellant is significantly erroneous in that the Appellant totally forgets the fact that the Invention is nothing more than one which was patented as a patent for a preparation which is characterized merely by its dosage form, that is, as a preparation which contains only "oxaliplatin" and "injectable water" and is free of any other ingredients.

Elplat Solutions, which are obtained merely by changing the dosage form of the Invention, are nothing more than those approved based on the approval standard that is almost the same as the approval standard for generic medicines, and they are virtually generic medicines. That is, Elplat Solutions fall merely under "medicines pertaining to addition of a dosage form" and an application therefor can be filed only by submitting materials that are almost the same as those required for filing an application for a generic medicine ("circled" items in "Appended Table 2-(1) Medicines for Medical Purposes, (7) Medicines pertaining to addition of a dosage form" of Notice [PFSB Notification No. 0331015] (Exhibit Otsu 21)).

In this manner, test items that are necessary to file application for approval for the manufacturing and sale of a medicine in relation to Elplat Solutions are limited, and even if a safety test was conducted for Elplat Solutions, it is nothing more than a safety test of a preparation which is free of any ingredients other than oxaliplatin and injectable water. On the other hand, a safety test of the Appellee's Products which contain concentrated glycerin was conducted separately from the safety test of the preparations of the Appellant ("5. Stability of preparation under various conditions" on page 7 of "Medicine Interview Form" (Exhibit Ko 6)).

Therefore, there is no fact that the Appellee's Products depended on the test of technical features of the preparations pertaining to the Invention.

Fourthly, in terms of the patent whose duration was extended, the "'products used for that usage,' which were unable to be worked because the dispositions in question ("Dispositions") were necessary to obtain" are preparations which contain only oxaliplatin and injectable water and are free of any other ingredients. On the other hand, the Appellee's Products differ from the "products used for that usage" in the "ingredients" as they contain concentrated glycerin, and due to said ingredient, they produce an effect completely different from that of the "products used for that usage" of the Invention, that is, restriction of generation of diaquo *DACH platin dimer* which is especially a concern for its toxicity (for example, Exhibit Otsu 22 (U.S. Patent Publication [US 2006/0063833 A1]) describes that diaquo DACH platin dimer is generated from oxaliplatin ([paragraph [0005]) and that diaquo DACH platin dimer is toxic ([paragraph 0034])). Therefore, it is also obvious that the Appellee's Products cannot be considered as the substantially identical products of the products used for that usage.

(2) Regarding "generic medicines and additives"

The allegation of the Appellant is erroneous because it mixes up the standard for safety handling in the approval system for additives that are used for generic medicines and the relationships between the Invention, "products subject to the patented invention" for which duration was extended (the act of working the patented invention in relation to the products subject to the dispositions), and the additive (concentrated glycerin) of the Appellee's Products.

The issues, such as whether or not the Appellee's Products depend, as generic medicines, on the effectiveness and safety of the original medicines and how the safety of the additive of the Appellee's Products is handled in the approval system, are related to the Invention and the "products subject to the patented invention" for which duration was extended (the act of working the patented invention in relation to the products subject to the dispositions), and are completely unrelated to the standard for determining substantially identical products, etc.

That is, concentrated glycerin is added to the Appellee's Products because the Appellee found new knowledge that addition of concentrated glycerin is effective for restraining the generation of diaquo DACH platin dimer whose toxicity is a concern (Exhibit Otsu 4;

paragraphs [0010] to [0014], etc.).

The Appellee filed a patent application in relation to said knowledge on July 9, 2012, and obtained the registration of establishment of a patent right on July 12, 2013 (Patent No. 5314790; Exhibit Otsu 4 is the patent gazette therefor; hereinafter said patent and the invention pertaining to the patent right are referred to as the "Appellee's Patent" and the "Appellee's Invention," respectively, and Exhibit Otsu 4 is referred to as "Exhibit Otsu 4 Publication"). The Appellee's Products are products in which the Appellee's Invention is worked.

In the same manner as many other additives, concentrated glycerin is also permitted to be used as an additive as long as safety is confirmed in an approval for the manufacturing of a medicine. However, this does not justify the necessity of adding concentrated glycerin to an injectable aqueous solution of oxaliplatin unless concentrated glycerin is found to produce a new effect as mentioned above.

(3) Regarding the "scope of substantially identical products, etc."

The allegation of the Appellant is equivalent to saying that a generic medicine necessarily falls under substantially identical products, etc. in relation to the patent for which extension of duration was registered, irrespective of by what the patented invention for which duration was extended is characterized. It is not discussing the scope of rights of the Invention and of the patented invention for which duration was extended but is discussing the scope of substantially identical products, etc. based only on the fact of being generic medicines. Therefore, the allegation of the Appellant is also obviously erroneous as an interpretation of Article 68-2 of the Act.

That is, the purpose of Article 68-2 of the Act is to limit the technical scope of the patented invention, for which the duration of the patent right is extended, to the products for which the patentee was unable to work the patented invention, as held in the Intellectual Property High Court Judgment on the Pacif Capsule Case. Therefore, it is obvious that the patent right whose duration was extended pursuant to Article 68-2 of the Act is not effective against the products which differ from the products for which the patentee was unable to work the patented invention (products subject to the dispositions) because of a difference in the "ingredients," as in the case of the Appellee's Products.

The issue of whether or not the Appellee's Products fall under the substantially identical products, etc. of the "products used for that usage" subject to the Dispositions leads to considering whether or not the Appellee's Products fall within the technical scope of the patented invention for which duration was further exceptionally extended in relation to the patent right limited as such.

Consequently, it is supposed to be originally necessary to consider what are the "ingredients" which are the matters for examination that specify the "products used for that

usage" subject to the registration of extension of duration in the Invention and whether or not a difference between said ingredients and the "ingredients" of the Appellee's Products can be considered as equivalent to or substantially identical with each other in relation to the technical scope of the Invention.

On the other hand, the Appellant alleges that generic medicines are substantially identical products, etc. without exception if they are those "manufactured and sold by obtaining an approval without independently conducting any test, etc. prescribed by laws and regulations for ensuring safety, etc. thereon." The allegation is intended to state that a medicine is covered by the extended patent right only if it is a generic medicine even if it differs from the product subject to the extended patent right in the "ingredients," by bringing the administrative handling standard that is set from another perspective, i.e., safety of medicines, into the interpretation of the scope of rights under the Patent Act.

However, such allegation goes against the judgment of the Third Petty Bench of the Supreme Court of November 17, 2015, Minshu, Vol 69, No. 7, at 1912 (hereinafter referred to as the "Supreme Court Judgment on the Bevacizumab Case"). In the judgment, the court held that "The matters for examination in both of these dispositions that are directly related to substantial identity as a medicine are the ingredients, quantity, dosage, administration, efficacy, and effects of the medicines," and ruled that substantial identity is lost if "ingredients" differ. That is, according to said judgment, the technical scope of the patented invention pertaining to the original medicine for which the duration of the patent right is extended is limited to the scope of the products which are substantially identical with the patented invention, and substantial identity is not recognized in relation to a generic medicine that differs from the patented invention in the "ingredients." Therefore, the Patent Right after the extension is not effective against the Appellee's Products. The allegation of the Appellee is not at all an interpretation under the Patent Act and also ignores the purpose of Article 68-2 of the Act.

The judgment of prior instance contains no error because the court accurately considers what are the Invention and the "ingredients" specified by the invention subject to the extended patent and whether or not a difference between said ingredients and the "ingredients" of the Appellee's Products can be considered as falling under substantially identical products, etc. in relation to the technical scope of the Invention.

In addition, the Appellant also alleges that the interpretation adopted by the Appellant also conforms to the legal systems of other countries and mentions the systems in the United States and South Korea. However, discussions in these countries and those in Japan significantly differ in the presupposed legal system and the already formed case law. Therefore, such allegation itself is completely meaningless.

(4) Regarding the point that "the patent right after the registration of extension of duration is

also effective even based on the interpretation adopted in the judgment of prior instance"

A. The fact that concentrated glycerin is common in medicines that are listed in Japanese Pharmaceutical Excipients Directory (Exhibit Ko 34) and the fact that it has no effect on pharmacological action and is harmless are not related to a determination concerning whether the Appellee's Products fall under substantially identical products, etc. in relation to the Invention for which extension of duration was registered.

As found in the judgment in prior instance, the Invention is related to a "pharmaceutically stable preparation of oxaliplatinum" and is an invention for which the entirety of the ingredients of the medicine is a characteristic part. The Appellant obtained the Dispositions for Elplat I.V. Solutions (preparations) which contain only oxaliplatin and injectable water and are free of any other ingredients, as a product in which the Invention is worked.

On the other hand, the Appellee's Products contain concentrated glycerin of the same quantity as oxaliplatin, as an ingredient other than the active ingredients, in addition to oxaliplatin and injectable water. Concentrated glycerin was added for the purpose of restraining the generation of diaquo DACH platin that is a related substance generated through decomposition of oxaliplatin and diaquo DACH platin dimer that is a concern for its especially high toxicity (paragraph [0034] of U.S. Patent Publication (Exhibit Otsu 22)) during storage of an aqueous solution of oxaliplatin.

Exhibit Otsu 4 Publication describes as follows in relation to the point that generation of diaquo DACH platin dimer is restrained through addition of glycerin.

"[Table 3]

Table 3: Ratio of decomposition products in the composition after 9-day storage at 70°C

	Compared preparation	Preparation 1	Preparation 2	Preparation 3	Preparation 4	Preparation 5
Ratio of diaquo DACH platin dimer (%)	0.41	0.28	0.22	0.12	0.15	0.12
Ratio of all related substances (%)	1.73	1.50	1.38	1.21	1.12	1.18

[0033]

As it is obvious in Table 3, the ratios of generation of diaquo DACH platin dimer and of all related substances are significantly smaller for all of Preparations 1 to 5 than the compared

preparation, and stability of an aqueous solution of oxaliplatin is improved. In addition, there is a correlation between improvement of stability and concentration of glycerin."

"[Table 4]

Table 4: Ratio of decomposition products in the composition after nitrogen replacement and 9-day storage at 70°C

	Compared preparation	Preparation 1	Preparation 2	Preparation 3	Preparation 4	Preparation 5
Ratio of diaquo DACH platin dimer (%)	0.40	0.25	0.22	0.15	0.13	0.10
Ratio of all related substances (%)	1.39	1.09	1.17	1.05	0.95	0.98

[0036]

As it is seen in Table 4, the ratios of generation of diaquo DACH platin dimer and of all related substances were significantly smaller for all of Preparations 1 to 5 than the compared preparation, and stability of an aqueous solution of oxaliplatin was improved. In addition, the ratios of all related substances for all of the compared preparation and Preparations 1 to 5 decreased in this working example in comparison with Working Example 1 (Table 3), and it was confirmed that nitrogen gas replacement is effective for increasing the stability of oxaliplatin."

On the other hand, the Description and Japanese Pharmaceutical Excipients Directory (Exhibit Ko 34) do not describe such knowledge at all, and it had not been known that addition of concentrated glycerin of the same quantity as oxaliplatin to an aqueous solution of oxaliplatin produces such effect, not only as of the time when a test necessary to obtain the Cabinet Order dispositions for Elplat Solutions was commenced but also as of the priority date of the Invention. Therefore, it cannot be said that addition of concentrated glycerin falls under a mere addition, etc. of well-known or commonly used art.

Moreover, the absence of the need to submit new data on the safety of concentrated glycerin in the approval procedure under the Pharmaceuticals and Medical Devices Act is an issue that is completely separate from whether or not the Appellee's Products in which concentrated glycerin is added fall under the substantially identical products, etc. of the "products used for that usage" subject to the Dispositions in relation to the Invention in the interpretation of the scope of rights of the Invention.

B. The Appellant compares the quantitative values after the storage of the Appellee's Products and Elplat Solutions by using the values stated in the interview forms of those products, respectively, and alleges that glycerin contained in the Appellee's Products does not have the effect of restraining the natural decomposition of oxaliplatin.

However, whether or not the Appellee's Products fall under the substantially identical products, etc. of the "products used for that usage" subject to the Dispositions is an issue of interpretation of the scope of rights in relation to the Invention, and the Appellee's Products should be compared with the "products used for that usage" of the Invention. As determined by the court of prior instance, the Appellee's Products differ from the Invention, for which the entirety of the ingredients of the medicine is a characteristic part, in the ingredients, and said difference in the ingredients cannot be considered to fall under a mere addition, etc. of well-known or commonly used art in relation to the Invention. Therefore, it is meaningless to directly compare Elplat Solutions and the Appellee's Products and discuss the relative merits thereof in the manner as alleged by the Appellant.

In the test results attached to this judgment, the Appellant compares the quantitative values (%) of oxaliplatin, which are not even the values of decomposition products, such as diaquo DACH platin dimer. In addition, those quantitative values exceed 100% (for example, the value for one of Elplat Solutions after a two year-storage is described as "100.26 to 100.51"), and it is clear that the values include errors. Moreover, for said one of Elplat Solutions, the value at the start of the test is described as "99.87 to 100.32." Therefore, if this value is strict, it shows a strange phenomenon for said one of Elplat Solutions, specifically, an increase of oxaliplatin after a two-year storage. This is totally inconsistent.

It is taken for granted that the accuracy of measurement by liquid chromatographic determination, which is adopted for both the Appellee's Products and Elplat Solutions, is "2.0% or less" (Exhibit Otsu 23), and these "quantitative" values of oxaliplatin include measurement errors. Differences in the values after the decimal point indicated by the Appellant are originally nothing more than those within the scope of measurement errors, and therefore, they cannot indicate a difference in the effect between the Appellee's Products and Elplat Solutions. It is impossible to discuss the quantity of decomposition products by comparing slight numerical differences in the upper and lower limits of oxaliplatin, which contain such measurement errors. Therefore, comparison conducted by the Appellant is completely meaningless.

As shown in [Table 3] and [Table 4] of Exhibit Otsu 4 Publication, the effect of restraining the generation of diaquo DACH platin dimer in the Appellee's Products differs by around 0.2 to 0.3% compared to the compared preparation in which no glycerin is added. It is not made clear how the quantity of diaquo DACH platin dimer changes after storage for a certain period by comparing the values of oxaliplatin in the Appellant's interview form.

Therefore, comparison conducted by the Appellant does not confirm that there is no difference between the effect of the Appellee's Products and that of Elplat Solutions.

C. In addition, the Appellant alleges that it has been a general practice to make glycerin contained in an aqueous solution of oxaliplatin, and cites Exhibits Ko 40-1 to 40-4, etc.

However, although these publications include those cited in the examination process of the application for the Appellee's Patent of Exhibit Otsu 4, none of them describe or suggest concentrated glycerin's effect of restraining the generation of diaquo DACH platin dimer in the Appellee's Invention. The Appellee's Invention was patented despite existence of those publicly-known examples. Therefore, it is obvious that the Appellee's Products in which said invention is worked do not fall under an addition, etc. of well-known or commonly used art.

No. 4 Court decision

This court also determines that the Patent Right whose duration was extended is not effective against the production, etc. of the Appellee's Products by the Appellee and that there is no reason for the claims in question.

The reasons thereof are as follows.

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

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

Article 68-2 of the Act provides that "Where the duration of a patent right is extended (including the case where the duration is deemed to have been extended under Article 67-2, paragraph (5)), such patent right shall not be effective against any act other than the working of the patented invention for the product which was the subject of the disposition designated by Cabinet Order under 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, the product used for that usage)."

This provision stipulates that the patent right whose duration was extended is effective not against the working of the entire scope of the patented invention but against 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)," taking into account that the system of the registration of extension of duration of a patent right is "intended to recover the period during which the patented invention is unable to be worked due to the need to obtain a Cabinet Order disposition" (Supreme Court Judgment on the Bevacizumab Case).

Said Article was stipulated in the manner as mentioned above for the following reason: It is considered necessary, for relieving a patentee who was unable to work the patented invention due to the need to obtain a Cabinet Order disposition, to have the extended patent right be

effective within said scope of the "product subject to a Cabinet Order disposition" (including the "product used for that usage"; the same applies hereinafter), but having the extended patent right be effective beyond said scope results in favorably treating the patentee beyond the extent necessary to eliminate disadvantage by recovery of the duration, which not only goes against the aforementioned purpose of the system of the registration of extension but also leads to lack of impartiality between the patentee and third parties.

(2) Regarding the scope of the act of working the patented invention for the "product which was the subject of the disposition designated by Cabinet Order" referred to in Article 68-2 of the Act

The Cabinet Order (Article 2 of the Order for Enforcement of the Patent Act) limits dispositions which constitute a reason for the registration of extension to two kinds of dispositions, specifically, approval under the Pharmaceuticals and Medical Devices Act and approval under the Agricultural Chemicals Control Act. In the case where the "disposition designated by Cabinet Order" is one pertaining to the former approval (approval for a medicine prescribed in the Pharmaceuticals and Medical Devices Act) like in this case, the following is recognized.

A. Article 14, paragraph (1) of the Pharmaceuticals and Medical Devices Act provides that "A person who intends to market pharmaceuticals … shall obtain approval from the Minister of Health, Labour and Welfare for each such item." The matters subject to examination that is necessary to obtain an approval for a medicine pertaining to said paragraph are provided as "name, ingredients, quantity, dosage, administration, efficacy, effects, side effects and other quality, effectiveness and safety related matters" (Article 14, paragraphs (2) and (9) of said Act).

According to this, where the "disposition designated by Cabinet Order" is an approval for a medicine prescribed in the Pharmaceuticals and Medical Devices Act, "dosage, administration, efficacy, and effects" are always included in the matters for examination. As "dosage, administration, efficacy, and effects" are included in "usage," said approval is understood as falling under the case "where the specific usage of the product is prescribed by the disposition" stated in the parentheses in Article 68-2 of the Act.

In a medicine subject to an approval under the Pharmaceuticals and Medical Devices Act, the "product which was the subject of a disposition designated by Cabinet Order" and "usage" referred to in Article 68-2 of the Act are those that specify the scope against which the patent right whose duration was extended is effective. Therefore, these matters should be reasonably interpreted in consideration of the purpose of the system of the registration of extension of duration of a patent right (where there is a period during which the patentee is unable to work a patented invention in order to obtain a disposition designated by Cabinet Order though he/she has the intention and ability to work the patented invention, the duration may be extended by a period not exceeding five years) and impartiality between patentees and third parties.

In that case, first, as mentioned above, the matters subject to examination that is necessary to obtain an approval for a medicine are the "name, ingredients, quantity, dosage, administration, efficacy, effects, side effects and other quality, effectiveness and safety related matters" of the medicine, and an approval is obtained for each "item" specified by these elements. Therefore, these elements formally serve as standards for defining the "product" and "usage."

However, in light of the purpose of the system of the registration of extension of duration of a patent right, it is not reasonable if the effect of a patent right is limited even where there is a difference in a matter for examination that is not directly related to substantial identity as a medicine, and it is reasonable to define the scope against which an extended patent right is effective by specifying the "product" and "usage" within the scope of "ingredients, quantity, dosage, administration, efficacy, and effects" of the medicine, taking into account that the matters for examination that are directly related to substantial identity as a medicine are said matters (Supreme Court Judgment on the Bevacizumab Case) for a patented invention of a product for the ingredient of a medicine.

Then, "ingredients and quantity" affect objective identity as a "product" itself but cannot fall under "usage" in terms of the nature thereof. Therefore, it is reasonable to consider them as matters to specify the "product." "Dosage, administration, efficacy, and effects" do not affect objective identity as a "product" itself but can fall under "usage" as mentioned above. Therefore, it is reasonable to consider them as the elements that specify the "usage."

Incidentally, "ingredients" subject to examination that is necessary to obtain an approval prescribed in the Pharmaceuticals and Medical Devices Act are not limited to ingredients that exert any medical effect (active ingredients). Therefore, "ingredients" mentioned here are needless to say not limited to active ingredients.

On these bases, it is reasonable to understand that in the case of a patented invention of a product for the ingredient of a medicine, the patent right whose duration was extended is effective against the "working of the patented invention" for the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" specified by a specific Cabinet Order disposition (however, "usage" in the registration of extension is more limited than the "dosage, administration, efficacy, and effects" in a Cabinet Order disposition which constituted a reason for the registration of extension, the "dosage, administration, efficacy, and effects" as the aforementioned elements to define the scope of effect are also naturally limited by the "usage" in the registration of extension; the same applies hereinafter).

B. According to A. above, if the product manufactured, etc. by the other party (hereinafter referred to as the "subject product") has a different part in "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by a specific Cabinet Order disposition, the subject product cannot be considered to fall under the scope against which the patent right

whose duration was extended is effective. However, if it is possible to easily escape from the exercise of rights, such as an injunction, by the patentee unless the subject product and the product subject to the Cabinet Order disposition are identical with each other in all of the aforementioned matters for examination prescribed by the Cabinet Order disposition as a result of formal comparison between them, it not only goes against the purpose of the system of the registration of extension, that is, recovering the period during which the patented invention was unable to be worked due to the need to obtain a Cabinet Order disposition, but is also against the principle of impartiality. From such perspective, it should be said that a patented invention pertaining to a patent right whose duration was extended is effective not only against the "product" (medicine) specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by a Cabinet Order disposition but also against products which are substantially identical with said product as a medicine. Third parties should expect this (incidentally, Article 68-2 of the Act provides that a patent right "shall not be effective against any act other than the working of the patented invention for the product …," but the "working of the patented invention" for the "product" in said Article should be considered as including both the literal working of said patented invention for the "product" and the working of said patented invention within the scope of substantial identity).

Therefore, even if there is a part that differs from the subject product in the aforementioned structures prescribed by a Cabinet Order disposition, if said part is merely a slight difference or formal difference as a whole, it is reasonable to understand that the subject product is included in the products which are substantially identical with the product subject to the Cabinet Order disposition as a medicine and falls within the scope against which the patent right whose duration was extended is effective.

C. Only looking at the cases where the subject product differs from a patented invention of a product for the ingredients of a medicine in any one or more of the "ingredients" prescribed by a Cabinet Order disposition or quantitative matters such as the "quantity" and "dosage and administration" and does not differ in other points, whether or not such differences are slight differences or formal differences as a whole should be determined in light of the common general technical knowledge of persons ordinarily skilled in the art and based on the content of the patented invention (including whether or not the patented invention is an invention that is characterized only by the active ingredient of the medicine, whether or not it is an invention for the stability or dosage form, etc. of the active ingredient of the medicine on the premise of the existence of the active ingredient, or what is the content of the technical features and function and effect; the same applies hereinafter) by comparatively considering identity between the technical features and function and effect of the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by a Cabinet Order disposition and

those of the subject product.

In the aforementioned limited case, the types of cases where the subject product is included in the products that are substantially identical as a medicine with the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by a Cabinet Order disposition are as follows.

That is, in the following cases, differences fall under the aforementioned slight differences or formal differences as a whole, and the subject product should be considered as being included in the products that are substantially identical as a medicine with the product subject to a Cabinet Order disposition (incidentally, types [i], [iii], and [iv] below are those in which the subject product is virtually and presumptively recognized as being identical with the product subject to the Cabinet Order disposition in the technical features and function and effect): [i] where in the subject product, a different ingredient is partially added, converted, etc. based on well-known or commonly used art as of the time of the filing of an application for the Cabinet Order disposition in relation to the "ingredients" of a patented invention, which is characterized only by the active ingredient of a medicine and for which extension of duration was registered, which are not active ingredients; [ii] where, in the subject product, a different ingredient is partially added, converted, etc. based on well-known or commonly used art as of the time of the filing of an application for the Cabinet Order disposition in a patented invention for the stability or dosage form, etc. of a medicine pertaining to a publicly known active ingredient, and the subject product and the product subject to the Cabinet Order disposition are recognized as being identical with each other in the technical features and function and effect in light of the content of the patented invention; [iii] where there is only a quantitatively meaningless difference between the subject product and the product subject to the Cabinet Order disposition in terms of the "quantity" or "dosage and administration" prescribed by the Cabinet Order disposition; and [iv] where the subject product and the product subject to the Cabinet Order disposition differ in the "quantity" prescribed by the Cabinet Order disposition but are recognized as being identical with each other in consideration of "dosage and administration" (Dispositions 1 and 2, and Dispositions 5 to 7 fall under this case).

On the other hand, this does not apply if there is a difference between the subject product and the product subject to the Cabinet Order disposition in the "dosage, administration, efficacy, and effects" of the medicine, except for the aforementioned limited case. This is because, for example, where a difference other than a quantitative difference arises in "dosage and administration" due to a difference in dosage form (e.g. spray and injection), it is necessary to examine the difference from multiple points of view according to the specific content of the difference. In addition, if "efficacy and effects" differ between the subject product and the product subject to the Cabinet Order disposition due to a difference in the subject diseases, it is

considered important to examine the difference from medical perspectives, such as the similarity of the diseases.

D. In the judgment of the Third Petty Bench of the Supreme Court of February 24, 1998, Minshu, Vol. 52, No. 1, at 113 (Supreme Court Judgment on the Ball Spline Bearing Case), the court established the following five requirements for equivalence in relation to the technical scope of the patented invention: [i] a part in which the structure stated in the scope of claims and the subject product, etc. differ is not the essential part of the patented invention; [ii] even if said part is replaced with the corresponding part of the subject product, etc., the purpose of the patented invention can be achieved and the same effect and function can be obtained; [iii] a person ordinarily skilled in the art to which the invention pertains (a person ordinarily skilled in the art) could have easily arrived at the aforementioned replacement at the time of the manufacturing, etc. of the subject product, etc.; [iv] the subject product, etc. is neither identical with publicly known art at the time of the filing of the patent application for the patented invention nor is one which a person ordinarily skilled in the art could have easily presumptively arrived at based on such publicly known art at the time of said filing; and [v] there are no special circumstances, such as the fact that the subject product, etc. falls under those that were intentionally excluded from the scope of claims in the patent application procedures for the patented invention (hereinafter requirements [i] to [v] mentioned above are referred to as the "First Requirement" to the "Fifth Requirement" in order of precedence). Therefore, whether or not these requirements are applicable or analogically applicable becomes a problem in the case of determining the scope of substantial identity referred to in Article 68-2 of the Act.

However, equivalence in terms of the technical scope of a patented invention defines the extension of the technical scope of the patented invention, and the applicable situation differs from that where the aforementioned substantial identity is applicable within the scope against which the patent right for which the registration of extension was granted on the premise of a specific Cabinet Order disposition is effective. Therefore, if the First to Third Requirements are applied as they are, this will excessively extend the scope against which the patent right for which extension of duration was registered referred to in Article 68-2 of the Act is effective, and is not reasonable.

That is, as it is obvious when considering the Dispositions, if the scope of equivalence is considered by applying the First to Third Requirements as they are in relation to the "working of the patented invention" for the "product" specified by each Cabinet Order disposition, products specified by respective Cabinet Order dispositions are all equivalents to each other, or the scope of equivalence for each of such products can extend to the technical scope of the patented invention or the scope of equivalence thereof. Therefore, it is obvious that such scope is excessively broad as the scope against which the patent right for which extension of duration was registered referred to in Article 68-2 of the Act is effective.

Moreover, regarding analogical application of the five requirements of the doctrine of equivalents, as multiple Cabinet Order dispositions are often rendered for one specific medicine (for example, the Dispositions), if these requirements are to be analogically applied, it is necessary to define the scope of specific "products" specified by Cabinet Order dispositions in the manner that each of the specific "products" specified by Cabinet Order dispositions has a certain broadness within an appropriate scope and the scope of substantial identity is not excessively broad (for example, for multiple Cabinet Order dispositions (for example, the Dispositions), in the manner that the products subject to some of the dispositions which differ in quantity are considered to be substantially identical, but all of them are not included in the scope of substantial identity).

However, first, looking at the First Requirement, it is difficult to assume a requirement for such analogical application. That is, the First Requirement is analogized as requiring that a difference between the "product" specified by a Cabinet Order disposition and the subject product is not the essential part of the "product" specified by the Cabinet Order disposition. In order to analogically apply the First Requirement in the manner that the scope of substantial identity does not become excessively broad, it is considered necessary to appropriately assume the essential part of the "product" specified by the Cabinet Order disposition (the more specific concept of the essential part of the patented invention), but such assumption is generally difficult. In addition, the Second Requirement is analogized as requiring the identity of function and effect between the "product" specified by a Cabinet Order disposition and the subject product. This requirement is considered as one of the necessary conditions for substantial identity, but it alone results in making the scope of substantial identity excessively broad. Therefore, in order to analogically apply the Second Requirement, it is necessary to take into consideration the First Requirement and other requirements. Consequently, it is difficult to assume the requirement for the analogical application of the Second Requirement.

On these bases, it is impossible to apply or analogically apply the aforementioned five requirements in determining the scope of substantial identity referred to in Article 68-2 of the Act.

E. However, based on the idea of general estoppel, it is considered that substantial identity referred to in Article 68-2 of the Act is not recognized if there are special circumstances, such as that the subject product falls under those that were intentionally excluded from the scope against which the patent right for which extension of duration was registered is effective in the application procedures for the registration of extension.

(3) Regarding the point that the subject product falls within the technical scope (including equivalents) of the patented invention

Article 68-2 of the Act provides for a system intended to relieve a patentee who was unable to substantially exercise his/her patent right due to extension of the duration of the patent right, and does not provide for a system intended to enlarge the technical scope of a patented invention.

Therefore, in order to find infringement of a patent right whose duration was extended, it is naturally necessary to allege and prove the fact that the subject product falls within the technical scope (including equivalents) of the patented invention. Incidentally, this is also obvious from the provisions of Article 68-2 of the Act that a patent right whose duration was extended "shall not be effective against any act other than the working of the patented invention" for the product which was the subject of a Cabinet Order disposition.

2. Consideration of this case

On these bases, a determination is made on whether or not the Patent Right for which extension of duration was registered is effective against the production, etc. of the Appellee's Products.

(1) Regarding whether or not the Appellee's Products are identical with the products subject to the Dispositions

In the case of a patented invention of a product for the ingredient of a medicine, a patent right whose duration was extended under Article 68-2 of the Act is effective within the scope of the "working of the patented invention" for the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects."

Seeing this point in terms of this case, as mentioned in No. 2, 2.(4)A. above, a medicine subject to Dispositions 1, 3, and 5 is Elplat 50, a medicine subject to Dispositions 2, 4, and 6 is Elplat 100, and a medicine subject to Disposition 7 is Elplat 200. According to evidence (Exhibit Ko 3), the composition and nature thereof are recognized as follows.

	Elplat 50	Elplat 100	Elplat 200
Content of oxaliplatin per vial	50 mg/10 mL	100 mg/20 mL	200 mg/40 mL
pH	4.0 to 7.0		
Osmotic pressure ratio (ratio to normal saline solution)	Approx. 0.04		
Nature (appearance)	Colorless and clear liquid		

In addition, according to evidence (Exhibits Ko 3, 4, and 11-1 to 11-6 and Exhibits Otsu 3-1 to 3-3 and 17 to 19) and the entire import of the oral argument, Elplat 50, Elplat 100, and Elplat 200 differ only in "quantity" among "ingredients" and "quantity," and regarding "ingredients," all of them contain only "oxaliplatin" and "injectable water" and are free of any other ingredients (however, after 12-month and 24-month storage at 25°C±2°C/60%RH±5%RH, they sometimes come to contain oxalic acid to a degree that slightly exceeds 0.1 wt% [in the range between 5 X 10^{-5}M to 1 X 10^{-4}M in terms of molarity]; this is caused by the natural occurrence of oxalate ions due to the decomposition of oxaliplatin in the aqueous solution according to

time).

The Patent Right for which extension of duration was registered is effective within the scope of the "working of the patented invention" for the "products" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by the Dispositions, and the "ingredients" prescribed by the Dispositions literally include only oxaliplatin and injectable water and do not include any other ingredients for all of said products.

On the other hand, the "ingredients" of the Appellee's Products include concentrated glycerin of the same quantity as oxaliplatin as an additive, in addition to oxaliplatin and injectable water, and concentrated glycerin is used as a stabilizer, as mentioned in No. 2, 2(4)B. above.

In that case, there is no other choice but to say that the products subject to the Dispositions and the Appellee's Products literally differ at least in "ingredients," and whether or not the Appellee's Products can be considered to be substantially identical with the products subject to the Dispositions as referred to in Article 68-2 of the Act should be determined while considering the difference in this point as a slight difference or formal difference as a whole.

In this regard, the Appellant alleges that all of the Appellee's Products fall under the products subject to the Dispositions because they contain oxaliplatin as the only active ingredient. However, where a Cabinet Order disposition is an approval for a medicine prescribed in the Pharmaceuticals and Medical Devices Act, "ingredients" as a matter to specify the product which was unable to be worked due to the need to obtain said Cabinet Order disposition are not limited to active ingredients, as indicated above. Therefore, the allegation of the Appellant should be considered to be unacceptable.

(2) Whether or not the Appellee's Products are included in those that are substantially identical with the products subject to the Dispositions

It is necessary to find and determine whether or not the aforementioned difference in "ingredients" between the Appellee's Products and the products subject to the Dispositions is a slight difference or formal difference as a whole and is a difference that falls within the scope of substantial identity in light of the common general technical knowledge of persons ordinarily skilled in the art and based on the content of the Invention by comparatively considering identity between the technical features and function and effect of the "products" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by the Dispositions and those of the subject products.

A. Looking at the statements in the Description, according to evidence (Exhibit Ko 2), the following statements are recognized.

"[Detailed explanation of the invention]

This invention is related to a pharmaceutically stable preparation of oxaliplatinum for

administration by the parenteral route.

Oxaliplatinum … is an optical isomer prepared … from a mixture of diaminocyclohexane derivatives (dach-platinum) … this complex compound of platinum is known to exhibit a therapeutic activity comparable or superior to that of other known complex compounds of platinum, such as cis-platinum.

… oxaliplatinum is a cytostatic antineoplastic agent which can be used in the therapeutic treatment of various types of cancer.

… At the present time, oxaliplatinum is available for pre-clinical and clinical trials in vials as lyophilisate for reconstruction just before the administration and for dilution with a 5% glucose solution, with injectable water or an isotonic 5% glucose solution, and the administration being carried out by infusion, intravenously.

However, such a dosage form implies the use of a manufacturing process (lyophilization), which is relatively complicated and expensive, as well as a reconstitution step, which requires both skill and care. Furthermore, in practice, such a method has proved to carry the risk of an error being made when reconstituting extemporaneously the solution; in actual fact, it is quite common to use a 0.9% NaCl solution for the reconstitution of injectable pharmaceutical preparations from lyophilisate or for the dilution of liquid preparations. The mistaken use of such a solution in the case of the lyophilized form of oxaliplatinum would be quite harmful to the active ingredient, which would form a precipitate (dichlolo-dach-platinum derivative) with NaCl and would bring about the rapid breakdown of said product.

Thus, in order to avoid all risk of misuse of the product and to make available to the medical practitioner or the nurse an oxaliplatinum preparation that may be used without the need of the above-mentioned operations, investigations were made to obtain an injectable solution of oxaliplatinum that would be ready to use and which, furthermore, would remain pharmaceutically stable before use for an acceptable duration of time according to recognized standards, and be easier and less expensive to manufacture than lyophilisates, while exhibiting a chemical purity (absence of isomerization) and therapeutic activity equivalent to those of the reconstituted lyophilisate. This is the purpose of this invention.

The inventors were able to show that this purpose can be attained, in a totally surprising and unexpected manner, by using, as the dose form for the administration by the parenteral route, an aqueous solution of oxaliplatinum, wherein the concentration of the active ingredient and the pH are within well-determined ranges respectively and wherein the active ingredient is free of any acidic or alkaline agent, buffer or other additive. It was found, in particular, that aqueous solutions of oxaliplatinum having a concentration less than approximately 1 mg/ml are not sufficiently stable.

Accordingly, the purpose of this invention is a stable pharmaceutical preparation of

oxaliplatinum for administration by the parenteral route, wherein the oxaliplatinum is dissolved in water at a concentration in the range from 1 to 5 mg/ml and at a pH in the range from 4.5 to 6, with the oxaliplatinum content in the preparation representing at least 95% of the initial content and the solution remaining clear, colorless and free of any precipitate after a storage of a pharmaceutically acceptable duration. This preparation is free of any other ingredients and should, in principle, not contain more than about 2% of impurities." (line 11 of page 2 to line 3 of page 3).

B. According to the above statements in the Description, oxaliplatinum is a publicly known cytostatic antineoplastic agent which can be used in the therapeutic treatment of various types of cancer, and the Invention is created for the purpose of obtaining an aqueous solution of oxaliplatinum that exhibits a chemical purity and therapeutic activity equivalent to the lyophilisate of oxaliplatinum (which falls under the patented inventions of type [ii] stated in 1.(2)C.). The Description then describes that the purpose of the Invention can be attained by using an "aqueous solution of oxaliplatinum that is free of any acidic or alkaline agent, buffer or other additive," in addition to specifying the concentration and pH of the active ingredient to fall within a limited scope. The Description also states that "This preparation is free of any other ingredients and should, in principle, not contain more than about 2% of impurities."

According to this, it is found that, in the Invention, the fact that the aqueous solution of oxaliplatinum is free of any additive constitutes one of the technical features of the Invention, in addition to the act of specifying the concentration and pH of the active ingredients to fall within a limited scope.

According to the above, the aforementioned difference in "ingredients" between the products subject to the Dispositions and the Appellee's Products (i.e., the products subject to the Dispositions are an aqueous solution consisting solely of oxaliplatinum and injectable water, while the Appellee's Products are those prepared by adding concentrated glycerin of the same quantity as oxaliplatinum to said aqueous solution) cannot be considered as a slight difference or formal difference as a whole in light of the aforementioned technical features of the Invention. Therefore, the Appellee's Products cannot be considered to be included in those that are substantially identical with the products subject to the Dispositions.

C. Consequently, the Appellee's Products cannot be considered to fall within the scope against which the Patent Right for which extension of duration was registered is effective, as products created by an act substantially identical with the working of the Invention for the "products" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" that were subject to the Dispositions.

(3) Regarding whether or not the Appellee's Products fall within the technical scope of the Invention

A determination is also made on whether or not the Appellee's Products fall within the technical scope of the Invention.

Regarding the issue of whether Constituent Feature C, "consisting of an aqueous solution of oxaliplatinum," as stated in the scope of claims of the Invention, means that the aqueous solution consists solely of oxaliplatinum and water, or that the aqueous solution consists of oxaliplatinum and water and can also contain other ingredients, such as additives, either interpretation is possible based on the statement of the scope of claims. Therefore, fulfillment of Constituent Feature C is determined in consideration of the statements in the Description and the prosecution history.

A. The statements in the Description are as mentioned in (2)A. above.

B. According to evidence (Exhibits Ko 1 and 2 and Exhibits Otsu 12-1 to 12-3, 13, and 14) and the entire import of the oral argument, the prosecution history of the Patent is as follows.

(A) On August 7, 1995, the Appellant filed a patent application for an invention titled "pharmaceutically stable preparation of oxaliplatinum" (the "Application").

Incidentally, the Application was an international application (International Application PCT/IB1995/000614; Patent Application No. 1996-507159; Publication of Japanese Translation of PCT International Application No. 1998-508289; Priority date: August 8, 1994; Priority country: Swiss Confederation).

(B) On July 11, 2003, the Appellant received a notice of reasons for refusal based on Article 29, paragraph (2) of the Act (Exhibit Otsu 12-1) from the JPO.

Said notice of reasons for refusal cites Publication of Unexamined Patent Application No. 1978-031648, the pamphlet of International Publication No. 94/12193, and Publication of Unexamined Patent Application No. 1991-024017 (hereinafter these documents are referred to as "Cited Document 1" to "Cited Document 3," respectively) as cited documents, and the following was stated in the remarks column.

"Cited Document 1 describes an invention of an antitumor medicine consisting of oxaliplatinum, but said invention differs from the invention claimed in the aforementioned claims (note in this judgment: referring to Claims 1 to 9) of the patent application in that it is not stated that a stable aqueous solution is obtained.

However, Cited Document 2 describes that a pharmaceutical composition consisting of cisplatin and oxaliplatinum is administered in the form of aqueous solution. In addition, Cited Document 3 describes that the concentration of cisplatin and the pH of the aqueous solution are adjusted for the purpose of obtaining a stable aqueous solution of cisplatin.

Therefore, it is what a person ordinarily skilled in the art could have easily done to constitute the invention claimed in the aforementioned claims of the patent application by adjusting the concentration of oxaliplatinum and the pH of the aqueous solution in the invention

described in Cited Document 1 for the purpose of obtaining a stable preparation of oxaliplatinum.

Moreover, regarding effects, the invention claimed in the aforementioned claims of the patent application is not recognized as having an especially advantageous effect compared to the inventions described in Cited Documents 1 to 3."

(C) In response, the Appellant submitted a written opinion (the "Written Opinion"; Exhibit Otsu 13) on January 21, 2004, and expressed the following opinion.

"[2] Explanation of the claimed invention

As stated in line 20 of page 3 to line 23 of page 4 in the description attached to the patent application, the purpose of the claimed invention is [i] to obtain a stable preparation of aqueous solution of oxaliplatinum, [ii] to ensure that the pH of said preparation is in the range from 4.5 to 6, and furthermore [iii] to ensure that said aqueous solution is free of any acidic or alkaline agent, buffer or other additive. The pH of the aforementioned solution in the patent application is unique to said solution, and it depends only on the concentration of the aqueous solution of oxaliplatinum. As described in detail in [3] below, oxaliplatinum is an organometallic complex and has the nature of the coordination bond being very weak. Therefore, a stable aqueous solution of oxaliplatinum can be obtained only by the structure of the claimed invention." (lines 12 to 21 of page 2)

"[3] Reason for the claimed invention not falling under Article 29, paragraph (2) of the Patent Act

[3-1] Regarding Cited Document 1

… Cited Document 1 describes an invention of an antitumor medicine consisting of oxaliplatinum, but does not describe that a stable aqueous solution is obtained.

[3-2] Regarding Cited Document 2

Cited Document 2 describes a composition containing oxaliplatinum and cisplatin. Said composition is a lyophilisate containing cisplatin, oxaliplatinum, and a buffer, as stated in the claims, and reconstitution for making it into a solution is required.

However, Cited Document 2 does not describe that a 'stable' medicine in the form of aqueous solution containing these compounds is obtained. Furthermore, …

[3-3] Regarding Cited Document 3

Cited Document 3 describes that a stable aqueous solution of cisplatin is obtained and that said aqueous solution contains NaCl and citric acid.

… However, even if a person ordinarily skilled in the art tries to obtain a stable aqueous solution of oxaliplatinum according to the process described in Cited Document 3, it is difficult to do so by using oxaliplatinum. This is because …

… As mentioned above, oxaliplatinum is very weak and is particularly very vulnerable to

citric acid. The coordination of citric acid in oxaliplatinum is susceptible to replacement by another ligand due to carboxylic group.

Therefore, it is very difficult for a person ordinarily skilled in the art to obtain a stable aqueous solution of oxaliplatinum according to the process described in Cited Document 3." (line 25 of page 2 to line 18 of page 4)

"[4] Summary

As mentioned in [3-1] to [3-3], for all the prior art documents (note in this judgment: "prior art documents" should be read as "cited documents"; the same applies hereinafter), the described inventions are not intended to obtain a stable aqueous solution despite a nature unique to oxaliplatinum, that is, the coordination bond of the complex being weak and being particularly very vulnerable to citric acid, and there is no statement that discloses or suggests the following special effects determined (note in this judgment: "determined" should be read as "produced") by the claimed invention: a stable preparation of aqueous solution of oxaliplatinum obtained thereby does not require reconstitution at the time of administration of the solution; a risk of a mistake or accident is very low; and the medical practitioner can immediately use it when necessary.

Therefore, the claimed invention is not one which a person ordinarily skilled in the art can easily arrive at or conceive of based on the inventions described in Prior Art Documents 1 to 3. In addition, a person ordinarily skilled in the art cannot easily arrive at or conceive of the claimed invention even by combining these inventions. Therefore, the claimed invention is patentable in terms of Prior Art Documents 1 to 3.

As mentioned above, the inventions claimed in Claims 1 to 9 of the patent application are not those that a person ordinarily skilled in the art could have easily made based on the inventions described in Cited Documents 1 to 3. Therefore, they do not fall under the provisions of Article 29, paragraph (2) of the Patent Act" (line 24 of page 4 to line 10 of page 5).

(D) After this, the Appellant received an examiner's decision to grant a patent on March 19, 2004, and obtained the registration of the Patent Right on April 23 of the same year.

C. According to the aforementioned statements in the Description, oxaliplatinum is a publicly known cytostatic antineoplastic agent which can be used in the therapeutic treatment of various types of cancer, and the Invention is created for the purpose of obtaining an aqueous solution of oxaliplatinum that exhibits chemical purity and therapeutic activity equivalent to the lyophilisate of oxaliplatinum. The Description describes that the purpose of the Invention can be attained by using an "aqueous solution of oxaliplatinum that is free of any acidic or alkaline agent, buffer or other additive," in addition to specifying the concentration and pH of the active ingredient to fall within a limited scope. The Description also states that "This preparation is free of any other ingredients and should, in principle, not contain more than about 2% of

impurities."

On the other hand, the Description states nothing about inconvenience that arises in the case where "said aqueous solution" contains "any acidic or alkaline agent, buffer or other additive." In addition, the working examples do not indicate any specific conditions for the existence or absence of additives, and there is no statement about comparative examples in which these additives are contained.

However, the following facts are purposely clearly stated in the Written Opinion submitted by the Appellant in the aforementioned prosecution history: The purpose of the Invention is "to obtain a stable preparation of aqueous solution of oxaliplatinum", "to ensure that the pH of said preparation is in the range from 4.5 to 6," and "to ensure that said aqueous solution is free of any acidic or alkaline agent, buffer or other additive"; Furthermore, the pH of the aqueous solution is unique to said solution, and it depends only on the concentration of the aqueous solution of oxaliplatinum; A "stable aqueous solution" of oxaliplatinum can be obtained only by the structure of the Invention in terms of the nature of oxaliplatinum. Based on these statements, it is specifically explained in the Written Opinion that such "stable aqueous solution" cannot be obtained by Cited Documents 1 to 3 cited by the examiner, or that it is (very) difficult to obtain a "stable aqueous solution of oxaliplatinum" by using a lyophilisate containing a buffer or an aqueous solution containing citric acid.

On that basis, the Written Opinion leads to the conclusion that the Invention does not fall under Article 29, paragraph (2) of the Act, and requests the examiner's reconsideration. As a result, the Appellant received the examiner's decision to grant a patent.

Comprehensively considering the aforementioned statements in the Description and such prosecution history, the problem to be solved of the Invention is to obtain an injectable solution of oxaliplatinum that is ready to use which remains pharmaceutically stable for an acceptable duration of time according to recognized standards and exhibits a chemical purity and therapeutic activity equivalent to those obtained from lyophilisate. The Invention indicates dissolution of oxaliplatinum in water at a concentration in the range from 1 to 5 mg/ml and at a pH in the range from 4.5 to 6 as a means for solving the problem. Furthermore, the Invention also indicates the following as an equivalent means for solving the problem: "Said aqueous solution is free of any acidic or alkaline agent, buffer or other additive."

On these bases, there is no other choice but to construe that the phrase which reads "consisting of an aqueous solution of oxaliplatinum" (Constituent Feature [C]) contained in the statements in the scope of claims of the Invention means that the Invention is an aqueous solution which consists solely of oxaliplatinum and water and contains no other ingredients, such as additives.

On the other hand, the Appellee's Products contain concentrated glycerin of the same

quantity as oxaliplatin as an ingredient other than the active ingredients. Therefore, there is no other choice but to say that the Appellee's Products do not fall within the technical scope of the Invention without the need to make determination on the other structures (incidentally, as mentioned in (1) and (2), in this case, a determination concerning the scope against which the patent right for which extension of duration was registered as referred to in Article 68-2 of the Act is effective was first made; however, this was only as a result of consideration of the development and content of this case, and by any ordinary understanding, it should be considered to first determine whether or not the other party's product falls within the technical scope of the patented invention).

(4) Summary

On these bases, the Patent Right for which extension of duration was registered is not effective against the Appellee's Products.

3. Determinations are made on the additional allegations of the Appellant in this instance to the necessary extent.

(1) The Appellant alleges as follows: As long as whether or not a product falls under substantially identical products, etc. within the scope against which the patent right for which extension of duration was registered is effective should be considered based on the purpose of the system of the registration of extension of duration of a patent right, what should be questioned is "whether or not an approval was obtained completely based on the outcome that was obtained as a result of the impossibility of working a patented invention for the purpose of obtaining a disposition for the original medicine, without independently conducting any test, etc. prescribed by laws and regulations for ensuring safety, etc. thereon"; therefore, it is erroneous to consider it in light of the ordinary understanding of the technical scope; even a generic medicine that differs from the original medicine in additives, like the Appellee's Products, should also be interpreted as naturally falling under substantially identical products, etc. if it is manufactured and sold after obtaining an approval completely based on an outcome, such as confirmation of safety, which was obtained as a result of impossibility of working a patented invention for the purpose of obtaining a disposition for the original medicine, without independently conducting any test, etc. prescribed in laws and regulations for ensuring safety, etc. thereon (as the grounds for this allegation, the Appellant cites the positioning of the Appellee's Products as generic medicines and the existence of strict regulations on additives used in generic medicines).

However, the allegation of the Appellant is, in short, equivalent to determining that all items that are approved as a generic medicine fall under substantially identical products, etc. (the patented invention for the original medicine is effective against them) from the perspective of the approval system for medicines, and it ignores the purpose of the system referred to in Article 68-2 of the Act and the interpretation of said Article, and is unacceptable.

That is, a generic medicine is a preparation that contains the same active ingredients as those of the original medicine and is administered by the same route as the original medicine, and it is a medicine which is in principle identical with the original medicine in efficacy and effects as well as dosage and administration and by which the same level of clinical effect and action as the original medicine can be obtained. As a premise, there is no basic difference in effectiveness and safety between a generic medicine and the original medicine. In addition, though an additive that differs from those used in the original medicine can be used in a generic medicine, a substance that exerts a pharmacological action or prevents the therapeutic effect of the active ingredients cannot be used in a generic medicine as an additive. In obtaining an approval as a medicine, it is necessary to confirm by a bioequivalence test that the blood concentration behavior of the major ingredient is equivalent to that of the original medicine (Exhibit Ko 30 and the entire import of the oral argument). In this manner, a generic medicine is approved for manufacturing and sale as one that is equivalent to the original medicine from a therapeutic perspective, and it is supposed to be offered to the market as a medicine that can substitute for the original medicine. Therefore, it is natural that a generic medicine originally depends on the original medicine in terms of quality as a medicine. However, this only means that a generic medicine is in principle identical with the original medicine in active ingredients and therapeutic effect (including effectiveness and safety) and does not question whether or not the generic medicine depends on the outcome of the original medicine from the perspective of a patented invention.

On the other hand, substantial identity in terms of the scope against which a patent right for which extension of duration was registered is effective is a concept that defines the scope against which the patent right is effective. As mentioned above, [i] the provisions of Article 68-2 of the Act stipulate that the patent right whose duration was extended is effective not against the working of the entire scope of the patented invention but against 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)," taking into account that the system of the registration of extension of duration of a patent right is intended to recover the period during which the patented invention was unable to be worked due to the need to obtain a Cabinet Order disposition. [ii] It is reasonable to understand that in the case of a patented invention of a product for the ingredient of a medicine, the patent right whose duration was extended under Article 68-2 of the Act is effective within the scope of the "working of the patented invention" for the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by a specific Cabinet Order disposition. [iii] However, even if the scope against which said patent right is effective is defined by these elements, it goes against the purpose of the system of the

registration of extension and is also against the principle of impartiality if the patent right for which extension of duration was registered is not effective against a product due to the existence of a slight or formal difference in these elements. Therefore, it should be considered that the extended patent right is effective against those that are substantially identical with the medicine subject to a Cabinet Order disposition even if there is such difference.

Consequently, substantial identity in relation to a difference in "ingredients" or a difference in quantitative matters such as the "quantity" and "dosage and administration" which does not affect "efficacy and effects" within the scope against which the patent right for which extension of duration was registered is effective should be determined in light of the common general technical knowledge of persons ordinarily skilled in the art and based on the content of the patented invention by comparatively considering identity between the technical features and function and effect of the "product" specified by the "ingredients, quantity, dosage, administration, efficacy, and effects" prescribed by a Cabinet Order disposition and those of the subject product, and it should not be discussed only from the perspective of active ingredients and therapeutic effect (effectiveness and safety) as a medicine apart from these matters. It is at least obvious that Article 68-2 of the Act is not intended to have the patent right be immediately effective against a product for the reason that the product is a generic medicine, that is, for the reason that the product has the same quality as the original medicine and depends on the original medicine.

The allegation of the Appellant is intended to discuss the scope against which an extended patent right is effective with a focus only on active ingredients and therapeutic effect as a medicine, irrespective of the content of the patented invention, and it obviously goes against the purpose of the system referred to in Article 68-2 of the Act and the interpretation of said Article as mentioned above. Therefore, said allegation should be considered to be unacceptable.

(2) The Appellant alleges as follows: The Appellee's Products are those prepared by merely adding concentrated glycerin in compliance with the usage, administration route, maximum amount of use as described in Japanese Pharmaceutical Excipients Directory (Exhibit Ko 34), which is a list prepared based on the results of the survey on the actual conditions of use of pharmaceutical additives conducted by the Ministry of Health, Labour and Welfare, and it is obvious that said addition is a mere addition of well-known or commonly used art and does not produce any new effect; therefore, the Appellee's Products fall under substantially identical products, etc. even in accordance with the judgment in prior instance; in addition, the Appellant conducted a test comparing the Appellee's Products and Elplat Solutions to see the effect of restraining the natural decomposition of oxaliplatin, and the results are as indicated in the Test Results attached to this judgment; according to the results, there was no difference in said effect.

However, a difference, i.e., the Appellee's Products contain concentrated glycerin of the

same quantity as oxaliplatin in addition to oxaliplatin and injectable water, cannot be considered as a slight difference or formal difference as a whole in light of the content and technical features of the Invention as found above. Therefore, the Appellee's Products cannot be considered to be substantially identical with the Invention. This is not affected by whether or not the addition of concentrated glycerin is a mere addition of well-known or commonly used art and whether or not it has the effect of restraining the natural decomposition of oxaliplatin.

Therefore, the allegation of the Appellant is unacceptable without the need to make determination on the propriety thereof.

(3) The Appellant alleges as follows: The interpretation of the phrase "consisting of an aqueous solution of oxaliplatinum" in the scope of claims is an issue that has already been settled in the judgment on another action, and it is obvious that the Appellee's Products containing an additive fall within the technical scope of the Invention; in addition, the content of the Written Opinion (Exhibit Otsu 13) questioned by the Appellee is nothing more than an explanation of the invention stated in the Description, and it is not an allegation of the point of being "free of any acidic or alkaline agent, buffer or other additive," as a reason that the Invention does not fall under Article 29, paragraph (2) of the Act, in order to show a difference from the cited document.

However, another action pointed out by the Appellant is originally an action to seek rescission of a JPO decision that was instituted by the party other than the Appellee in this case, and a determination in the reasons in said action is not binding at all to the proceedings and determination in this case.

Moreover, according to the instruction in 2.(3)C. above, it is obvious that the allegation of "being free of any acidic or alkaline agent, buffer or other additive" in the Written Opinion was made just for the purpose of explaining a difference from the invention described in the cited document and was also made as a reason for not falling under Article 29, paragraph (2) of the Act.

Therefore, the aforementioned allegation of the Appellant is also unreasonable.

No. 5 Conclusion

On these bases, the judgment in prior instance dismissing all of the Appellant's claims is reasonable, and there is no reason for this appeal filed by the Appellant.

Therefore, the judgment shall be rendered in the form of the main text.

Intellectual Property High Court, Special Division

Presiding judge: SHITARA Ryuichi

Judge: SHIMIZU Misao

Judge: TAKABE Makiko

Judge: TSURUOKA Toshihiko

Judge: TERADA Toshihiko

(Attachment)

Appellee's Product List

1. Oxaliplatin I.V. Infusion 50 mg "Towa"
2. Oxaliplatin I.V. Infusion 100 mg "Towa
3. Oxaliplatin I.V. Infusion 200 mg "Towa"

(Attachment) Registrations of Extensions of Durations

No.	Application No. (Filing date)	Period of extension	Date of registration of extension	Description of the disposition designated by Cabinet Order under Article 67, paragraph (2) of the Patent Act			
				Disposition which constitutes a reason for the registration of extension of duration of the patent right	Number specifying the disposition	Product subject to the disposition	Usage specified for the product subject to the disposition
1	2009-700142 (2009.Nov.20)	4 years, 5 months, and 22 days	October 6, 2010	Approval set forth in Article 14, paragraph (1) of the Pharmaceutical Affairs Act pertaining to a medicine provided in said paragraph	Approval No: 22100AMX02237000	Oxaliplatin (Brand/trade name: Elplat I.V. Infusion Solution 50 mg)	Postoperative adjuvant chemotherapy for colon cancer
2	2009-700145 (2009.Nov.20)	11 months and 21 days	October 6, 2010	Approval set forth in Article 14, paragraph (1) of the Pharmaceutical Affairs Act pertaining to a medicine provided in said paragraph	Approval No: 22100AMX02236000	Oxaliplatin (Brand/trade name: Elplat I.V. Infusion Solution 100 mg)	Postoperative adjuvant chemotherapy for colon cancer
3	2009-700143 (2009.Nov.20)	4 years, 5 months, and 22 days	October 17, 2012	Approval set forth in Article 14, paragraph (1) of the Pharmaceutical Affairs Act pertaining to a medicine provided in said paragraph	Approval No: 22100AMX02237000	Brand/trade name: Elplat I.V. Infusion Solution 50 mg Active ingredient: Oxaliplatin	Unresectable advanced or recurrent colorectal cancer Postoperative adjuvant chemotherapy for colon cancer

4	2009-700144 (2009.Nov.20)	4 years, 5 months, and 22 days	October 17, 2012	Approval set forth in Article 14, paragraph (1) of the Pharmaceutical Affairs Act pertaining to a medicine provided in said paragraph	Approval No: 22100AMX02236000	Brand/trade name: Elplat I.V. Infusion Solution 100 mg Active ingredient: Oxaliplatin	Unresectable advanced or recurrent colorectal cancer Postoperative adjuvant chemotherapy for colon cancer
5	2014-700029 (2014.Mar.19)	2 years, 9 months, and 21 days	June 18, 2014	Approval set forth in Article 14, paragraph (9) of the Pharmaceutical Affairs Act pertaining to a medicine provided in said paragraph	Approval No: 22100AMX02237000	Brand/trade name: Elplat I.V. Infusion Solution 50 mg Active ingredient: Oxaliplatin	Unresectable pancreas cancer
6	2014-700030 (2014.Mar.19)	2 years, 9 months, and 21 days	June 18, 2014	Approval set forth in Article 14, paragraph (9) of the Pharmaceutical Affairs Act pertaining to a medicine provided in said paragraph	Approval No: 22100AMX02236000	Brand/trade name: Elplat I.V. Infusion Solution 100 mg Active ingredient: Oxaliplatin	Unresectable pancreas cancer
7	2014-700031 (2014.Mar.19)	2 years, 9 months, and 21 days	June 18, 2014	Approval set forth in Article 14, paragraph (9) of the Pharmaceutical Affairs Act pertaining to a medicine provided in said paragraph	Approval No: 22400AMX01369000	Brand/trade name: Elplat I.V. Infusion Solution 200 mg Active ingredient: Oxaliplatin	Unresectable pancreas cancer

(Attachment)

Test Results

Name		At the start of the test	25℃, 60% RH 2 years (24 months)	Lower limit difference [i]	Upper limit difference [ii]
Elplat I.V. Infusion Solution 50 mg (original medicine)	Fixed quantity (%)	99.87 to 100.32	100.26 to 100.51	-0.39	-0.19
Oxaliplatin I.V. Infusion 50 mg "Towa"	Fixed quantity (%)	101.7 to 102.3	101.0 to 101.6	0.7	0.7

Name		At the start of the test	25℃, 60% RH 2 years (24 months)	Lower limit difference [i]	Upper limit difference [ii]
Elplat I.V. Infusion Solution 100 mg (original medicine)	Fixed quantity (%)	98.34 to 98.92	100.15 to 100.43	-1.81	-1.51
Oxaliplatin I.V. Infusion 100 mg "Towa"	Fixed quantity (%)	100.8 to 101.3	99.8 to 101.6	1.0	-0.3

Name		At the start of the test	25℃, 60% RH 1.5 years (18 months)	Lower limit difference [i]	Upper limit difference [ii]

Elplat I.V. Infusion Solution 200 mg (original medicine)	Fixed quantity (%)	100.01 to 100.19	99.93 to 100.41	0.08	-0.22
Oxaliplatin I.V. Infusion 200 mg "Towa"	Fixed quantity (%)	100.4 to 101.7	99.6 to 101.1	0.8	0.6