Judgment rendered on March 30, 2016; the original was delivered on the same day; court clerk

2015 (Wa) 12414 Case of Seeking Injunction against Patent Right Infringement

Date of conclusion of oral argument: February 15, 2016

Judgment

Plaintiff: Debiopharm International S.A.

Counsel attorney: OHNO Seiji

Same as above: OHNO Hiroyuki

Counsel patent attorney: MATSUTOYA Yuko

Defendant: Towa Pharmaceutical Co., Ltd.

Counsel attorney: YOSHIZAWA Takao

Counsel patent attorney: KONNO Akio

Same as above: INAMI Minoru

Patent attorney as an assistant in court: ITO Takeyasu

Main text

1. All of the plaintiff's claims shall be dismissed.

2. The plaintiff shall bear the court costs.

3. For the plaintiff, the additional period for filing an appeal against this judgment shall be specified as 30 days.

Facts and reasons

No. 1 Claims

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

2. The defendant shall dispose of the preparations stated in 1 to 3 of the Defendant's Product List attached to this judgment.

No. 2 Outline of the case

1. Summary of the case

The plaintiff, who is the patentee of Patent No. 3547755 (**hereinafter referred to as the "Patent"; the patent right pertaining thereto is referred to as the "Patent Right"**), alleged that the preparations stated in the Defendant's Product List attached to this judgment (**hereinafter each of the preparations is referred to as "Defendant's Product 1," etc. in accordance with the number assigned thereto in said attachment, and these preparations are collectively referred to as the "Defendant's Products"**), which are manufactured and sold by the defendant, fall within the technical scope of the invention claimed in Claim 1 in the scope of claims (**hereinafter referred to as the "Invention"**; incidentally, **hereinafter the part of the Patent pertaining to the Invention is referred to as the "Patent for the Invention,"** taking into account that whether or not a patent is recognized as one that should be

invalidated by a trial for patent invalidation should be determined with respect to each claim) in the description attached to the application for the Patent (**hereinafter referred to as the "Description"**; incidentally, as the Patent is related to an application filed before June 30, 2003, the Description includes the scope of claims [Article 1, item (ii) and Article 3, paragraph (1) of the Supplementary Provisions of Act No. 24 of 2002; Cabinet Order No. 214 of 2003]) and that the Patent Right for which the registration of extension of duration was obtained is effective against the production, assignment, and offering for assignment (**hereinafter sometimes referred to as the "production, etc."**) of the Defendant's Products by the defendant. Based on this allegation, the plaintiff filed this action against the defendant to seek an injunction against the production, etc. of the Defendant's Products and disposal thereof.

2. Facts on which the decision is premised (facts on which the parties agree or facts that are easily recognized based on the evidence, etc. shown later)

(1) Parties

The plaintiff is a Swiss corporation engaging in the business of manufacturing, selling, exporting, or otherwise handling medicines, etc.

The defendant is a stock company engaging in the business of manufacturing, selling and purchasing, exporting, importing, or otherwise handling medicines, etc.

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

The plaintiff is the patentee of the Patent with the following content. The plaintiff 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 (**hereinafter, each of the registrations is referred to as "Registration of Extension 1," etc. in accordance with the number assigned thereto in said attachment, and these registrations are collectively referred to as 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 (**hereinafter each of the dispositions is referred to as "Disposition 1," etc. in accordance with the number assigned thereto in said attachment, and these dispositions are collectively referred to as the "Dispositions"**) are as described in the "Description of the disposition designated by Cabinet Order under Article 67, paragraph (2) of the Patent Act" column in said attachment (Exhibits Ko 1 and 2).

Patent number: Patent No. 3547755

Date of registration: April 23, 2004

Application number: Patent Application No. 1996-507159

(International application number: PCT/IB1995/00614)

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 (**hereinafter each constituent feature pertaining to segmentation is referred to as "Constituent Feature [A]," etc. corresponding to reference letters**).

[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) Defendant's act

A. The defendant first obtained approvals for the manufacturing and sale of a medicine from the Minister of Health, Labour and Welfare on August 15, 2014 for Defendant's Products 1 and 2, as generic medicines of "Elplat I.V. Infusion Solution 50 mg" (**hereinafter referred to as "Elplat 50"**) and "Elplat I.V. Infusion Solution 100 mg" (**hereinafter referred to as "Elplat 100"**), both of which are manufactured and sold by Yakult Honsha Co., Ltd. (**hereinafter referred to as "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 defendant started selling these medicines on the same day (Exhibit Ko 6). In addition, the defendant also subsequently obtained an approval for the manufacturing and sale of a medicine from the Minister of Health, Labour and Welfare for Defendant's Product 3, as a generic product of "Elplat I.V. Infusion Solution 200 mg" (**hereinafter referred to as "Elplat 200"; it, together with Elplat 50 and Elplat 100, are collectively referred to as "Elplat I.V. Infusion**

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 Defendant's Product 1 (Product name: Oxaliplatin I.V. Infusion 50 mg "Towa"), Defendant's Product 2 (Product name: Oxaliplatin I.V. Infusion 100 mg "Towa"), and Defendant's Product 3 (Product name: Oxaliplatin I.V. Infusion 200 mg "Towa") are as follows, respectively (Exhibit Ko 5). The efficacy and effects and dosage and administration of the Defendant's Products are identical with those of Elplat I.V. Infusion Solutions (the parties agree on this point). In addition, the Defendant'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

	Oxaliplatin I.V. Infusion 50 mg "Towa"	Oxaliplatin I.V. Infusion 100 mg "Towa"	Oxaliplatin I.V. Infusion 200 mg "Towa"
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

	Oxaliplatin I.V. Infusion 50 mg "Towa"	Oxaliplatin I.V. Infusion 100 mg "Towa"	Oxaliplatin I.V. Infusion 200 mg "Towa"
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 Defendant's Products 1 and 2 (Exhibit Ko 6).

(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 unresectrable 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

(1) Whether or not the Defendant's Products fulfill Constituent Features [C], [D], and [G] (Issue 1)

(2) Whether or not the Defendant's Products are the products subject to the Dispositions or equivalents thereof, or products which are evaluated as being substantially identical with the products subject to the Dispositions (Issue 2)

(3) Whether or not the Invention comes to lack 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 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 concerning the issues

1. Regarding Issue 1 (whether or not the Defendant's Products fulfill Constituent Features [C], [D], and [G])

[Allegations of the plaintiff]

(1) Structures of the Defendant's Products

Showing the structures of Defendant's Product 1, 2, and 3 in comparison with the constituent features of the Invention, they are as described in 1, 2, and 3, respectively, in the Description of Defendant's Products attached to this judgment.

(2) Regarding fulfillment of Constituent Feature [C]

A. Structure [c] of the Defendant's Products corresponds to Constituent Feature [C] "consisting of an aqueous solution of oxaliplatinum."

B. The defendant alleges that the Defendant's Products do not fulfill Constituent Feature [C] as they contain glycerin of the same quantity as oxaliplatinum (oxaliplatin).

However, a liquid is an "aqueous solution of oxaliplatinum" as mentioned in Constituent Feature [C] if it is a liquid wherein oxaliplatinum is dissolved in water. Even if such liquid contains a substance, such as glycerin, it remains an "aqueous solution of oxaliplatinum" as long as it contains oxaliplatinum (in the JPO decision [Exhibit Ko 10] which was rendered on April 22, 2015, regarding the trial for patent invalidation in relation to the Patent [Invalidation Trial No. 2014-800083], the JPO gave an instruction to the effect that the term "consisting of" is not an "expression that is used in the sense that other elements are not constituent elements," and indicated a determination based on the premise that the Invention may contain the third ingredient other than oxaliplatinum; moreover, it is common general technical knowledge of persons ordinarily skilled in the art that even an aqueous solution containing solute other than oxaliplatin is also called an "aqueous solution of oxaliplatin" [Exhibits Ko 14 and 15 and Exhibit Otsu 4].).

Both the statements in the Description and those in the written opinion dated January 21, 2004 (**hereinafter referred to as the "Written Opinion"**; Exhibit Otsu 13), as pointed out by the defendant, only mention the fact that the purpose of the Invention could have been achieved by using an aqueous solution of oxaliplatinum which does not contain any additives, etc., and these statements do not mean that in the Invention, the solution must not contain any ingredient other than "oxaliplatinum" and water.

The defendant also makes an allegation about the interpretation of an "aqueous solution of oxaliplatinum" through comparison with the claims for the corresponding U.S. application (Application No. 08/776240), but there is no ground for the application of U.S. practice to the Patent, which is a Japanese patent.

(3) Regarding fulfillment of Constituent Feature [D]

A. Structure [d] of the Defendant's Products corresponds to Constituent Feature [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."

B. The "pharmaceutically acceptable duration of time" mentioned in Constituent Feature [D] is understood as a "duration generally required in the art" on the basis of the statements in the Description, and a period of "3 to 5 years at room temperature or at the temperature of a refrigerator" is an example thereof.

Long-term storage tests for two years and one and a half years were conducted for the Defendant's Products, and the defendant is considered to determine these durations as "durations" "required" "in the art." Moreover, 24-month long-term storage tests have been conducted for the products of other generic medicine manufacturers that sell Elplat I.V. Infusion

Solutions and preparations of an aqueous solution of oxaliplatin (Exhibits Ko 4 and 16-1 to 16-13).

Therefore, it is obvious that the period of two years (24 months) or one and a half years (18 months) for the Defendant's Products is included in the "durations" "required" "in the art."

(4) Regarding fulfillment of Constituent Feature [G]

A. Structure [g] of the Defendant's Products corresponds to Constituent Feature [G] "a pharmaceutically stable preparation of oxaliplatinum."

B. Many generic medicine manufacturers, including the defendant, make a statement to the effect that the medicine is "stable for two years" in a document attached to the medicine. The expression "pharmaceutically stable" is used in comparison with the conditions where a "freeze-dried preparation" was used by reconstituting it through dissolution in water in the past, and persons ordinarily skilled in the art understand that meaning.

(5) Summary

As mentioned above, all of the Defendant's Products fulfill Constituent Features [C], [D], and [G] of the Invention (the defendant also agrees that the Defendant's Products fulfill Constituent Features [A], [B], [E], and [F]). Therefore, the Defendant's Products fall within the technical scope of the Invention.

[Allegations of the defendant]

(1) Structure of the Defendant's Products

All of the Defendant's Products contain glycerin of the same quantity as oxaliplatinum.

(2) Regarding fulfillment of Constituent Feature [C]

A. In Constituent Feature [C] "consisting of an aqueous solution of oxaliplatinum," the part "consisting of" was provided in French as "constitueé par" in the scope of claims as of the filing date of the international application pertaining to the Patent. When said international application was transferred into the national phase in the United States (U.S. Application No. 08/776240), the expression "constitueé par" was translated into "consisting of" in English in the "Claims," and this English translation was translated into Japanese (Exhibits Otsu 1 and 2). Therefore, the corresponding Japanese translation is synonymous with the expression "consisting of," which is used to state constituents in a limited manner. Therefore, the phrase "consisting of an aqueous solution of oxaliplatinum" means that the Invention is an aqueous solution consisting solely of oxaliplatinum and water and that no other additives are contained.

B. The following is clearly stated in the Description: This purpose "can be attained by using oxaliplatinum wherein the active ingredient is free of any acidic or alkaline agent, buffer or other additive"; "This preparation is free of any other ingredients and should, in principle, not contain more than about 2% of impurities" (see Exhibit Ko 2 [line 43 of page 2 to line 3 of page 3]). Taking this fact into account, the Invention can be considered to be an aqueous solution

consisting solely of "oxaliplatinum" and "water" and can also be considered not to contain any other additives.

C. The plaintiff, who is the applicant of the Patent, received a notice of reasons for refusal from the JPO examiner in the application procedures. In response to that, the plaintiff alleged in the Written Opinion that "the aqueous solution is free of any acidic or alkaline agent, buffer, or other additive" in the Invention, and thereby obtained an examiner's decision to the effect that a patent is to be granted. Consequently, it goes against the good faith principle and is impermissible for the plaintiff to allege in this action that the Invention can contain an "additive" (file wrapper estoppel).

(3) Regarding Constituent Feature [D]

Constituent Feature [D] "a pharmaceutically acceptable duration of time" is understood as a period of "3 to 5 years" as stated in the Description. However, the plaintiff has not proven that the Defendant's Products fulfill Constituent Feature [D] after storage for such a period.

(4) Regarding Constituent Feature [G]

The term "pharmaceutically stable" in Constituent Feature [G] "a pharmaceutically stable preparation of oxaliplatinum" is understood as having a meaning unique to the Invention, such as "no isomerization for a certain period of time," taking into account the following statement in the Description: The term "pharmaceutically stable" is "understood as referring to the stability of the specific rotatory power of oxaliplatinum, namely the optical purity of the solution (no isomerization." However, the plaintiff has not proven at all the point that the Defendant's Products have "stability" in such sense.

(5) As mentioned above, the Defendant's Products cannot be considered to fulfill Constituent Features [C], [D], and [G] of the Invention. Therefore, they do not fall within the technical scope of the Invention.

2. Regarding Issue 2 (whether or not the Defendant's Products are the products subject to the Dispositions or equivalents thereof, or products which are evaluated as being substantially identical with the products subject to the Dispositions)

[Allegations of the plaintiff]

(1) Regarding the point that the Defendant's Products fall under the products subject to the Dispositions

A. The Dispositions are approvals for manufacturing and sale, which were obtained as a result of filing applications for approval while designating oxaliplatin as the active ingredient. For all of the Defendant's Products, oxaliplatin is the only active ingredient. Therefore, the Defendant's Products fall under the products subject to the Dispositions.

B. The defendant also recognizes that the "usage" of the Defendant's Products is identical with the "usage" of the products subject to the Dispositions. Therefore, the Patent Right pertaining to

the Registrations of Extensions is also effective against the Defendant's Products.

(2) Regarding the point that the Defendant's Products fall under at least equivalents of the products subject to the Dispositions, which constituted a reason for the Registrations of Extensions

Even if the allegation mentioned in (1)A. above is unacceptable, concentrated glycerin contained in the Defendant's Products is just an additive. In addition, approvals for the Defendant's Products were obtained by utilizing the clinical performance that was used in the Dispositions as it is, on the premise that they have bioequivalence with the products subject to the Dispositions (Elplat 50, Elplat 100, or Elplat 200). Therefore, the Defendant's Products fall under at least equivalents of the products subject to the Dispositions.

[Allegations of the defendant]

(1) Regarding the point that the Defendant's Products do not fall under the products subject to the Dispositions

The Defendant's Products contain concentrated glycerin. However, the products subject to the Dispositions (Elplat 50, Elplat 100, or Elplat 200) are specified as containing only "oxaliplatin" and "injectable water" as "ingredients" but not containing any other ingredients (Exhibits Ko 11-1 to 11-3).

Therefore, it is clear that the Defendant's Products do not fall under the products subject to the Dispositions as long as they differ from the products subject to the Dispositions in terms of the "ingredients" (incidentally, it goes without saying that the "ingredients" are not limited to those that produce a medical effect [active ingredients]).

(2) Regarding the point that the Defendant's Products do not fall under equivalents of the products subject to the Dispositions or products that are evaluated as being substantially identical with the products subject to the Dispositions

In the first place, according to the statements in the Description, being a preparation consisting solely of oxaliplatin and water should be considered to be the essential part of the Invention (see Exhibit Ko 2 [line 43 of page 2 to line 3 of page 3]), while the Defendant's Products also contain concentrated glycerin. Therefore, the Defendant's Products differ from the Invention in the essential part.

Moreover, the Defendant's Products came to contain concentrated glycerin against the background that in the case of an aqueous solution wherein only oxaliplatin is dissolved in injectable water, related substances and dimers are sometimes generated through decomposition of oxaliplatin, and the defendant found that it is useful to add three-carbon polyol (glycerin) for restraining such decomposition. The defendant filed a patent application based on these pieces of knowledge and obtained Patent No. 5314790 (Exhibit Otsu 4). The Defendant's Products are those in which the invention pertaining to said patent is worked, and they contain concentrated

glycerin as an "ingredient" for a purpose that differs from the purpose of the Invention. By containing concentrated glycerin, the Defendant's Products produce an effect that the Invention does not have, and they are neither equivalents of the Invention nor fall under equivalents of the products subject to the Dispositions or products that are evaluated as being substantially identical with the products subject to the Dispositions.

3. Regarding Issue 3 (whether or not the Invention comes to lack novelty or an inventive step by citing Exhibit Otsu 5 or 9 as the primarily cited document)

[Allegations of the defendant]

(1) Regarding the background information about the Invention

A patent application was filed for oxaliplatin as an application for a substance patent on September 6, 1976, and publication of the examined patent application was made on September 13, 1985. After that, the application was registered as Patent No. 1314396, and the duration expired on September 6, 1996. Oxaliplatin is a substance that had been publicly known before the priority date of the Patent. In addition, it had been publicly known to use a high-purity aqueous solution of oxaliplatin as an anticancer drug.

The Invention is one that was made only by specifying pH as being "4.5 to 6" and adding the fact of being "pharmaceutically stable" to the constituent features in relation to the publicly known aqueous solution of oxaliplatin, and it is thus substantially identical with the publicly known aqueous solution of oxaliplatin or at least an invention which a person ordinarily skilled in the art could have easily made based on the publicly known aqueous solution of oxaliplatin.

That is, as described in detail later, the Invention comes to lack novelty or an inventive step by citing Exhibit Otsu 5 or 9 as the primarily cited document, and the patent for the Invention is recognized as one that should be invalidated by a trial for patent invalidation. Therefore, the plaintiff is unable to exercise the Patent Right against the defendant.

(2) Ground for Invalidation 1 (lack of novelty or an inventive step by citing Exhibit Otsu 5 as the primarily cited document)

As mentioned below, the Invention is substantially identical with the invention (**hereinafter referred to as "Exhibit Otsu 5 Invention"**) described in Publication of Unexamined Patent Application No. 1994-211883 (**hereinafter referred to as "Exhibit Otsu 5 Document"**; Exhibit Otsu 5), which is a publication that was distributed before the priority date of the Patent, or could have been easily made by a person ordinarily skilled in the art based on Exhibit Otsu 5 Invention or Exhibit Otsu 5 Invention and the knowledge (**hereinafter referred to as "Exhibit Otsu 7 Knowledge"**) described in "*Yakugaku Zasshi* (Journal of the Pharmaceutical Society of Japan), vol. 105 (10) (1985): 909-925" (Exhibit Otsu 7).

A. Common features between the Invention and Exhibit Otsu 5 Invention

Comparing the Invention and Exhibit Otsu 5 Invention, [0.5%H_2O], which was obtained by

using oxaliplatin with high optical purity in Exhibit Otsu 5 Invention, is an aqueous solution equivalent to one at a concentration of 5mg/ml. There is no room for inclusion of impurities, and [0.5%H_2O] is identical with the "aqueous solution of oxaliplatinum" at a concentration of "1 to 5 mg/ml" in the Invention.

Moreover, as Exhibit Otsu 5 Invention is intraperitoneally administered in a mouse, it is also identical with the Invention in that it is "for the administration by the parenteral route."

Incidentally, "cis-oxalato (trans-1-1,2-cyclohexanediamine) Pt (II)" of Exhibit Otsu 5 Invention is a compound that is identical with "oxaliplatinum" (generic name: oxaliplatin) in the Invention.

B. Formal differences between the Invention and Exhibit Otsu 5 Invention

The Invention and Exhibit Otsu 5 Invention formally differ from each other in the following points.

The "aqueous solution of oxaliplatinum" of the Invention is specified as "having a pH of 4.5 to 6." On the other hand, there is no statement about pH value in Exhibit Otsu 5 Invention (Difference 1).

The Invention is "a pharmaceutically stable preparation, 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." On the other hand, there is no such statement in Exhibit Otsu 5 Invention (Difference 2).

C. Regarding Difference 1

As indicated in the written experiment report dated September 1, 2015 (Exhibit Otsu 6), the written experiment report (2) dated October 21 of the same year (Exhibit Otsu 8), and the written experiment report (4) dated December 15 of the same year (Exhibit Otsu 15), the defendant conducted the additional tests and confirmatory experiments of Exhibit Otsu 5 Invention (**hereinafter referred to as "Exhibit Otsu 6 Experiment," etc., respectively**) and thereby confirmed that the pH values are in the range from "4.5 to 6." That is, if high-purity oxaliplatin is dissolved in water, the pH value naturally becomes as specified by the Invention.

Therefore, the structure of the Invention pertaining to Difference 1 is nothing more than the structure which Exhibit Otsu 5 Invention has naturally had.

D. Regarding Difference 2

Judging by the results of Exhibit Otsu 6 Experiment, Exhibit Otsu 8 Experiment, and Exhibit Otsu 15 Experiment, the structure of the Invention pertaining to Difference 2 is nothing more than the property which Exhibit Otsu 5 Invention has inevitably had.

In addition, according to Exhibit Otsu 7 Knowledge, Exhibit Otsu 5 Invention is also presumed to be "stable" "after storage for a pharmaceutically acceptable duration of time."

E. Summary

On these bases, both Differences 1 and 2 are not substantial, or the structures of the Invention pertaining to these differences are those that a person ordinarily skilled in the art could have easily arrived at based on Exhibit Otsu 5 Invention (or Exhibit Otsu 5 Invention and Exhibit Otsu 7 Knowledge). Therefore, the Invention lacks novelty or an inventive step.

Incidentally, the defendant disputes the plaintiff's allegation to the effect that it is impermissible to make a defense under Article 104-3 of the Patent Act based on Exhibit Otsu 5 Invention on the grounds of the fact that a JPO decision dismissing a request for a trial for patent invalidation, to which the defendant is not the party, has become final and binding.

(3) Ground for Invalidation 2 (lack of an inventive step by citing Exhibit Otsu 9 as the primarily cited document)

As mentioned below, the Invention is one which a person ordinarily skilled in the art could have easily made based on the invention (**hereinafter referred to as "Exhibit Otsu 9 Invention"**) described in "*Cancer Research*, vol. 49 (June 15, 1989): 3362-3368" (**hereinafter referred to as "Exhibit Otsu 9 Document"**; Exhibit Otsu 9) and Exhibit Otsu 5 Invention.

A. Common features between the Invention and Exhibit Otsu 9 Invention

"Platinum analogue, 1,2-diamminocyclohexane (trans-1) oxalatoplatinum (II)" or "1-OHP" used in Exhibit Otsu 9 Invention is a compound that is identical with "oxaliplatinum" (generic name: oxaliplatin) in the Invention.

The following is stated in the "INTRODUCTION" section and the "Drug" section of Exhibit Otsu 9 Document: The effect as an anticancer drug and toxicity were tested by diluting oxaliplatin with distilled water to make it an aqueous solution at a concentration of 3.4 mg/ml and by intravenously injecting said aqueous solution into orbital venous plexus.

In that case, the aqueous solution at a concentration of 3.4 mg/ml of Exhibit Otsu 9 Invention is an aqueous solution consisting solely of water and oxaliplatin, and it is identical with the "aqueous solution of oxaliplatinum" "at a concentration of 1 to 5 mg/ml" of the Invention.

In addition, in Exhibit Otsu 9 Invention, the aqueous solution is administered in the orbital venous plexus of a mouse by intravenous injection. Therefore, the Invention and Exhibit Otsu 9 Invention are identical with each other in that they are "for the administration by the parenteral route."

B. Formal differences between the Invention and Exhibit Otsu 9 Invention

The Invention and Exhibit Otsu 9 Invention formally differ from each other in the following points.

The "aqueous solution of oxaliplatinum" of the Invention is specified as "having a pH of 4.5 to 6." On the other hand, there is no statement about pH value in Exhibit Otsu 9 Invention (Difference 1).

The Invention is "a pharmaceutically stable preparation, 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." On the other hand, there is no such statement in Exhibit Otsu 9 Invention (Difference 2).

C. Regarding Difference 1

The following is stated in paragraph [0003] [Problem to be solved of the invention] of Exhibit Otsu 5 Document: "Large differences exist in connection with a carcinostatic activity and a secondary effect between isomers of many optically active medicines, and their optical purity is especially important when they are employed as medicines." In addition, Table 4 referred to in paragraphs [0023] and [0027] of said document disclose the results of an acute toxicity test and a tumor resistance test. Therefore, it can be said that a person ordinarily skilled in the art who sees Exhibit Otsu 5 Document easily arrives at the idea of using oxaliplatin with high optical purity which is disclosed in Exhibit Otsu 5 Document (Exhibit Otsu 5 Invention) in the aqueous solution of oxaliplatin at a concentration of 3.4 mg/ml of Exhibit Otsu 9 Invention.

Therefore, the structure of the Invention pertaining to Difference 1 (pH value) is not a special value, and it is nothing more than a structure that is naturally achieved by using the oxaliplatin with high optical purity of Exhibit Otsu 5 Invention when preparing the aqueous solution of oxaliplatin at a concentration of 3.4 mg/ml of Exhibit Otsu 9 Invention.

D. Regarding Difference 2

As indicated in the written experiment report (3) dated October 23, 2015 (Exhibit Otsu 10), the defendant prepared an aqueous solution of oxaliplatin at a concentration of 3.4 mg/ml of Exhibit Otsu 9 Invention by dissolving high-purity oxaliplatin that is the same as that used in Exhibit Otsu 5 Invention in injectable water, stored it by a storage method of prior art for a certain period of time, and conducted a confirmatory experiment on the "stability" of said aqueous solution (**hereinafter referred to as "Exhibit Otsu 10 Experiment"**). As a result, it was confirmed that the oxaliplatinum content in said aqueous solution was at least 95% of the initial content and said aqueous solution remained clear, colorless and free of any precipitate even after one month.

Therefore, the structure of the Invention pertaining to Difference 2 is also nothing more than a structure that is naturally achieved by using oxaliplatin with high optical purity of Exhibit Otsu 5 Invention when preparing the aqueous solution of oxaliplatin at a concentration of 3.4 mg/ml of Exhibit Otsu 9 Invention.

E. Summary

On these bases, the structures of the Invention pertaining to Differences 1 and 2 are those that a person ordinarily skilled in the art could have easily arrived at based on Exhibit Otsu 9 Invention and Exhibit Otsu 5 Invention. Therefore, the Invention lacks an inventive step.

Incidentally, the defendant disputes the plaintiff's allegation to the effect that it is impermissible to make a defense under Article 104-3 of the Patent Act based on Exhibit Otsu 9 Invention on the grounds of the fact that a JPO decision dismissing a request for a trial for patent invalidation, to which the defendant is not the party, has become final and binding.

[Allegations of the plaintiff]

(1) Regarding Ground for Invalidation 1

A. Regarding the pH of an aqueous solution of oxaliplatin (2mg/ml), an aqueous solution of oxaliplatin having a pH of 6.7 or 6.6 is indicated (Exhibits Ko 19 and 20). Therefore, the defendant's allegation that pH naturally becomes within the numerical range of pH as specified by the Invention disagrees with the fact. In addition, oxaliplatin used in Exhibit Otsu 8 Experiment differs from that used in Exhibit Otsu 5 Invention, and water used when measuring rotary power in Exhibit Otsu 5 Invention is not "injectable water," different from Exhibit Otsu 8 Experiment. Therefore, Exhibit Otsu 8 Experiment is not an additional test of Exhibit Otsu 5 Invention.

B. Exhibit Otsu 5 Invention is an aqueous solution of oxaliplatin, which was dissolved merely for the purpose of measuring rotary power. Therefore, it is difficult in itself to pay attention to pH and concentration out of many parameters, different from the Invention.

C. Exhibit Otsu 5 Document is a document that was submitted as evidence in a trial for patent invalidation in relation to the Patent (Invalidation Trial No. 2010-800191). In said trial, the JPO rendered a decision dismissing the request for the trial to the effect that involvement of an inventive step in the Invention cannot be denied based on Exhibit Otsu 5 Invention. The final and binding JPO decision was registered on October 11, 2011. Said registration was made before April 1, 2012, on which Act No. 63 of 2011 pertaining to the amendment of Article 167 of the Patent Act was enforced. Therefore, Article 167 of the Patent Act prior to said amendment is applicable to the effect of the aforementioned JPO decision dismissing the request. Therefore, it is considered impermissible to make a defense under Article 104-3 of the Patent Act in relation to the Patent on the basis of the same facts and evidence in an infringement action, taking into account that said Article provides "When a final and binding trial decision in a trial for patent invalidation … has been registered, no one may file a request for a trial on the basis of the same facts and evidence."

Therefore, the defendant is not permitted to make a defense under Article 104-3 of the Patent Act based on Exhibit Otsu 5 Invention.

(2) Regarding Ground for Invalidation 2

A. Exhibit Otsu 9 Document is also a document that was submitted as evidence in a trial for patent invalidation in relation to the Patent (Invalidation Trial No. 2010-800191). In said trial, the JPO rendered a decision dismissing the request for the trial to the effect that involvement of

an inventive step in the Invention cannot be denied based on Exhibit Otsu 9 Invention. The final and binding JPO decision was registered on October 11, 2011, as mentioned in (1)C. above.

Therefore, the defendant is not permitted to make a defense under Article 104-3 of the Patent Act based on Exhibit Otsu 9 Invention.

B. In addition, even leaving aside the point mentioned in A. above, the defendant has not alleged that Exhibit Otsu 10 Experiment is a reproduction of Exhibit Otsu 9 Invention. Therefore, the allegation itself is unreasonable. In particular, an intravenous injection is conducted in Exhibit Otsu 9 Invention, and according to common general technical knowledge, an injectable solution contains a buffer. Therefore, in the case of reproducing Exhibit Otsu 9 Invention, it is necessary to use an aqueous solution containing a buffer. Therefore, Exhibit Otsu 10 Experiment is not a reproduction of Exhibit Otsu 9 Invention. Moreover, in Exhibit Otsu 9 Invention, oxaliplatin is dissolved in distilled water and administered in a mouse on the very day of the test, and it is not at all considered to store the relevant aqueous solution of oxaliplatin for a long period. Therefore, it is not easily assumable that a "pharmaceutically stable" aqueous solution of oxaliplatin, "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" can be obtained.

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

[Allegations of the defendant]

(1) Regarding the ground for invalidation of the registration of extension of duration to the effect that a disposition designated by Cabinet Order under Article 67, paragraph (2) of the Patent Act is not deemed to have been obtained for the working of the Invention

As alleged in relation to Issue 1, the Invention should be understood as a preparation consisting solely of oxaliplatin and water. All of Elplat 50, which is the product subject to Dispositions 1, 3, and 5, Elplat 100, which is the product subject to Dispositions 2, 4, and 6, and Elplat 200, which is the product subject to Disposition 7, sometimes contain oxalic acid as a buffer (Exhibits Otsu 17 to 19), and they do not fall under the products in which the Invention is worked.

In that case, a disposition designated by Cabinet Order under Article 67, paragraph (2) of the Patent Act is not deemed to have been necessary to obtain for the working of the Invention. Therefore, the Invention falls under the provisions of Article 125-2, paragraph (1), item (i) of the Patent Act.

Consequently, all of the Registrations of Extensions are those that should be invalidated by a trial for invalidation of the registration of extension of duration.

(2) Regarding the ground for invalidation of the registration of extension of duration to the

effect that there is an error in the calculation of the "period during which the patented invention was unable to be worked"

As mentioned below, the periods of extension of Registrations of Extensions 1, 3, and 4 obviously exceed the period during which the patented invention was unable to be worked. Therefore, Registrations of Extensions 1, 3, and 4 are those that should be invalidated by a trial for invalidation of the registration of extension of duration under Article 125-2 of the Patent Act.

A. Regarding Registration of Extension 1

The disease subject to a clinical trial based on a clinical trial plan report (date of report: February 28, 2005) was "unresectable advanced or recurrent colorectal cancer," and it differs from "postoperative adjuvant chemotherapy for colon cancer" (Exhibit Ko 1) which is "(4) Usage specified for the product subject to the disposition" of Registration of Extension 1. On the other hand, the usage is clearly specified as "unresectable advanced or recurrent colorectal cancer; postoperative adjuvant chemotherapy for colon cancer" in the efficacy and effect column in the written application for approval for the manufacturing and sale of a medicine (date of application: August 29, 2008). The latter part of the usage is identical with the usage of Registration of Extension 1.

Regarding the "period during which the patented invention was unable to be worked," the following is stated in 3.1.3 in "Examination Guidelines for Patent and Utility Model in Japan, Part VI Extension of Patent Term" (**hereinafter merely referred to as the "Examination Guidelines"**): "This period begins on the date on which a test necessary for obtaining the disposition designated by Cabinet Order commences or on which the establishment of the relevant patent right is registered, whichever comes later; and ends on the day before the day on which the approval or registration reaches the applicant, i.e., the day on which the applicant actually learns of the approval or registration or could have learned of it." The period during which a test is conducted cannot be included in "the period during which the patented invention was unable to be worked" unless the test satisfies all of the requirements listed in [i] to [iii] mentioned in the Examination Guidelines. Out of these requirements, in order to satisfy requirement [ii] "Enterprises have little discretion in conducting the test because the test needs to be conducted in line with the standards for methods, description, etc. of test set forth by administrative agencies," it is naturally necessary that the usage in conducting the subject clinical test is the same as that of the patented invention. It is also natural in light of the purpose of the registration of extension of duration of a patent right that the usage should remain the same throughout the "period during which the patented invention was unable to be worked."

Therefore, the first day of the calculation of the "period during which the patented invention was unable to be worked" should be the date of filing the aforementioned application for

approval (August 29, 2008). As of the time of preparation of the clinical trial plan report, the clinical trial plan was on a clinical trial for a usage that differs from the usage pertaining to Registration of Extension 1. Therefore, considering the first day of the calculation of the "period during which the patented invention was unable to be worked" as the date of submitting the clinical trial plan report (February 28, 2005) in relation to Registration of Extension 1 leads to unjustly bringing forward the first day of the calculation beyond the period during which the patented invention was unable to be worked, which should be essentially recognized. It is thus erroneous.

B. Regarding Registrations of Extensions 3 and 4

Regarding Registrations of Extensions 3 and 4, the period of extension therein obviously exceeds the period during which the patented invention was unable to be worked, in relation to the usage "postoperative adjuvant chemotherapy for colon cancer," in the same manner as mentioned in A. above.

[Allegations of the plaintiff]

(1) Regarding the ground for invalidation of the registration of extension of duration to the effect that a disposition designated by Cabinet Order under Article 67, paragraph (2) of the Patent Act is not deemed to have been obtained for the working of the Invention

The Invention permits containment of ingredients other than oxaliplatin and water. Therefore, all of the defendant's allegations are erroneous in their premise.

(2) Regarding the ground for invalidation of the registration of extension of duration to the effect that there is an error in the calculation of the period during which the patented invention was unable to be worked

Regarding requirement [ii] mentioned in 3.1.3 in the Examination Guidelines, the defendant alleges that it is naturally necessary that the usage in conducting the subject clinical test is the same as that of the patented invention. However, the aforementioned requirement [ii] stipulates a requirement for a "test" itself. Therefore, it is sufficient if the conducted "test" is one that fulfills the requirement "Enterprises have little discretion in conducting the test because the test needs to be conducted in line with the standards for methods, description, etc. of test set forth by administrative agencies." In this regard, the clinical trial for oxaliplatin was conducted under the instruction of the Ministry of Health, Labour and Welfare, and it is obvious that said clinical trial is "in line with the standards for methods, description, etc. of test set forth by administrative agencies." Therefore, there is no error in the calculation of the "period during which the patented invention was unable to be worked" in relation to the Patent.

No. 4 Court decision

In consideration of the circumstances of this case, a determination is first made on Issue 2.

1. Regarding Issue 2 (whether or not the Defendant's Products are the products subject to

the Dispositions or equivalents thereof, or products which are evaluated as being substantially identical with the products subject to the Dispositions)

(1) Regarding the products subject to the Dispositions

A. Purpose of the system of the registration of extension of duration of a patent right

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 because an "approval 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" (**hereinafter referred to as a "Cabinet Order Disposition"**) is necessary to obtain (see the judgment of the Third Petty Bench of the Supreme Court of November 17, 2015, 2014 (Gyo-Hi) 356 [**hereinafter referred to as the "2015 Supreme Court Judgment"**]).

That is, the Patent Act provides in Article 67, paragraph (1) thereof that the duration of a patent right shall be 20 years from the filing date of the patent application. However, at the same time, the Patent Act established the system of the registration of extension of duration of a patent right by providing in paragraph (2) of said Article that where there is a period during which the patented invention is unable to be worked because a Cabinet Order Disposition is necessary to obtain for the working of the patented invention, the duration of the patent right may be extended by a period not exceeding 5 years. Where a Cabinet Order Disposition is necessary to obtain for the "working of the patented invention," the patentee is unable to work the patented invention even if he/she has the patent right, which results in the substantial erosion of the patent term (however, even during such period, the fact remains that the patentee has the exclusive "right to work the patented invention as a business" and the patentee is not precluded from claiming an injunction or compensation for damage against a third party who works the patented invention without obtaining license from the patentee in relation to said third party's act of working the patented invention; therefore, the system is considered to be one that focuses only on the point that the patentee was unable to work the patented invention, as the content of disadvantages suffered by the patentee, out of all the effects of the patent right). Such result brings to the patentee disadvantages, such as impossibility of recovering the costs required for research and development, and it also causes developers and researchers to lose the incentive for research and development. Therefore, the Patent Act made it possible to extend duration of a patent right in relation to the period during which the patented invention was unable to be worked by a period not exceeding 5 years, for the purpose of eliminating such disadvantages and increasing the incentive for research and development.

Incidentally, Article 2 of the Order for Enforcement of the Patent Act provides for an approval under the Law on Securing Quality, Efficacy and Safety of Products Including

Pharmaceuticals and Medical Devices (the title of the law prior to amendment by Act No. 84 of 2013 was the Pharmaceutical Affaires Act; **hereinafter referred to as the "Pharmaceuticals and Medical Devices Law" for the entire period before and after said amendment**) and a registration under the Agricultural Chemicals Control Act as Cabinet Order Dispositions. These dispositions fall under scholarly permissions, and the act of manufacturing, sale, etc. is generally and abstractly prohibited and is permitted only after obtaining an individual and specific disposition based on each administrative law. Therefore, the legal situation where said act of manufacturing, sale, etc. is prohibited continues unless the patentee tries to obtain permission. However, the Patent Act provides that only the period during which the patented invention was unable to be worked though the patentee had the intention and ability to work the patented invention, that is, the period that was necessary to obtain the relevant Cabinet Order Disposition, is to be subject to the extension of duration, instead of using, as a basis for the calculation of the period of extension of duration, the entire period during which the patented invention was unable to be worked (leaving aside the five-year limit), including the period during which the patentee did not try to obtain permission. This point is also obvious in light of a court case (judgment of the Second Petty Bench of the Supreme Court of October 22, 1999, 1998 (Gyo-Hi) 43, Minshu, Vol. 53, No. 7, at 1270), in which the court ruled that the "period during which the patented invention was unable to be worked" should be understood as meaning the period from the date on which a test necessary to obtain a Cabinet Order Disposition was commenced or the date of registration of establishment of the patent right, whichever comes later, to the day before the day on which said Cabinet Order Disposition becomes effective due to its arrival at the applicant.

In this manner, the system of the registration of extension of duration of a patent right can be considered to be a system intended to eliminate the disadvantage of having been unable to work a patented invention by taking a measure to extend the duration of a patent right in relation to the act of working the patented invention, for which prohibition was withdrawn through obtainment of a Cabinet Order Disposition, in relation to a patentee who had the intention and ability to work the patented invention but was unable to work the patented invention, for the period that was necessary to obtain said Cabinet Order Disposition (see the judgment of the Special Division of the Intellectual Property High Court of May 30, 2014, 2013 (Gyo-Ke) 10195 [**hereinafter referred to as the "2014 Intellectual Property High Court Judgment"**] and the judgment of the Third Division of Intellectual Property High Court of May 29, 2009, 2008 (Gyo-Ke) 10460).

B. Effect of a patent right in the case where the duration of the patent right was extended

Article 68-2 of the Patent 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)."

According to these provisions, a patent right whose duration was extended is effective only against the act of working the patented invention for the product subject to a Cabinet Order Disposition (where the specific usage of the product is prescribed by the disposition, the product used for that usage [**hereinafter referred to as "product used for that usage" with double quotation marks**]) **(hereinafter the product subject to the relevant Cabinet Order Disposition is sometimes referred to as "product (used for that usage)" with double quotation marks)**.

In addition, in light of the explanation in A. above, the system of the registration of extension of duration of a patent right is understood as one that recovers the eroded patent term, that is, the period during which the patentee was unable to work a patented invention because a Cabinet Order Disposition was necessary to obtain though he/she had the intention and ability to work the patented invention, in relation not to the entire scope of the patented invention (Article 70 of the Patent Act) but the scope of the patented invention for the "product (used for that usage)" which was unable to be worked because said Cabinet Order Disposition was necessary to obtain.

Therefore, it is reasonable to understand that where the duration of a patent right is extended, said patent right is, in principle, effective only against the act of working the patented invention, for which prohibition was withdrawn by obtaining a Cabinet Order Disposition, that is, the act of working the patented invention for the "product (used for that usage)" which was unable to be worked because said Cabinet Order Disposition was necessary to obtain, and is not effective against other acts of working the patented invention.

However, 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 for the purpose of increasing the incentive for research and development as well as making it possible for patentees to recover the costs required for research and development, it should not be considered that a patent right whose duration was extended is no longer effective against the subject item in an infringement action if said subject item goes out of the scope of the "product (used for that usage)" subject to the relevant Cabinet Order Disposition even a little, but it is reasonable to understand that even if the subject item differs from the "product (used for that usage)" subject to the Cabinet Order Disposition in some points, if it falls under equivalents of the "product (used for that usage)" subject to the Cabinet Order Disposition or products that are evaluated as being substantially

identical with the "product (used for that usage)" subject to said Cabinet Order Disposition (**hereinafter sometimes referred to as "substantially identical products"**) (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 as of the time when preparation for manufacturing, sale, etc. of said subject item was commenced [if a Cabinet Order Disposition is necessary for manufacturing, sale, etc. of the subject item, the time when a test necessary to obtain said Cabinet Order Disposition was commenced]), the patent right whose duration was extended is also effective against the working of said subject item. A third party who has intended to work the patented invention after the expiration of the original duration of the patent right should keep that point in mind. Incidentally, based on the aforementioned understanding, the scope of working of a patented invention against which the patent right whose duration was extended is effective is broader than the scope of working of the patented invention, for which prohibition is withdrawn by obtaining a Cabinet Order Disposition, but it should be said that interest of a third party is not unjustly harmed as long as the former scope is within the scope of the act of working for equivalents and substantially identical products in the aforementioned sense.

C. Regarding the case where a Cabinet Order Disposition is an approval pertaining to a medicine prescribed in the Pharmaceuticals and Medical Devices Law

All the Dispositions are approvals pertaining to a medicine given by the Minister of Health, Labour and Welfare.

The matters for examination for approval for the manufacturing and sale of a medicine under the provisions of the Pharmaceuticals and Medical Devices Law are provided as the "name, ingredients, quantity, dosage, administration, efficacy, effects, side effects, and any other matters concerning quality, effectiveness, and safety" of the medicine (main paragraph of Article 14, paragraph (2), item (iii) of the Pharmaceuticals and Medical Devices Law). Therefore, before the Minister of Health, Labour and Welfare gives an approval pertaining to a medicine prescribed in the Pharmaceuticals and Medical Devices Law, the "dosage, administration, efficacy, and effects" of the medicine that are considered to fall under the matters to specify the "usage" of the medicine are examined without fail. Therefore, said approval is considered to fall under the cases "where the specific usage of the product is prescribed by the disposition" as set forth in the parentheses in Article 68-2 of the Patent Act. If a Cabinet Order Disposition is an approval pertaining to a medicine prescribed in the Pharmaceuticals and Medical Devices Law, it is necessary to determine whether the relevant working is the working of the patented invention for the "product used for that usage" when considering the scope against which the patent right whose duration was extended is effective as set forth in Article 68-2 of said Act, and

therefore, it is necessary to specify the "product" and the "usage."

Even if it is understood that the act which is permitted as a result of obtaining an approval for the manufacturing and sale of a medicine (for which the prohibition is lifted) under the provisions of the Pharmaceuticals and Medical Devices Law is the manufacturing and sale of the medicine which is specified by each approval in relation to all of the "name, ingredients, quantity, dosage, administration, efficacy, effects, side effects, and any other matters concerning quality, effectiveness, and safety" (main paragraph of Article 14, paragraph (2), item (iii) of the Pharmaceuticals and Medical Devices Law) of the medicine, which are the matters for examination for the approval, it should be considered reasonable to specify the "product used for that usage" ("product" and "usage"), which was unable to be worked because said Cabinet Order Disposition was necessary to obtain, not based on all of the aforementioned matters for examination but based only on the matters for examination that are directly related to substantial identity as a medicine (in the case of an invention of an ingredient of a medicine, "ingredients, quantity, dosage, administration, efficacy, and effects" [see the 2015 Supreme Court Judgment]) in light of the type and subject of the patented invention pertaining to the patent right whose duration was extended, taking into account the purpose of the system of the registration of extension of duration of a patent right as mentioned in A. and B. above.

Out of the aforementioned matters for examination, "name" does not affect substantial identity as a medicine, and "side effects and any other matters concerning quality, effectiveness, and safety" are those that are the same between products if the products are substantially identical as a medicine. Therefore, all of these matters are not required to become independent matters to specify the "product" and the "usage." On the other hand, "ingredients and quantity" affect objective identity as a "product" itself but cannot fall under "usage" in terms of the nature thereof. Therefore, "ingredients and quantity" should be considered as matters to specify the "product." On the other hand, "dosage, administration, efficacy, and effects" cannot be considered to affect objective identity as a "product" itself but can fall under "usage" in terms of the nature thereof, and should be considered as matters to specify the "usage."

Consequently, in the case of a patented invention for an ingredient of a medicine, it is reasonable to understand that the patent right whose duration was extended under Article 68-2 of the Patent Act is effective against the scope of working of the patented invention, which is specified by "ingredients (not limited to active ingredients) and quantity" in relation to the "product" and is specified by "efficacy and effects" and "dosage and administration" in relation to the "usage." However, as indicated above, equivalents of the "product used for that usage" and substantially identical products of the "product used for that usage" are included in said scope, in light of the legislative purpose of the system of the registration of extension (incidentally, in the 2014 Intellectual Property High Court Judgment, the court held that

"quantity" "cannot be considered to be an element that limits the effect of the patent right whose duration was extended"; however, it seems to be reasonable to understand the holding as a cautionary statement of the point that "quantity" is a matter to specify the "product" together with "ingredients," but if only "quantity" of a product differs from that of a patented invention, the extended patent right for said patented invention is ordinarily effective against said product, deeming said product as an equivalent or a substantially identical product of the patented invention in relation to the "product" and "usage" subject to the Cabinet Order Disposition in combination with "dosage and administration").

D. Regarding the "products used for that usage" which were unable to be worked because the Dispositions were necessary to obtain

According to the aforementioned facts on which the decision is premised, it is recognized that the medicine subject to Dispositions 1, 3, and 5 is Elplat 50, the medicine subject to Dispositions 2, 4, and 6 is Elplat 100, and the medicine subject to Disposition 7 is Elplat 200. According to evidence (Exhibit Ko 3), their nature and composition are recognized as follows.

Brand/trade name	Elplat I.V. Infusion Solution 50 mg	Elplat I.V. Infusion Solution 100 mg	Elplat I.V. Infusion Solution 200 mg
Oxaliplatin content 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 isotonic sodium chloride 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 Exhibit 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" out of "ingredients" and "quantity," which are matters to specify the "product," and all of them are considered to contain only "oxaliplatin" and "injectable water" and not to contain 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]; incidentally, according to evidence [Exhibit Ko 2 and Exhibits Otsu 11, 13 and 16-2], it is considered that oxaliplatin in the aqueous solution decomposes according to time and thereby, oxalate ions naturally occur).

In that case, leaving aside "quantity" in relation to the "product" and "efficacy, effects,

dosage, and administration" in relation to the "usage" for now, the "products used for that usage," which were unable to be worked because the Dispositions were necessary to obtain, are recognized as preparations which contain only "oxaliplatin" and "injectable water" but do not contain any other ingredients (however, the preparations sometimes come to contain oxalic acid as a result of natural decomposition of oxaliplatin during storage).

(2) Regarding whether or not the Defendant's Products can be considered to be the "products used for that usage" subject to the Dispositions

According to the aforementioned facts on which the decision is premised, the determined facts mentioned in (1)D. above, and the entire import of the oral argument, the "ingredients" of all of the "products used for that usage" subject to the Dispositions are only "oxaliplatin" and "injectable water" (however, the products sometimes come to contain oxalic acid as a result of natural decomposition of oxaliplatin during storage). On the other hand, the "ingredients" of all of the Defendant's Products include "concentrated glycerin" as an additive, in addition to "oxaliplatin" and "water," and it is recognized that concentrated glycerin is used as a "stabilizer" (the purpose of use of an additive (concentrated glycerin) in Defendant's Product 3 is presumed to be the same as that in Defendant's Products 1 and 2).

In that case, there is no other way but to say that the "products used for that usage" subject to the Dispositions and the Defendant's Products differ in the "ingredients." Therefore, the Defendant's Products cannot be considered to be the "products used for that usage" subject to the Dispositions without the need of considering "quantity, dosage, administration, efficacy, and effects."

On the other hand, the plaintiff alleges that all the Defendant's Products fall under the products subject to the Dispositions because their only active ingredient is oxaliplatin. However, where a Cabinet Order Disposition is an approval pertaining to a medicine prescribed in the Pharmaceuticals and Medical Devices Law, "ingredients" pertaining to the "product" which are taken into account as a matter to specify the "product used for that usage," which was unable to be worked because said Cabinet Order Disposition was necessary to obtain, are not limited to active ingredients, as indicated above. Therefore, the aforementioned allegation of the plaintiff is unacceptable.

(3) Regarding whether or not the Defendant's Products can be considered to fall under equivalents or substantially identical products of the "products used for that usage" subject to the Dispositions

A. Way of thinking

As mentioned in (2) above, even if the Defendant's Products cannot be considered to be the "products used for that usage" subject to the Dispositions, according to the instruction mentioned in (1)B. above, if differences between the Defendant's Products and the "products

used for that usage" subject to the Dispositions are mere addition, deletion, conversion, etc. of well-known or commonly used art and do not produce any new effect in light of the type and subject of the Invention as of the time when a test necessary to obtain a Cabinet Order Disposition for the Defendant's Products was commenced, it is reasonable to recognize the Defendant's Products as equivalents of the "products used for that usage" or substantially identical products of the "products used for that usage."

For example, the following idea is possible in determining whether a product is an equivalent of the "product used for that usage" or a substantially identical product of the "product used for that usage" in relation to a patented invention pertaining to a medicine prescribed in the Pharmaceuticals and Medical Devices Law. If said patented invention is an invention for which only the active ingredient (ingredient that produces medical effects) of the medicine is a characteristic part, such as an invention for a new compound and an invention for the use of a specific compound for a specific medicinal usage, if said patented invention and a product differ only in the ingredients other than the active ingredient in relation to the "product" and the "usage" subject to a disposition, which constituted a reason for the registration of extension, and are recognized as having bioequivalence with each other, said difference in the ingredients falls under an addition, deletion, conversion, etc. of well-known or commonly used art in relationship to said patented invention and does not produce any new effect in many cases. Therefore, such product is considered to fall under equivalents or substantially identical products of the "product used for that usage" in many cases. On the other hand, where said patented invention is an invention for a preparation for which the entirety of the ingredients of the medicine is a characteristic part, if ingredients other than the active ingredient of a product differ from those of the patented invention in relation to the "product" and the "usage" subject to a disposition, which constituted a reason for the registration of extension, even if said product is recognized as having bioequivalence with the patented invention, said difference in the ingredients cannot be considered to fall under a mere addition, deletion, conversion, etc. of well-known or commonly used art in relationship to the patented invention and can sometimes produce a new effect. Therefore, there are probably a certain number of cases where such product should be considered not to fall under equivalents or substantially identical products of the "product used for that usage."

B. Type and subject of the Invention

Then, considering the type and subject of the Invention, there are the following statements concerning prior art, the purpose of the invention, and solution of the problem in the Description.

"At the present time, oxaliplatinum is available for pre-clinical and clinical trials in vials as lyophilisate for reconstitution just before the administration and for dilution with a 5% glucose

solution, with injectable water or an isotonic 5% glucose solution, 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." (Exhibit Ko 2 [lines 27 to 32 of page 2])

"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 a therapeutic activity equivalent to those of the reconstituted lyophilisate. This is the purpose of this invention." (Exhibit Ko 2 [lines 37 to 42 of page 2])

"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." (Exhibit Ko 2 [line 43 of page 2 to line 3 of page 3])

In addition, the plaintiff received a notice of reasons for refusal dated July 11, 2003 (Exhibit Otsu 12-1) from the Commissioner of the JPO, and submitted the Written Opinion in response to said notice. There are the following statements in the Written Opinion (page 2).

"[2] Explanation of the claimed invention

As stated in line 20 of page 3 to line 24 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 of the claimed invention in this 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."

In addition to the aforementioned statements in the Description and the Written Opinion, according to the aforementioned facts on which the decision is premised, evidence (Exhibit Ko 2 and Exhibits Otsu 5, 7, 9, 12-1 to 12-3, and 13), and the entire import of the oral argument, the Invention is related to a "pharmaceutically stable preparation of oxaliplatinum" and is an invention for the entirety of the ingredients of the medicine. Oxaliplatinum (oxaliplatin) is a substance that had been publicly known before the priority date of the Patent, and it is recognized that it had also been publicly known before the same priority date to use oxaliplatinum for an anticancer drug as the active ingredient. Therefore, the Invention is not an invention for which only the active ingredient of the medicine is a characteristic part, such as an invention for a new compound and an invention for the use of a specific compound for a specific medicinal usage, but an invention for a preparation, and it is recognized as an invention for which the entirety of the ingredients of the medicine is a characteristic part.

C. Consideration

As mentioned above, the Invention is an invention for "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 plaintiff obtained the Dispositions for Elplat I.V. Solutions (preparations), which contain only "oxaliplatin" and "injectable water" and do not contain any other ingredients, in terms of the working of the Invention. On the other hand, according to the aforementioned facts on which the decision is premised, the determined facts mentioned in (1)D. and (2) above, evidence (Exhibit Otsu 4), and the entire import of the oral argument, the Defendant's Products contain "concentrated glycerin" of the same quantity as "oxaliplatin," as an ingredient other than the active ingredients, in addition to "oxaliplatin" and "water" or "injectable water." It is recognized that glycerin was added to a solution of oxaliplatin in water (**hereinafter referred to as an "aqueous solution of oxaliplatin," irrespective of inclusion of any ingredients other than "oxaliplatin" and "water" or "injectable water"**) for the purpose of restraining the natural decomposition of oxaliplatin itself because decomposition of oxaliplatin gradually proceeds during storage of an aqueous solution of oxaliplatin and various impurities, mainly, diaquo DACH platin that is a related substance and diaquo DACH platin dimer that is the dimer of diaquo DACH platin, are thereby generated. Considering this point in

relation to the Invention, 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 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 (incidentally, regarding the "products used for that usage" subject to the Dispositions, oxaliplatin naturally decomposes during storage and sometimes comes to contain oxalic acid, as indicated above; in addition, it is known that oxalic acid added to an aqueous solution of oxaliplatin restrains the natural decomposition of oxaliplatin, but oxalic acid is a substance that is harmful to humans).

In that case, the Defendant's Products are inventions for "a pharmaceutically stable preparation of oxaliplatinum," and they differ from the products subject to the Dispositions in the ingredients other than the active ingredients in relationship to the Invention for which the entirety of the ingredients of the medicine is a characteristic part. Said difference in the ingredients cannot be considered to fall under a mere addition, etc. of well-known or commonly used art in relationship to the Invention as of the time when a test necessary to obtain a Cabinet Order Disposition for the Defendant's Products was commenced, and it should be considered as one that produces a new effect.

Therefore, the Defendant's Products cannot be considered to fall under equivalents or substantially identical products of the "products used for that usage" subject to the Dispositions without the need of considering "quantity, dosage, administration, efficacy, and effects."

In this regard, the plaintiff alleges that "concentrated glycerin" contained in the Defendant's Products is just an "additive" and that approvals for the Defendant's Products were obtained by using the clinical performance used in the Dispositions as it is on the premise that the Defendant's Products have bioequivalence with the products subject to the Dispositions (Elplat 50, Elplat 100, and Elplat 200). However, this allegation is based on the idea that the Defendant's Products have commonality with Elplat I.V. Infusion Solutions in the active ingredient, "oxaliplatin," and have bioequivalence with Elplat I.V. Infusion Solutions, and even if "concentrated glycerin" itself is an "additive," the fact that the Defendant's Products have commonality with Elplat I.V. Infusion Solutions in the active ingredient, "oxaliplatin," and have bioequivalence with Elplat I.V. Infusion Solutions is not sufficient to immediately recognize that the Defendant's Products are equivalents or substantially identical products of the products subject to the Dispositions, taking into account that the Invention for "a pharmaceutically stable preparation of oxaliplatinum" is not an invention for which only the active ingredient of the medicine is a characteristic part but is an invention for which the entirety of the ingredients of

the medicine is a characteristic part and that in relationship to the Invention as such, the aforementioned difference in the ingredients other than the active ingredient does not fall under a mere addition, etc. of well-known or commonly used art and should be considered to produce a new effect, as mentioned above. Therefore, the aforementioned allegation of the plaintiff is unacceptable.

(4) Summary

On these bases, the Defendant's Products are neither the "products (used for that usage)" subject to the Disposition nor can be considered to fall under equivalents or substantially identical products of the "products (used for that usage)" subject to the Disposition. Therefore, it should be said that the Patent Right whose duration was extended is not effective against the production, etc. of the Defendant's Products by the defendant.

2. Conclusion

Under these circumstances, all of the plaintiff's claims shall be dismissed as there is no reason therefor without the need of considering other points, and the judgment shall be rendered in the form of the main text.

Tokyo District Court, 29th Civil Division

Presiding judge: SHIMASUE Kazuhide

Judge: SUZUKI Chiho

Judge: SASAMOTO Tetsuro

(Attachment)

Defendant'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	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

				in said paragraph			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)

Description of Defendant's Products

1. Structure of Defendant's Product 1

[g] A pharmaceutically stable preparation of oxaliplatinum

[f] for the administration by intravenous drip infusion,

[c] consisting of an aqueous solution of oxaliplatinum

[a] at a concentration of 5 mg/ml and

[b] having a pH of 4.9 or 4.9 to 5.0, 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.

2. Structure of Defendant's Product 2

[g] A pharmaceutically stable preparation of oxaliplatinum

[f] for the administration by intravenous drip infusion,

[c] consisting of an aqueous solution of oxaliplatinum

[a] at a concentration of 5 mg/ml and

[b] having a pH of 4.9 or 4.9 to 5.0, 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.

3. Structure of Defendant's Product 3

[g] A pharmaceutically stable preparation of oxaliplatinum

[f] for the administration by intravenous drip infusion,

[c] consisting of an aqueous solution of oxaliplatinum

[a] at a concentration of 5 mg/ml and

[b] having a pH of 4.9, 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.