Judgment rendered on March 31, 2010; the original was received on the same day; court clerk

2007 (Wa) 35324, Case of Seeking an Injunction against a Patent Infringement

Date of conclusion of oral argument: February 1, 2010

Judgment

Indication of the parties: As stated in the List of the Parties attached to this judgment

Main Text

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

2. The plaintiff shall bear the court costs.

Facts and reasons

No. 1 Claims

1. The defendant shall neither manufacture nor sell the medicine, "Pravastatin Na Tablets 10mg 'KH'."

2. The defendant shall dispose of the inventory of the medicine, "Pravastatin Na Tablets 10mg 'KH.'"

No. 2 Background

1. Facts, etc. undisputed by the parties (evidence, etc. is stated at the end for matters other than undisputed facts)

(1) Parties

A. The plaintiff is a company engaging in the business of manufacturing and selling, etc. medicines.

B. The defendant (former trade name is Kyowa Hakko Co., Ltd.) is a company engaging in the business of manufacturing and selling, etc. medicines.

(2) Patent right of the plaintiff

A. The plaintiff holds the following patent right (hereinafter referred to as the "Patent Right") (hereinafter the inventions pertaining to the claims in the scope of claims are called "Invention 1," etc., respectively; the patent pertaining to Inventions 1 to 9 is referred to as the "Patent"; the description pertaining to the Patent is referred to as the "Description"; Inventions 1 to 9 are collectively referred to as the "Inventions"; the patent gazette for the Patent is attached at the end).

Patent number: Patent No. 3737801

Title of the invention: Pravastatin sodium substantially free of pravastatin lactone and epi-pravastatin, and compositions containing the same

Application date: October 5, 2001

Application number: Patent Application No. 2002-533858

Registration date: November 4, 2005

Priority date: October 5, 2000

Scope of claims (hereinafter Steps (a) to (e) stated in Claim 1 are referred to as "Plaintiff's Step (a)," etc., respectively, and these steps are collectively referred to as the "Plaintiff's Manufacturing Process"):

[Claim 1]

Pravastatin sodium containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava, which is prepared by a process comprising the steps of: (a) forming an enriched organic solution of pravastatin, (b) precipitating pravastatin as its ammonium salt, (c) purifying the ammonium salt by recrystallization, (d) transposing the ammonium salt to pravastatin sodium, and (e) conducting pravastatin sodium isolation.

[Claim 2]

Pravastatin sodium stated in Claim 1 wherein an enriched organic solution of pravastatin is formed by extracting an aqueous fermentation broth with a first organic solvent, back-extracting pravastatin with an aqueous solution at pH of 8.0 to 9.5, acidifying the basic aqueous solution to a pH of 2.0 to 3.7 and extracting the acidified aqueous solution with a second organic solvent.

[Claim 3]

Pravastatin sodium stated in Claim 2 wherein the first and second organic solvents are isobutyl acetate.

[Claim 4]

Pravastatin sodium stated in Claim 1 wherein the ammonium salt is purified by at least one crystallization process from a mixture of water and an anti-solvent.

[Claim 5]

Pravastatin sodium stated in Claim 4 wherein the anti-solvent is selected from the group consisting of isobutyl acetate and acetone.

[Claim 6]

Pravastatin sodium stated in Claim 4 wherein ammonium chloride is added to the mixture of water and anti-solvent to induce crystallization of the ammonium salt.

[Claim 7]

Pravastatin sodium stated in Claim 1 wherein the ammonium salt is transposed using an acidic or chelating ion exchange resin.

[Claim 8]

Pravastatin sodium stated in Claim 1 wherein the pravastatin sodium is isolated by recrystallization.

[Claim 9]

Pravastatin sodium stated in Claim 1 wherein the pravastatin sodium is isolated by lyophilization.

B. On July 22, 2008, the plaintiff filed a request for correction (Exhibit Ko No. 7; hereinafter this correction is referred to as the "Correction"; the inventions pertaining to Claims 1 to 9 after the Correction are referred to as "Corrected Invention 1," etc., respectively, and Corrected Inventions 1 to 9 are collectively referred to as the "Corrected Inventions") to correct Claim 1 of the Patent as follows: [i] correcting the statement concerning the mixed amount of pravastatin lactone and that of epiprava to "Pravastatin sodium containing less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava;" and [ii] correcting the statement, "(e) conducting pravastatin sodium isolation," to "(e) isolating pravastatin sodium."

(3) Defendant's product

A. The defendant sells "Pravastatin Na Tablets 10mg 'KH'" (the name of the medicine was changed from "Pravastatin Na Tablets 10mg 'Merck'" to this name along with the change of the manufacturing company's name from "Company A" to "Company B"; hereinafter referred to as the "Defendant's Product"), which is a medicine for hyperlipidemia, hypercholesteremia, etc., as a business in Japan (the plaintiff alleges that the defendant manufactures the Defendant's Product; however, according to evidence (Exhibit Ko No. 3), the defendant is not recognized as manufacturing it).

B. The Defendant's Product is pravastatin sodium containing less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava.

The defendant disputes the reliability of the results of measurement by the plaintiff of the amount of pravastatin lactone and epiprava mixed in the Defendant's Product. However, there is no need to consider the allegation of the defendant in this regard because the parties agree on the point that the Defendant's Product contains less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava. Therefore, it is not necessary to consider the reliability of the results of measurement of the Defendant's Product by the plaintiff as an issue in this action. Consequently, this point is not stated in the issues and in the allegations of the parties concerning the issues described later.

2. Issues

(1) Whether the Defendant's Product falls under the technical scope of the Inventions

A. Whether the manufacturing process should be taken into consideration in relation to the technical scope of the Inventions

B. Whether the Defendant's Product fulfills the constituent features

(2) Whether the Patent should be invalidated by a trial for patent invalidation

A. Gist of the Inventions

B. Lack of novelty based on Exhibit Otsu No. 1

C. Lack of an inventive step based on Exhibit Otsu No. 1

D. Lack of novelty and an inventive step based on Exhibit Otsu No. 6

E. Non-compliance with Article 36 of the Patent Act

(3) Whether the Correction is proper (whether the ground for invalidation in relation to Issue (2) is avoided by the Correction)

No. 3 Allegations of the parties concerning the issues

1. Regarding Issue (1)A. (whether the manufacturing process should be taken into consideration in relation to the technical scope of the Inventions)

(Allegations of the plaintiff)

(1) Regarding a product-by-process claim

A. With regard to the scope of right of a product-by-process claim, even if the scope of claims is limited by a manufacturing process, it is not generally necessary to limit the subject-matter of the patent to the product manufactured by said manufacturing process, and products which are manufactured by a different manufacturing process but are identical with said product are also included. That is, it is considered that the technical scope of the relevant invention is not limited by the manufacturing process stated in the claims.

B. Counterargument against the allegations of the defendant

(A) In judicial precedents, the court takes a relevant manufacturing process into consideration "on a case-by-case basis" only in the cases where it is indispensable to take the manufacturing process into consideration in order to specify the structure of the product claimed in the claims. It is not that the court takes the manufacturing process into consideration based on the prosecution history and the statements in the description without relation to the need for specifying the structure of the product. In addition, even if a manufacturing process is taken into consideration, it is that the statement about the manufacturing process is borrowed as a means for specifying the structure of the product, and it is not that the scope of right of a patent of a product is limited by the manufacturing process. In addition, as long as clearly distinguishing patents of products and those of manufacturing processes is the legal principle that is fundamental to the Patent Act, if a manufacturing process makes no contribution to the specification of a product that is subject to a patent, it is not necessary to take the manufacturing process stated in writing into consideration when finding the gist of the invention in determining the validity of the patent, let alone when determining the scope of right.

The structure of the pravastatin sodium of Invention 1 is clearly specified by the statement, "Pravastatin sodium containing less than 0.5 (0.2 after the Correction) wt% of pravastatin lactone and less than 0.2 (0.1 after the Correction) wt% of epiprava." Therefore, it is not that the structure of the product cannot be specified without taking the manufacturing process into consideration.

In the Patent, the manufacturing process is stated in the claims in order to clearly indicate

that highly pure pravastatin sodium was actually obtained by overcoming a difficult technical problem, that is, reduction of impurities.

(B) The defendant sees the prosecution history of the Patent as a problem.

a. However, as long as it is the principle of the Patent Act to clearly distinguish patents of products and those of manufacturing processes, there is no room to establish the interpretation that the scope of right of a patent of a simple product is limited on the basis of prosecution history estoppel.

In addition, as the plaintiff filed a request for correction of the Patent, the prosecution history for the claims before the Correction makes no sense in relation to the claims after the Correction.

b. Even if the prosecution history and the statements in the Description are taken into consideration, it is not that the plaintiff made an inordinate allegation with regard to the part relating to the manufacturing process, as mentioned below. There is thus no reason for limiting the scope of right.

A substance that is publicly known as a compound but is new in the sense that impurities therein are extremely reduced is recognized as having novelty or an inventive step if the substance is difficult to obtain or has a prominent effect. Therefore, if an applicant intends to allege the novelty and an inventive step of such an invention in the application process, he/she has no choice but to refer to the difficulty of obtaining the substance, that is, the newness of the process to manufacture the product wherein impurities are extremely reduced.

Therefore, the following allegation of the defendant is unreasonable: "Referring to the manufacturing process in the application process and in the Description is regarded as inordinately alleging the feature in the part relating to the manufacturing process, and the scope of right is thereby limited by the manufacturing process."

In addition, the plaintiff had not waived the right for the pravastatin sodium identical with the Inventions which is manufactured by other manufacturing processes, during the application procedures for the Patent. Therefore, there is no basis for the application of the prosecution history estoppel.

Incidentally, the plaintiff deleted Claims 3 and 6 of the time, which do not describe the manufacturing process, after it received an examiner's decision of refusal in the application process for the Patent for the purpose of obtaining the right for the claims, for which no reason for refusal has been indicated, at an early date. Therefore, there is no reason for the limited interpretation of the scope of right of the existing claims even if the plaintiff deleted the claims that do not describe the manufacturing process.

c. Even if it becomes possible to obtain a new product wherein impurities are extremely reduced for the first time owing to the obtainment of a new manufacturing process, an invention

pertaining to the product is not limited by the manufacturing process and is patentable as an invention of a product. This is a conventional and established practice in the chemical field in Japan.

d. Both the finding of the gist of a patented invention and the determination of the scope of right of a patented invention are conducted on the basis of the statement of the scope of claims and the statements in the description, as provided for in Article 70 of the Patent Act. Therefore, they naturally comply with each other.

Furthermore, for the same patent right, the defendant limits the scope of right in terms of infringement and thereby increases the probability of an infringement not being established while, in terms of the validity of the patent, it does not adopt the limited interpretation and thereby intends to increase the probability of the patent being invalidated. Therefore, the allegations of the defendant are extremely unfair from the perspective of protection of patent rights.

(2) Regarding this case

Consequently, the technical scope of the Inventions covers "pravastatin sodium containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava."

(Allegations of the defendant)

(1) Regarding a product-by-process claim

A. With regard to a product-by-process claim, the court determines the scope of right of a relevant patented invention by taking into consideration statements concerning the process in line with the relevant case in most judicial precedents.

A product-by-process claim is exceptionally accepted in principle in such cases as where it is impossible to appropriately identify an invention without adopting a form wherein the invention is limited by a manufacturing process because its structure and composition are unclear though the invention is a new substance.

However, pravastatin sodium is a publicly known substance that had already been obtained without depending on the process of the Inventions, and its structural formula is also clear. Therefore, it does not fall under the cases where it is impossible to identify the invention without adopting a form wherein the invention is limited by its manufacturing process. Despite that, in this case, the plaintiff, who is the applicant, deleted all the claims that describe only a product, which was subject to the application at the beginning, in the application process in response to an examiner's decision of refusal, and alleged that it is the feature of the invention that the manufacturing process differs from manufacturing processes of publicly known arts. As a result, the invention was registered (Exhibits Otsu No. 3-1 to No. 3-18). As long as this is true, the statements concerning the process should not be excluded in interpreting the technical scope of the Inventions.

In addition, the Description contains the statements, "The pravastatin sodium isolated by the working of the process of this invention is substantially free of pravastatin lactone and epiprava" (paragraph [0031]) and "The highly pure pravastatin sodium manufactured by the process of this invention is preferably useful for hypercholesteremia therapy" (paragraph [0032]). The Description states that the feature of the Inventions exists in the manufacturing process.

Consequently, it is obvious that the circumstances exist where the technical scope of the Inventions should be found in consideration of the statements concerning the process.

B. Counterargument against the allegations of the plaintiff

(A) If it is not necessary to take into consideration the "manufacturing process" in order to specify the structure of the Inventions, it should be unnecessary to state the manufacturing process in the claims. The applicant took time to state it for the purpose of identifying the Inventions. In addition, the Inventions were not recognized as having novelty and an inventive step without the statements concerning the manufacturing process.

(B) In fact, in the application process, the plaintiff alleged that the Inventions have their feature in their manufacturing process. Therefore, the allegation of the plaintiff to the effect that the technical scope can be specified in disregard of the statements concerning the manufacturing process goes against the principle of estoppel.

(2) Regarding this case

Consequently, it is impossible to interpret the technical scope of the Inventions in the absence of the statements concerning the process.

2. Regarding Issue (1)B. (whether the Defendant's Product fulfills the constituent features)

(Allegations of the plaintiff)

(1) Regarding the structure of the Defendant's Product

The Defendant's Product is pravastatin sodium containing less than 0.5 (0.2) wt% of pravastatin lactone and less than 0.2 (0.1) wt% of epiprava. Therefore, it falls under the technical scope of the Inventions.

(2) Regarding the process to manufacture the Defendant's Product

The Defendant's Product falls under the technical scope of the Inventions even in consideration of its manufacturing process.

A. Regarding the Plaintiff's Process

(A) Pravastatin lactone and epiprava, which are impurities that are subject to removal in the Inventions, are very similar to pravastatin in structure, and are very difficult to separate and remove from pravastatin. Of these, epiprava does not increase once it is reduced. However, pravastatin lactone is further generated in the purification process through the molecular reaction of pravastatin itself. Pravastatin lactone is generated and increases in HPLC purification.

(B) The Inventions have their feature in the steps of removing these specific impurities through purification by converting pravastatin into ammonium salt (Plaintiff's Steps (b) and (c)).

That is, the fermentation broth which is an aqueous solution containing pravastatin that was obtained through fermentation is converted into an organic solution, and the organic solution is enriched (Plaintiff's Step (a)).

Various forms of pravastatin in this enriched organic solution are converted into the form of ammonium salt by ammonium cation, and the ammonium salt is precipitated (Plaintiff's Step (b)). Then, it is dissolved into an aqueous vehicle to make an aqueous solution, and precipitation of pravastatin ammonium is promoted (salting-out) by adding ammonium salt thereto and pravastatin ammonium is recrystallized (Plaintiff's Step (c)). Thereby, extremely highly pure pravastatin ammonium is obtained. Hereby, it is possible to reduce the content of pravastatin lactone by avoiding the increase thereof as well as to reduce the content of epiprava close to zero by repeating this salting-out crystallization.

Furthermore, this highly pure pravastatin ammonium is converted into highly pure pravastatin sodium by using sodium cation (Plaintiff's Step (d)). Highly pure pravastatin sodium is obtained by isolating it (Plaintiff's Step (e)).

B. The highly pure pravastatin sodium in the Patent is a new product. Therefore, the Patent falls under a patent for a process for producing a product if there is a limitation by a manufacturing process. In addition, the purpose of Article 104 of the Patent Act, remedy for the difficulty of the plaintiff's proving a manufacturing process, applies. Consequently, application or mutatis mutandis application of said Article leads to a presumption that the Defendant's Product was produced by the process stated in the claims of the Patent.

Moreover, if the defendant invented an innovative manufacturing process that enables obtainment of highly pure pravastatin sodium, it should have filed a patent application therefor because it has filed multiple patent applications for pravastatin sodium-related technologies. However, the defendant has not filed such a patent application. Therefore, it is presumed that the process to manufacture the Defendant's Product is identical with the Plaintiff's Manufacturing Process.

In this regard, the defendant has not made an allegation nor has presented proof that is sufficient to reverse this presumption, as mentioned below.

C. The disclosure of the manufacturing process by the defendant is insufficient and fails to be specific in the following points.

(A) The process to manufacture the Defendant's Product alleged by the defendant (hereinafter referred to as the "Defendant's Manufacturing Process") omits the fact of "●(omitted)●" stated in the "application for approval of manufacturing of a medicine" (Exhibit Otsu No. 5; hereinafter referred to as the "Defendant's Application for Approval").

(B) The process to manufacture pravastatin sodium is divided into two steps: [i] generation of pravastatin by fermentation and [ii] purification of the pravastatin obtained by fermentation.

As mentioned above, the Plaintiff's Manufacturing Process mainly relates to step [ii]. In particular, Plaintiff's Steps (b) and (c) that adopt the method of salting-out crystallization play a central part in the formal purification, and these steps are the features of the Plaintiff's Manufacturing Process.

On the other hand, Defendant's Steps (A) and (B) alleged by the defendant are the steps wherein pravastatin is generated by fermentation, and Defendant's Steps (C) and (D) are the steps of crude purification. It is impossible to increase the level of purity of pravastatin sodium up to the level of the purity of the Defendant's Product through these steps. Defendant's Step (E) is a step that relates to the formal purification and should be compared with Plaintiff's Steps (b) and (c). However, the specific method of Defendant's Step (E) is not disclosed. Without disclosure of said method, it is impossible to say that Defendant's Step (E) does not infringe the Patent Right.

Moreover, the step of introducing sodium is essential to obtain pravastatin sodium from pravastatin in fermentation liquor. However, the relevant step is not disclosed in relation to the Defendant's Manufacturing Process. In addition, whether the cation of ammonium ion or sodium ion, etc. was introduced in the fermentation liquor is also not disclosed. Moreover, it is very highly likely that the liquid-liquid extraction method is used in these steps.

(C) The defendant seems to intend to change the process to manufacture the Defendant's Product (Exhibit Ko No. 38), but has not disclosed the manufacturing process after the change.

D. Whether the Defendant's Manufacturing Process fulfills Plaintiff's Step (a) [i] (regarding "forming an enriched organic solution")

(A) The "enriched organic solution of pravastatin" in Plaintiff's Step (a) refers to "organic solution that is enriched in pravastatin relative to the initial concentration of pravastatin in the fermentation broth" (paragraph [0008] in the Description). Therefore, if "●(omitted)●" used in Defendant's Step (D) consists mainly of ●(omitted)● and the concentration of pravastatin in the eluate obtained in Defendant's Step (D) is higher than the initial concentration of pravastatin in the fermentation broth, said eluate falls under the enriched organic solution of pravastatin in Plaintiff's Step (a).

In addition, according to the Defendant's Application for Approval, ●(omitted)● crystallization is conducted in the Defendant's Manufacturing Process. However, if the concentration of pravastatin at the time of ●(omitted)● is higher than the initial concentration of pravastatin, the mixed liquid at the time of ●(omitted)● falls under the enriched organic solution. For crystallization, it is necessary to make the concentration of a crystalline material higher than the saturation solubility. Therefore, the concentration of pravastatin in the solution is

considerably high at the step immediately before crystallization occurs. Consequently, the organic solution of pravastatin immediately before crystallization, which is obtained through the step of "crystallization by ●(omitted)●," is very highly likely to be the "organic solution that is enriched in pravastatin relative to the initial concentration of pravastatin in the fermentation broth."

Furthermore, it is impossible to crystallize pravastatin sodium from the enriched aqueous solution of pravastatin in a good yield. It is common general technical knowledge among persons ordinarily skilled in the art to use a method whereby an enriched organic solution is formed by adding organic solvent, such as acetone. Therefore, the allegation of the defendant to the effect that "enriched aqueous solution" alone is formed is unreasonable.

(B) The defendant makes a comparison with Plaintiff's Step (a) while including part of Defendant's Step (E), ●(omitted)●, in Defendant's Step (D). However, the subject of comparison with Plaintiff's Step (a) is Defendant's Step (D) alone, and part of Defendant's Step (E) should not be included.

a. As ●(omitted)● is an organic solvent, it is obvious that pravastatin of Defendant's Step (D) eluted by ●(omitted)● is the organic solution of pravastatin.

As the concentration of pravastatin in the fermentation broth is usually extremely low, it is usual to enrich the fermentation broth at the stage of crude purification and provide the enriched fermentation broth for formal purification for the purpose of improving efficiency. Hereby, the concentration of pravastatin in the solution is raised. In light of such common general technical knowledge, it is obvious that, in the Defendant's Manufacturing Process, the concentration of pravastatin in the eluate obtained in Defendant's Step (D) is also higher than the concentration of pravastatin in the fermentation broth because elution is conducted in Defendant's Step (D) by using ●(omitted)●.

Moreover, as mentioned above, in order to have "crystallization" in Defendant's Step (E) occur, it is necessary to raise the concentration of pravastatin sodium to an extremely high level, that is, higher than the saturation solubility. Therefore, the concentration of pravastatin sodium in the solution must be considerably high at the time of start of enrichment in Defendant's Step (E) from the perspective of improving the efficiency of operation, etc.

Consequently, the solution obtained in Defendant's Step (D) falls under the "enriched organic solution" in Plaintiff's Step (a).

b. The defendant intends to conceal that an enriched organic solution is formed in Defendant's Step (D) by alleging that an enriched aqueous solution is obtained by ●(omitted)● through addition of Defendant's Step (E) to Defendant's Step (D). The allegation of the defendant is thus arbitrary and unreasonable.

E. Whether the Defendant's Manufacturing Process fulfills Plaintiff's Step (a) [ii]

(counterargument regarding the process to form an enriched organic solution)

The defendant has added a limitation to the effect that Plaintiff's Step (a) is limited to those using a liquid-liquid extraction method without using chromatography. However, there is no reason for such limitation.

(A) Regarding chromatography

a. The defendant alleges that Invention 1 does not include chromatographic purification. However, there is the possibility that the defendant implements the steps stated in the claims of the Patent while conducting chromatographic purification. Therefore, conducting chromatographic purification does not immediately mean that the defendant does not adopt the Plaintiff's Manufacturing Process.

b. Claim 1 of the Patent does not include any limitation in relation to a process to form an enriched organic solution.

As stated above, the feature of the Plaintiff's Manufacturing Process exists in the steps (Plaintiff's Steps (b) and (c)) of purification (formal purification) using salting-out crystallization. Plaintiff's Step (a) does not fall under a characteristic structure, and is merely a step that can be easily realized by conventional art. Consequently, there is no meaning in excluding use of a chromatographic method from such a step.

Moreover, the statement in paragraph [0006] in the Description, "without the need for chromatographic purification," means that highly pure pravastatin sodium can be obtained without the need for chromatographic purification in the method of formal purification (it is possible to obtain pravastatin sodium, in which epiprava and pravastatin lactone are reduced to such a level that pravastatin sodium is substantially free of them, only by the Plaintiff's Manufacturing Process). This does not exclude use of a chromatographic method. The aforementioned statement in paragraph [0006] refers to the feature of the formal purification step, and does not refer to the feature of the enrichment and crude purification steps before the formal purification. Therefore, the allegation of the defendant that interprets the enrichment and crude purification steps in a limited way only on the basis of the aforementioned statement in paragraph [0006] regarding the formal purification is unreasonable.

Furthermore, there is no inconvenience in carrying out chromatography in addition to Plaintiff's Steps (a) to (e). Actually, it is stated in paragraphs [0008], [0024] to [0027], and [0045] in the Description that a chromatographic method is carried out for the purpose of scavenging excess sodium ions.

Moreover, the explanation of circumstances concerning accelerated examination (Exhibit Otsu No. 3-5) points out the difference from conventional art by stating that a salting-out crystallization method is used in the Inventions. This does not lead to a limited interpretation that a chromatographic method is not used.

(B) Regarding the liquid-liquid extraction

The scope of claims of the Patent does not include a statement that the liquid-liquid extraction is used. Therefore, there is no reason for the interpretation limited thereto.

The statements in paragraph [0008], etc. in the Description as pointed out by the defendant also indicate a "preferred embodiment" for obtaining an enriched organic solution, and do not impose a limitation that use of the liquid-liquid extraction method is essential. It is also possible to obtain an "enriched organic solution of pravastatin" by conventional art, such as a vacuum concentration method and chromatographic method. Plaintiff's Step (a) includes all the steps for obtaining an "enriched organic solution of pravastatin." Actually, "concentration under reduced pressure" is adopted in Working Example 5 in the Description in order to obtain an enriched organic solution (paragraph [0050]).

On the other hand, a process wherein highly pure pravastatin sodium like the Defendant's Product is obtained by ●(omitted)● alone, which is disclosed in the Defendant's Manufacturing Process, is not known among persons ordinarily skilled in the art at this moment. It is also impossible to eliminate the possibility that the defendant carries out the liquid-liquid extraction method in addition to these steps.

F. As mentioned above, it is obvious that the Defendant's Manufacturing Process fulfills Plaintiff's Step (a).

(Allegations of the defendant)

(1) Regarding the structure of the Defendant's Product

The defendant disputes the allegation that the Defendant's Product falls under the technical scope of the Inventions.

(2) Regarding the process to manufacture the Defendant's Product

A. Article 104 of the Patent Act is applicable only to an invention of a process. As long as the Inventions are inventions of products, it is obvious that said Article is not applicable to the Inventions.

In addition, the defendant has specifically indicated that the Defendant's Manufacturing Process differs from the manufacturing process stated in Claim 1 of the Patent, and the pravastatin sodium of the Inventions has no novelty. Therefore, there is no room for the application of the presumption set forth in Article 104 of the Patent Act.

B.(A) The Defendant's Manufacturing Process is roughly as follows (hereinafter each step therein is referred to as "Defendant's Step (A)," etc.).

(A) A step wherein ●(omitted)● pravastatin is generated

(B) A step wherein a reaction liquid containing this pravastatin is ●(omitted)●

(C) A step wherein ●(omitted)● pravastatin is ●(omitted)●

(D) A step wherein ●(omitted)● pravastatin is eluted by ●(omitted)●

(E) A step wherein the eluate is ●(omitted)● crystallized and purified to obtain pravastatin sodium

(B) The plaintiff alleges that there has been a change to the process to manufacture the Defendant's Product. However, the defendant has not made any change to the manufacturing process, and does not plan to make a change thereto in the near future.

C. An "enriched organic solution" is not formed in the Defendant's Manufacturing Process

(A) In Defendant's Steps (D) and (E), the eluate obtained by ●(omitted)● is ●(omitted)● solution containing pravastatin, and an aqueous solution containing pravastatin is obtained by removing ●(omitted)● from the eluate. Therefore, an enriched aqueous solution of pravastatin is formed in Defendant's Step (E) in the Defendant's Manufacturing Process.

Therefore, the Defendant's Manufacturing Process does not fulfill the constituent feature of Plaintiff's Step (a), "forming an enriched organic solution of pravastatin."

(B) The plaintiff alleges that the Defendant's Manufacturing Process alleged by the defendant omits the fact of ●(omitted)● stated in the Defendant's Application for Approval and that there is the possibility that an enriched organic solution is formed by ●(omitted)●.

Certainly, ●(omitted)● is carried out in Defendant's Step (E) in the Defendant's Manufacturing Process.

However, the step of the Inventions wherein an enriched organic solution is formed means a step that "involves extraction of pravastatin from an aqueous fermentation broth into an organic solvent, back-extraction of pravastatin into a basic aqueous solution and re-extraction into an organic solvent, resulting in an organic solution that is enriched in pravastatin relative to the initial concentration of pravastatin in the fermentation broth" (paragraph [0008] in the Description). It is not that an organic solution that is enriched in pravastatin relative to the initial concentration always fulfills the structure of Plaintiff Step (a).

In addition, the ●(omitted)● crystallization step stated in the Defendant's Application for Approval differs from the step wherein an enriched organic solution is formed from an aqueous fermentation broth by the liquid-liquid extraction. That is, "crystallization" refers to a phenomenon wherein crystals precipitate from a liquid phase (Exhibit Otsu No. 40). The "●(omitted)● 'crystallization'" step in the Defendant's Manufacturing Process corresponds to the "crystallization" step stated in paragraphs [0029], [0045], etc. in the Description. Therefore, it is a step that is clearly distinguished from the step of "(a) forming an enriched organic solution of pravastatin."

Furthermore, as crystals are generated through crystallization, the liquid may be diluted by ●(omitted)● in a aqueous solution, but will not be enriched. Therefore, no "enriched organic solution" is formed.

In addition, in the Defendant's Manufacturing Process, the Defendant's Product is obtained

by separating pravastatin sodium after ●(omitted)● crystallization. The Defendant's Manufacturing Process does not involve any step corresponding to Plaintiff's Step (b) and thereafter after the "●(omitted)● crystallization." Consequently, the allegation of the plaintiff that intends to compare the "●(omitted)● crystallization" step and Plaintiff's Step (a), that is, the "liquid-liquid extraction" step wherein an enriched organic solution of pravastatin is formed, is originally chemically erroneous, is completely unsupportable and is unreasonable.

Therefore, in consideration of the statement of the scope of claims, it is impossible to equate the operation carried out in relation to the "crystallization" step with the operation intended to form an enriched organic solution. Consequently, it is obvious that carrying out ●(omitted)● does not fall under the step of "(a) forming an enriched organic solution of pravastatin" before the step of precipitation of crystals in the Inventions.

D. In the Defendant's Manufacturing Process, ●(omitted)● is used in Defendant's Step (C) and the liquid-liquid extraction is not carried out.

(A)a. It is stated in the Description that "This invention meets a need in the art for an efficient method of isolating pravastatin sodium from a fermentation broth … without the need for chromatographic purification" (paragraph [0006]). Moreover, only the liquid-liquid extraction that is conducted by using two clearly separated liquid layers, a "water-immiscible organic solution layer" and an "aqueous solution layer," is disclosed in order to form an enriched organic solution without the need for chromatographic purification. In light of these, it can be said that the Inventions are inventions that were made to obtain highly pure pravastatin sodium by using the liquid-liquid extraction method without the need for chromatographic purification.

That is, there are the following statements in paragraph [0008] in the Description: "relative to the initial concentration of pravastatin in the fermentation broth" and "Pravastatin may be obtained from the enriched solution by precipitation as its ammonium salt … purification by recrystallization …." There is also the following statement in paragraph [0016]: "In the next step, pravastatin may be salted out from the enriched organic solution with ammonia or an amine." Therefore, the "enriched organic solution" is considered as an organic solution, which is enriched in pravastatin relative to the concentration of pravastatin in the fermentation broth, in the step before the precipitation of crystals of pravastatin. This is also obvious from the statements about Plaintiff's Step (b) and thereafter following Plaintiff's Step (a).

As mentioned above, the following process is stated as a process of "forming an enriched organic solution of pravastatin" of the Inventions in paragraph [0008] in the Description: the process that "involves extraction of pravastatin from an aqueous fermentation broth into an organic solvent, back-extraction of pravastatin into a basic aqueous solution and re-extraction into an organic solvent, resulting in an organic solution that is enriched in pravastatin relative to the initial concentration of pravastatin in the fermentation broth."

Moreover, according to paragraphs [0011] to [0016] and [0039] in the Description and the statements in a written opinion (Exhibit Otsu No. 3-10) submitted by the applicant in the application process for the Patent, it is not a chromatographic method but an extraction method which is another purification method, i.e. the "liquid-liquid extraction," that is used in the Inventions. Even in consideration of the Description and the prosecution history, it is impossible to consider that a purification method other than the "liquid-liquid extraction" method is used in the Inventions.

Furthermore, it is clearly stipulated in paragraph [0031] in the Description that the pravastatin sodium containing less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava, which is Corrected Invention 1, is isolated by "adhering to" the embodiments stated in Examples 1 and 3. It is stated in Examples 1 and 3 that should be "adhered to" that an "enriched organic solution is formed" by only using the "liquid-liquid extraction" method when forming an "enriched organic solution" in the step before the precipitation of crystals of pravastatin.

In addition, the applicant explains that the cited document differs from the Inventions as it uses chromatography, in the statement in paragraph [0006] in the Description ("without the need for chromatographic purification") and in the explanation of circumstances concerning accelerated examination (Exhibit Otsu No. 3-5) submitted in the application process for the Patent. In light of this, the applicant actively excludes the chromatographic method from the Inventions. Therefore, it goes against the matter stated as a problem in the Description to allege that the Inventions include a method wherein the chromatographic method is used for the purification of pravastatin from the fermentation broth, and it also goes against the allegations of the plaintiff concerning the establishment of the Patent. Thus, such allegation is unacceptable.

Based on the above, "forming an enriched organic solution of pravastatin" in Plaintiff's Process (a) should be interpreted as meaning forming an organic solution, which is enriched in pravastatin relative to the concentration of pravastatin in the fermentation broth, in the step before the precipitation of crystals of pravastatin, that is, forming an enriched organic solution by using the "liquid-liquid extraction" method without using a chromatographic method.

b. The plaintiff alleges that Example 5 in the Description adopts a method of enrichment under reduced pressure.

However, according to the statements in paragraphs [0049] and [0050] in the Description, it is obvious that the liquid-liquid extraction is also carried out in Example 5 in order to obtain an enriched solution. Enrichment under reduced pressure is also carried out in addition to the liquid-liquid extraction.

(B)a. On the other hand, in the Defendant's Manufacturing Process, an "enriched" liquid in the step before "crystallization" for the precipitation of crystals of pravastatin from the fermentation broth is formed by going through the following steps: "(c) a step wherein ●(omitted)●

pravastatin is ●(omitted)●, (d) a step wherein ●(omitted)● pravastatin is eluted by ●(omitted)●, (e) a step wherein the eluate is enriched through ●(omitted)●." The Defendant's Manufacturing Process involves purification by ●(omitted)●, but does not involve any step wherein an enriched organic solution of pravastatin is formed by using the "liquid-liquid extraction" method.

Therefore, the Plaintiff's Manufacturing Process and the Defendant's Manufacturing Process fundamentally differ in the technical idea, and the Defendant's Manufacturing Process is not included in the technical scope of the Inventions.

b. The plaintiff alleges that there is the possibility that the defendant adopts the "liquid-liquid extraction" method, for the following reasons: [i] the defendant has given no explanation about the way it eventually obtains highly pure pravastatin sodium by introducing sodium cation in a pravastatin solution and [ii] a process consisting solely of●(omitted)● whereby highly pure pravastatin sodium like the Defendant's Product is obtained is not at all known among persons ordinarily skilled in the art at present.

However, regarding [i], the Plaintiff's Manufacturing Process and the Defendant's Manufacturing Process are sufficiently distinguished based on the matters concerning the Defendant's Manufacturing Process disclosed by the defendant. Therefore, there is no need to further disclose the details of other steps of the Defendant's Manufacturing Process.

In addition, regarding [ii], the ground on which the plaintiff alleges that the process is not known among persons ordinarily skilled in the art is unclear. However, in fact, the defendant has obtained highly pure pravastatin sodium by using ●(omitted)● without using the "liquid-liquid extraction" method at all. Regarding [ii], the plaintiff alleges that "There is the possibility that the defendant adopts the "liquid-liquid extraction" method only because the plaintiff does not know any other processes to obtain highly pure pravastatin sodium. However, such allegation is obviously unreasonable.

E. As mentioned above, in the Defendant's Manufacturing Process, an "enriched aqueous solution" containing pravastatin is obtained from an aqueous fermentation broth by going through a step using ●(omitted)● in the first step. Plaintiff's Step (a) is not adopted either in the first step or in any of the subsequent steps. Therefore, it is obvious that the statements concerning the "manufacturing process" of the Patent and the Defendant's Manufacturing Process completely differ from each other.

(3) Consequently, the Defendant's Product does not fall under the technical scope of Invention 1.

Moreover, the Defendant's Product does not fall under the technical scope of Inventions 2 to 9 as these inventions are those citing Invention 1.

3. Regarding Issue (2)A. (gist of the Inventions)

(Allegations of the defendant)

In determining the validity of a product-by-process claim like that for the Inventions, whether the invention has novelty and an inventive step should be determined deeming that the invention means a product obtained in the end, irrespective of the manufacturing process. Therefore, the validity of the Patent should be determined deeming that the Inventions mean "pravastatin sodium containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava."

Incidentally, the following is also stated in the JPO's Examination Guidelines for Patent and Utility Model in Japan (hereinafter referred to as the "Examination Guidelines"): "It is understood that claims defining products by the manufacturing processes means definitions that represent products per se gained as final products, unless otherwise interpreted according to 1.5.1(2) above. Accordingly, the novelty of the claimed invention is denied when other manufacturing processes are able to produce an identical product to that of the claimed manufacturing process and the product is publicly known." This JPO practice is also supported by the court in actions to seek rescission of a JPO decision.

(Allegations of the plaintiff)

(1) The defendant says that the process should be taken into consideration in interpreting the technical scope of the Inventions, but also says that the validity of the Patent should be determined in relation to the product. However, it is logically inconsistent to adopt different subjects of determination in terms of these two points.

Both the finding of the gist of a patented invention and the determination of the scope of right of a patented invention are conducted on the basis of the statement of the scope of claims and the statements in the description, as provided for in Article 70 of the Patent Act. Therefore, it is natural that they are consistent with each other. Therefore, a manufacturing process should also be taken into consideration in finding the gist of an invention only where it is necessary to take into consideration the manufacturing process to specify the structure of the product, in the same way as mentioned with regard to the technical scope of the Inventions.

If both a product and a manufacturing process are taken into consideration in relation to the scope of right of a patented invention, both of them should also be taken into consideration in determining the validity of the patent. In addition, if the gist of an invention is found based on a "product" and a "manufacturing process," there will be no dispute over the validity of the Patent because the defendant has alleged no ground for invalidation regarding the manufacturing process.

(2) In addition, the problem to be solved by the Inventions is provision of highly pure pravastatin sodium wherein the content of pravastatin lactone and that of epiprava are extremely reduced. As pravastatin lactone is likely to be further generated and increase in the purification process, it is impossible to overcome this problem only by simply repeating conventional

purification processes.

4. Regarding Issue (2)B. (lack of novelty based on Exhibit Otsu No. 1)

(Allegations of the defendant)

(1) As mentioned above, the validity of a product-by-process claim should be determined based on the novelty and an inventive step of a product manufactured in the end. The Inventions merely stipulate that impurities are as few as possible, and are not recognized as having any inventiveness by itself.

(2) Statements in Exhibit Otsu No. 1 Document and release of mevalotin tablets

It is stated on page 10 of the "Drug Interview Form" (Exhibit Otsu No. 1; revised version of October 1997; hereinafter referred to as "Exhibit Otsu No. 1 Document") for mevalotin tablets, which is a publication distributed by Company D around October 1997 prior to the priority date of the Patent, that the relevant mevalotin tablet is a highly pure product containing about 99 % of pravastatin sodium and contains 0.02 to 0.06 % of "RMS-414" (i.e. pravastatin lactone) and 0.19 to 0.65 % of "RMS-418" (i.e. epiprava), both of which are related substances of pravastatin.

Moreover, mevalotin tablets and fine granules were put on sale on October 2, 1989, and mevalotin tablets 10 and mevalotin fine granule 1% were put on sale on December 6, 1991 (Exhibit Otsu No. 1). Accordingly, preparations of pravastatin sodium having the abovementioned ingredients could have been publicly obtained prior to the priority date of the Patent.

(3) Lack of novelty of the Inventions

As mentioned in (2), Invention 1 is the invention stated in Exhibit Otsu No. 1 Document and is one that had been publicly worked prior to the priority date of the Patent. Therefore, it falls under Article 29, paragraph (1), item (ii) or (iii), and is thus invalidated.

In addition, Inventions 2 to 9 are also considered as inventions of products in the same manner as Invention 1. Therefore, they are also invalidated for the same reason as that for Invention 1.

(4) Counterargument against the allegations of the plaintiff

A. The statement concerning product-by-process claims in the Examination Guidelines indicated by the plaintiff merely shows that a process is nothing more than a means for specifying a product and that if a produced product is publicly known, the produced product is considered identical as a specified product and the novelty of the invention is denied irrespective of the manufacturing process. It is sufficient if a cited reference that denies the novelty and an inventive step of the invention states the structure of a relevant product. In the judgment of the Tokyo High Court of October 1, 1991, the court also ruled as follows: "Setting aside the case where the invention claimed in the patent application is an invention of a process,

the invention claimed in the patent application is an invention of a product. Therefore, it should be considered sufficient for determining the identity as a product if the structure of a product is disclosed in a publication compared with the invention claimed in the patent application. It should be said that there is not necessarily the need for further disclosure of a specific process to manufacture the product (or a clue to the obtainment of such a specific process)."

Consequently, Exhibit Otsu No. 1 Document is a document that is sufficient to deny the novelty of Invention 1.

B. The plaintiff alleges that a cited reference that denies the novelty of an invention needs to disclose a manufacturing process as well as a product.

However, if a product already exists, it is obvious that a previous maker had manufactured the product in some way. As an invention, the product has already been completed by the previous maker. It is thus not necessary to protect an invention for the same product which is subsequently manufactured. As for the statements in a publication, it is necessary that the structure of a product is disclosed to the extent that is necessary for comparison with the content of a patented invention. However, it is sufficient if a person ordinarily skilled in the art can obtain or manufacture, and use the product based on the statements in the publication and common general technical knowledge at the time of filing of the patent application. The argument that an invention cannot be regarded as publicly known as a product unless the manufacturing method of the product is also disclosed is unacceptable.

Exhibit Otsu No. 1 Document is a piece of evidence that proves the existence of pravastatin sodium as a product of Invention 1, and it discloses the entire structure as a product.

In addition, mevalotin tablets had been manufactured and sold by Company D prior to the priority date of the Patent, and it is obvious that a person ordinarily skilled in the art could obtain or manufacture, and use the product on the basis of the statements in Exhibit Otsu No. 1 Document and common general technical knowledge as of the priority date.

C. As alleged by the plaintiff, if it is not necessary to take into consideration a difference from a publicly known substance in the manufacturing process in determining the validity of a patent, the substance pertaining to Invention 1 is identical with the publicly worked substance and the Patent is invalid.

(Allegations of the plaintiff)

(1) With regard to the determination of the novelty of an invention of a product claimed in a product-by-process claim, the Examination Guidelines state as follows: "the novelty of the claimed invention is denied when other manufacturing processes are able to produce an identical product to that of the claimed manufacturing process and the product is publicly known." Therefore, a cited reference that denies the novelty of such an invention needs to disclose the following two points: [i] it is possible to manufacture an identical product by a

process other than the claimed process; and [ii] the product is publicly known.

However, Exhibit Otsu No. 1 Document only numerically states the content of pravastatin lactone and that of epiprava, and makes no disclosure of the process to manufacture pravastatin sodium containing the impurities of those quantities.

Consequently, Exhibit Otsu No. 1 Document is not eligible for a publication on which the novelty and an inventive step of an invention is determined because it does not disclose that the product was obtained by another process.

(2)A. In the first place, the invention mentioned in the Patent Act refers to a technical idea as a whole, and is required to be workable by a person ordinarily skilled in the art. If an application lacks the statement of a manufacturing process, it becomes subject to an examiner's decision of refusal on the ground that it does not comply with the enablement requirement or that the disclosure of the content of the invention is insufficient. Therefore, the Patent Act is considered as being based on the idea that an invention is treated as an invention only when a process to acquire the invention is disclosed to the extent that a person ordinarily skilled in the art can reproduce it.

Therefore, it is a logical conclusion that for the invention as mentioned in Article 29, paragraph (1) of the Patent Act, a process to obtain a relevant product is to be disclosed in relation to a patent of a "product."

In addition, for a chemical substance like the Inventions, a person ordinarily skilled in the art can obtain an identical chemical substance only when the process to manufacture the chemical substance is disclosed. If a cited reference does not disclose the manufacturing process, the substance cannot be obtained. Therefore, the novelty of the relevant invention is still maintained.

The process to manufacture the product that is disclosed in Exhibit Otsu No. 1 Document had been kept secret within Company D as know-how. Therefore, the manufacturing process had not been disclosed, and it thus does not contribute to the development of industry. Therefore, it is not eligible for a cited invention. Consequently, there is no reason that the patent that had contributed to the development of industry is invalidated based on said manufacturing process.

B. Moreover, even if a product subject to a patent can be obtained in the market, the relevant invention is neither disclosed nor is considered as being publicly worked unless the process to manufacture the product is disclosed, in the same manner as in the case of a publication.

In contrast to a machine with a simple structure, it is difficult for a person ordinarily skilled in the art to immediately understand the process to manufacture a chemical substance even if a relevant product alone is indicated. Therefore, the fact that a product has been circulated in the market is not sufficient to say that an invention including the process to produce the product has been revealed to the public.

C. The Old Patent Act, the Examination Guidelines, and juridical precedents also indicate such idea that the technical idea as a whole, including the process to manufacture a relevant product, should be disclosed in relation to a cited invention that denies the novelty of another invention.

According to the Examination Guidelines and juridical precedents, if it is possible to understand a process to manufacture a product from a cited reference in consideration of common general technical knowledge of the time, the relevant invention can be regarded as a cited invention. However, it is impossible for a person ordinarily skilled in the art to understand the process to manufacture pravastatin sodium disclosed in Exhibit Otsu No. 1 Document on the basis of Exhibit Otsu No. 1 Document even in consideration of common general technical knowledge as of the priority date of the Patent. Therefore, Exhibit Otsu No. 1 Document cannot become a cited document.

D. Mevalotin tablets, the product disclosed in Exhibit Otsu No. 1 Document, can also not become a cited invention in the same way as Exhibit Otsu No. 1 Document.

E. Therefore, the novelty of the Inventions is not denied on the basis of either Exhibit Otsu No. 1 Document or mevalotin tablets.

5. Regarding Issue (2)C. (lack of an inventive step based on Exhibit Otsu No. 1)

(Allegations of the defendant)

(1)A. Trying to increase the level of purity of a useful chemical substance used for a medicine, etc. and thereby reduce the mixed amount of related substances of the useful chemical substance, which are impurities, is what a person ordinarily skilled in the art commonly conducts.

Taking into account that highly pure pravastatin sodium containing about 99 % of pravastatin sodium is disclosed on page 10 of Exhibit Otsu No. 1 Document, Invention 1 is an invention made through exertion of the ordinary creative ability of a person ordinarily skilled in the art. In addition, it is not stated in the Description that Invention 1 produces a prominent technical effect (e.g. excellent therapeutic effect) that goes beyond the prediction of persons ordinarily skilled in the art. Therefore, Invention 1 is one that a person ordinarily skilled in the art could have easily conceived of.

Therefore, Invention 1 is unpatentable pursuant to Article 29, paragraph (2) of the Patent Act.

B. Inventions 2 to 9 for which the purification process is specified are also inventions of products in the same way as Invention 1. Therefore, Inventions 2 to 9 can be regarded as those that a person ordinarily skilled in the art could have easily made, for the same reason as that for Invention 1.

(2) For the allegations of the plaintiff concerning the difficulty of separation and removal of pravastatin lactone and epiprava, difficulty of the manufacturing process is merely used as a reason for existence of an inventive step. It does not serve as a reason that supports existence of

an inventive step of an invention of a product, setting aside the case that it is adopted in a discussion on an inventive step of an invention of a manufacturing process.

(3)A. The plaintiff alleges that it is obvious from the statements in the "pravastatin development report" (Exhibit Ko No. 30), etc. that reducing the content of epiprava has an excellent effect. However, there is no statement supporting this in the Description, and an effect alleged and proven in a written opinion, etc. which a person ordinarily skilled in the art is unable to presume from the statements in the description or drawings should not be taken into account (Part II, Chapter 2, 2.5(3)II of the Examination Guidelines). Therefore, it is not permissible to allege and prove such an effect in certified examination results ex-post.

In addition, [i] according to Tables 1 and 2 in Exhibit Ko No. 30, the result of the test does not indicate the result of the case where highly pure pravastatin sodium containing a slight amount of epiprava is treated by acid, as it is obvious from the facts that the content of pravastatin sodium in the solution used for the test, that is, the solution before acid treatment, is low at 80.12 area %, and that the ratio between epiprava and pravastatin sodium is high at 9.58%. Additionally, [ii] the reaction conducted at 50°C by using phosphoric acid or sulfuric acid (both of which have a pH of 3.0) as stated in (3-1) and (3-2) in Exhibit Ko No. 30 does not indicate the result obtained through the reaction conducted at 37°C by using hydrochloric acid (it has a pH of 1 to 2), that is, the reaction under the "acid condition that simulates gastric conditions." [iii] Furthermore, Exhibit Ko No. 30 indicates the behavior of impurities in pravastatin sodium under the acid condition, and Tables 1 and 2 merely describe that epiprava in pravastatin sodium is more reduced through acid treatment compared to other impurities.

As mentioned above, Exhibit Ko No. 30 does not indicate any effect obtained by reducing the amount of epiprava mixed in pravastatin sodium (to less than 0.1%).

Moreover, there is no statement in the Description concerning the point that epiprava "produces epoxy derivative when it is enzymatically oxidized and is likely to put an excess load on the liver" (Exhibit Ko No. 31). The plaintiff intends to allege and prove this point ex-post in the certified examination results. This is unacceptable. Even if it is possible to "presume" the possibility that a decomposition product whose property is unknown which was converted from epiprava will have an undesired effect on a patient in consideration of the relevant statements, the specific details of the undesired effect are completely unclear. The relevant statements merely indicate that there is an ordinary problem in the pharmaceutical industry, that is, to "reduce the amount of related substances of a useful chemical substance, which are impurities, mixed" in preparations of pravastatin sodium.

The preparations of highly pure pravastatin sodium (mevalotin tablets) stated in Exhibit Otsu No. 1 Document had been manufactured and sold as a medicine prior to the priority date of the Patent. Therefore, it is a mere practice which a person ordinarily skilled in the art commonly

conducts to try to reduce the amount of impurities mixed in the relevant preparations of pravastatin sodium. It is thus obvious that there is no reasonable ground for the allegation of the plaintiff to the effect that the Inventions that reduce the amount of epiprava mixed in pravastatin sodium (to less than 0.1 wt% after the Correction) have an excellent effect.

B. The plaintiff alleges as follows: For an invention that reduces impurities in a medicine, if a high level of purity that has been technically difficult to achieve up to then is achieved for the first time, the achievement thereof per se may be recognized as a special excellent function and effect.

However, the difficulty of a manufacturing process, that is, the difficulty of the removal, etc. of impurities, does not serve as a reason that supports an inventive step of an invention of a "product" as in this case, as mentioned above. Moreover, even if difficulty of the manufacturing process serves as a reason that supports an inventive step, a person ordinarily skilled in the art could have easily obtained the pravastatin sodium wherein the mixed amount of pravastatin lactone and that of epiprava are as stipulated by the Inventions, by using the publicly known pravastatin sodium stated in Exhibit Otsu No. 1 Document, etc. as a starting material and by separating and purifying it by using the publicly known process stated in Exhibit Otsu No. 11, etc. Therefore, it is obvious that the allegation of the plaintiff to the effect that a high level of purity that had been technically difficult to achieve up to then was achieved for the first time.

(Allegations of the plaintiff)

(1) Article 29, paragraph (2) of the Patent Act provides that existence of an inventive step of an invention is determined on the basis of cited inventions that are the same as those used for the determination of the novelty of the invention. Therefore, Exhibit Otsu No. 1 Document or mevalotin tablets cannot be used as the basis for the determination of existence of an inventive step, as mentioned in relation to determination of novelty.

(2) Even if the existence of fewer impurities is desirable for a medicine, that point is a separate issue from the existence of an inventive step of an invention. If a highly pure medicine is achieved by overcoming many technical difficulties in the reduction of impurities, an inventive step is recognized. It is obvious from the provisions of Article 29, paragraph (2) of the Patent Act, which provides for an inventive step with a focus on the easiness or difficulty of conceiving of the structure of an invention, that if a person conceives of a "structure" that has been difficult to achieve based on conventional art, that fact is sufficient to affirm existence of a "special function and effect." In addition, an invention that increases the level of purity of a medicinal active substance is not an invention wherein a specific numerical range is selected, but an invention that is oriented toward a high level of purity without limit. Therefore, it is unreasonable to bring up the meaning of numerical values as limits.

The essence of the Inventions exists in the achievement of highly pure pravastatin sodium

by overcoming technical difficulty with the separation and removal of pravastatin lactone and epiprava that had been very difficult to separate or remove by conventional art due to their close similarity to pravastatin in the structure and their similarity thereto in the physical and chemical property. Said achievement has an excellent effect as a medicine (in particular, fewer impurities and a high level of purity have an important meaning in relation to pravastatin sodium, which is a medicine taken for a long period of time), and its "special function and effect" can be affirmed. Therefore, it is obvious that the Inventions have an inventive step.

Moreover, for epiprava, the goal was to reduce the content thereof to less than 0.1% (see Exhibits Ko No. 28 and No. 29). This goal was achieved for the first time by the Inventions. In addition, epiprava is expected to be converted into a decomposition product whose property is unknown in stomach fluid (Exhibit Ko No. 30). It is impossible to deny the possibility that this would have an undesired effect on a patient. Therefore, the Inventions have an inventive step in terms of a high level of purity, and are patentable as inventions of products.

(3) The defendant criticizes the content of the "pravastatin development report" (Exhibit Ko No. 30).

However, a person ordinarily skilled in the art can predict that a favorable effect can be obtained by increasing the level of purity of a medicinal active substance, and Exhibits Ko No. 30 and No. 31 indicate the possibility that existence of epiprava may have an adverse effect on a patient. Therefore, there is no problem in alleging the effect of the Inventions by reducing the content of epiprava.

Moreover, the plaintiff points out that the pravastatin sodium of Exhibit Ko No. 30 has a high epiprava content and that the temperature and pH differ from those under the acid condition that simulates gastric conditions.

However, the content of epiprava does not matter in relation to the matter to be proven, that is, whether there is the possibility that epiprava will convert into a decomposition product whose property is unknown under the acid condition and will have an undesired effect on a patient. Moreover, said difference in temperature merely affects the reaction speed, and does not affect the fact that epiprava converts into a decomposition product whose property is unknown. Furthermore, regarding said difference in pH, as long as the conversion occurs under the acid condition, it is possible to say that the conversion is likely to occur under higher acid conditions.

6. Regarding Issue (2)D. (lack of novelty and an inventive step based on Exhibit Otsu No. 6)

(Allegations of the defendant)

(1) Around April 2000 prior to the priority date of the Patent, Biogal Gyogyszergyar Rt. (hereinafter referred to as "Biogal"), which is the predecessor of the plaintiff, was distributing its own pravastatin sodium to Company C, which is a pharmaceutical manufacturer in Japan, through a trading company (hereinafter this distributed pravastatin sodium is referred to as

"Exhibit Otsu No. 6 Sample").

It is clearly stipulated in the "Related substances" column in the "Product Specifications and Certificate of Analysis; Certificate No. 205/00; Batch No. PR-00100" (Exhibit Otsu No. 6; hereinafter referred to as "Exhibit Otsu No. 6 Document"), which was distributed as an attached document showing the results of specification testing of Exhibit Otsu No. 6 Sample along with the distribution of Exhibit Otsu No. 6 Sample, that the content of epiprava is 0.11% and that the content of pravastatin lactone is 0.03%.

Therefore, it is obvious that the content of pravastatin lactone in Exhibit Otsu No. 6 Document falls under the content thereof of Invention 1, "less than 0.5 wt%," and the content of epiprava in Exhibit Otsu No. 6 Document falls under the content thereof of Invention 1, "less than 0.2 wt%," respectively.

(2) Eligibility of Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample for cited references

A. Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample are considered as having been distributed before April 6, 2000 because Exhibit Otsu No. 6 Document is datemarked ("00.4.06") with a rubber stamp and because the "written request for a test on a development material" (Exhibit Otsu No. 7) regarding Exhibit Otsu No. 6 Sample is dated April 6, 2000.

There has been neither contract nor explanation, etc. indicating that Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample are secret matters. Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample have been available for anyone to see. Consequently, Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample became publicly known at the time when they were provided.

B.(A) The plaintiff alleges that a pharmaceutical company that has received a sample, etc. assumes the duty of confidentiality in terms of the general practice in the industry in Japan and that it is common sense in the pharmaceutical industry not to conclude a confidentiality agreement.

However, it is neither such common practice nor sense in the industry that the duty of confidentiality arises even without conclusion of a confidentiality agreement. In addition, it is common sense not to disclose any confidential matters to other party if said other party refuses to conclude a confidentiality agreement. Actually, the defendant has received a confirmation from Company C and the intermediate trading company that the plaintiff did not request them to keep Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample secret when distributing them.

(B) Moreover, although the plaintiff alleges that Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample were distributed to limited persons, it is rather reported that the plaintiff was actively advertising and selling pravastatin sodium to Japanese pharmaceutical manufactures at

that time.

(C) The statement in Exhibit Otsu No. 6 Document, "Sample for experimental purposes only," merely indicates that the sample is used for experimental purposes only and cannot be used for commercial or clinical purposes, and it has no relation to confidentiality. Actually, there is no such statement in many test reports distributed by the plaintiff.

Moreover, for a product that was distributed without the duty of confidentiality, how a pharmaceutical company that received the distribution thereof has handled the product does not matter in determining whether the relevant invention has been described in a publication or has been publicly worked.

(D) The allegation of the plaintiff based on the fact that the basic patent of Company D had been maintained is on the assumption of a fact that goes against law and ethics, and it is thus unacceptable. It is natural that an invention becomes publicly known at the time of publication if it is published without any confidentiality agreement.

In addition, originally, there is no such common sense as alleged by the plaintiff in the industry, and the allegation of the plaintiff is unreasonable, taking into account that Biogal and other medicinal material manufacturers had actively conducted promotion activities during the period when the basic patent of Company D existed. Rather, the statement in Exhibit Otsu No. 6 Document, "Sample for experimental purposes only," is an indication intended to publicly distribute the sample by showing that the distribution is an act of working the invention for the purpose of development of generic drugs.

(E) Consequently, Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample are not subject to the duty of confidentiality. It should also be said that there were no special circumstances where these pieces of information should be kept secret.

C. Regarding the issue of disclosure of the manufacturing process

Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample were distributed to Company C without the duty of confidentiality, and a person ordinarily skilled in the art was able to obtain the relevant "product" prior to the priority date of the Patent. Therefore, it is obvious that the "invention of a product" has been disclosed, for the same reason as that mentioned in relation to Exhibit Otsu No. 1 Document and mevalotin tablets.

Consequently, Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample are "eligible" for cited inventions, and are used in determining the novelty and an inventive step of Invention 1 both before and after the Correction.

(3) Therefore, Invention 1 falls under Article 29, paragraph (1), items (ii) and (iii) of the Patent Act, or is one that a person ordinarily skilled in the art could have easily conceived of based on Exhibit Otsu No. 6 Document or Exhibit Otsu No. 6 Sample. Invention 1 thus falls under paragraph (2) of said Article.

In the same manner, Inventions 2 to 9 are also inventions of products, and the same as Invention 1 applies.

(Allegations of the plaintiff)

(1) Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample are secret matters, as mentioned below. They fall under neither inventions that have been publicly worked nor inventions that have been described in a publication.

A. Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample were provided by Biogal only to pharmaceutical companies that were due to become its customers at the time when it intended to enter the Japanese market. It is not the case that anyone could obtain them. This is also obvious from the fact that there is the statement, "Sample for experimental purposes only," in Exhibit Otsu No. 6 and that the use thereof was limited to the research and development departments of the relevant pharmaceutical companies that received the sample.

B. It is obvious that Company C assumed the duty of confidentiality, taking into consideration that there is the statement, "Sample for experimental purposes only," in Exhibit Otsu No. 6 Document and that Company C had not disclosed Exhibit Otsu No. 6 Document and information about Exhibit Otsu No. 6 Sample to any third party over eight years up to the filing of this action.

In addition, it is common sense in the pharmaceutical industry not to conclude a confidentiality agreement at the stage of start of transactions, that is, at the stage of provision of a sample, for the purpose of promptness of transactions. It is also common sense in business transactions to handle the content of business transactions as information kept only between the parties concerned. Moreover, Company C and the plaintiff or the parent company thereof have a continuous business relationship. This also serves as the basis for the duty of confidentiality.

Furthermore, in this case, there are the following circumstances: [i] as the sample, etc. was provided for the development of generic drugs during the duration of the basic patent (Patent No. 1347361) for pravastatin sodium of Company D, it is common sense in the industry that the relevant research and development or transactions related thereto are kept secret; in particular, there is a constraint unique to Japan, specifically, consideration to the manufacturers of original drugs; and [ii] Company C and Biogal have agreed that Company C does not divulge information about the sample and that Biogal does not divulge Company C's development plan because Company C is at risk of being accused of a patent infringement if it externally indicates that it is carrying out the development with the aim of entering into the relevant business after the expiration of the duration of the aforementioned Company D's patent and because Biogal, which is an active pharmaceutical ingredient manufacturer, is also at risk of being accused of a patent infringement, as well as because of a problem in terms of competition against competing manufacturers, etc.

Taking this into account, it is natural that Company C assumes the duty of confidentiality in relation to Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample. Company C should acknowledge that there was an agreement to handle these pieces of information as secrets.

(2) Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample do not disclose the manufacturing process to obtain the pravastatin sodium disclosed therein, and they fall under neither inventions that have been publicly worked nor inventions that have been described in a publication, in the same way as Exhibit Otsu No. 1 Document and mevalotin tablets.

(3) As mentioned above, the novelty and an inventive step of the Inventions are not denied based on Exhibit Otsu No. 6 Document or Exhibit Otsu No. 6 Sample.

7. Regarding Issue (2)E. (non-compliance with Article 36 of the Patent Act)

(Allegations of the defendant)

(1) Non-compliance with the description requirements [i]

A.(A) The actual measured values of pravastatin lactone and epiprava are not stated in the Description as the working examples, etc. In this regard, the plaintiff clearly indicated the absence of support by experiment in a written opinion (Exhibit Otsu No. 3-10) that it submitted in the examination process at the JPO.

In addition, as a theoretical base for the values of pravastatin lactone and epiprava, it is stated in said written opinion that the amount of pravastatin lactone and epiprava can be specified because the ratio between them is known as about two to one. However, such content ratio is not stated in the Description. Moreover, the content ratio between them that is indicated in the table in the right column on page 10 of Exhibit Otsu No. 1 Document significantly differs from said ratio, "two to one." The same applies to the statements in the "Related substances" column in Exhibit Otsu No. 6 Document and the data in the detailed purification table (Exhibit Ko No. 12) concerning Example 1 and Examples 3 to 6 in the Description.

(B) The statement in paragraph [0031] in the Description, on which the allegation of the plaintiff is based, does not mention the method of measuring pravastatin lactone and epiprava and the measured values thereof at all, even in consideration of Examples 1 and 3 cited in said paragraph. The plaintiff says that Exhibits Ko No. 12 and No. 13 were the results of measurement based on the plaintiff's in-house standards, but it is impossible to understand such in-house standards from the Description. Therefore, a person ordinarily skilled in the art could not understand said in-house standards as of the priority date of the Patent.

Moreover, the plaintiff alleges that it is obvious from the statements of Examples 1 and 3 in the Description and the statement in paragraph [0031] in the Description that the measured values are based on the working examples. However, the expressions, "may be isolated" and "was obtained," are used in the PCT application (International Application No. W02002/030415 A1; Exhibit Otsu No. 10), which serves as the basis for the patent application in question. The

expression, "may be isolated," is also used in the Description. Therefore, it is impossible to say that such statements are the same as those in the working examples or that they are supported by the working examples.

(C)a. The plaintiff alleges that the fact that the content of pravastatin lactone after the Correction is less than 0.2 wt% is supported by the statements concerning the purity of pravastatin sodium in Examples 1, 3, and 5 in the Description.

However, according to the statement, "98.0-101.0%," in the "SPECIFICATION" in the "Assay (on water-free and solvent-free basis)" column in Exhibit Otsu No. 6 Document prepared by Biogal, the purity of pravastatin sodium may become 101.1%. This is also supported by the following statement in the General Notices of the Japanese Pharmacopoeia, "31. For the content of an ingredient determined by Assay in the monographs, if it is expressed simply as 'not less than a certain percentage' without indicating its upper limit, 101.0% is understood as the upper limit."

Therefore, even the pravastatin sodium with a purity of 99.9% of Example 5 in the Description contains up to about 1.1% of impurities. Consequently, it cannot be said that the content of pravastatin lactone is inevitably less than 0.2%.

b. There is no ground indicating that the purity in Examples 1, 3, and 5 in the Description is measured by an area ratio method, and it cannot be said that it was common sense among persons ordinarily skilled in the art to use an area percentage method. According to the fact that the plaintiff stated the values measured by a quantitative method in Exhibit Otsu No. 6 Document, it is natural to consider that the purity stated in the Description is also the value measured by a quantitative method.

(D) The plaintiff submits the detailed purification table (Exhibit Ko No. 12) and the sample information (Exhibit Ko No. 13) as pieces of evidence indicating that the values are based on the working examples.

However, Exhibit Ko No. 12 neither objectively describes the source of supply and the analysis method, etc., nor does it contain a statement indicating that one stated in Exhibit Ko No. 12 corresponds to the examples of pravastatin in the Description.

Moreover, there is no objective indication that Exhibit Ko No. 13 corresponds to the examples in the Description.

Consequently, the allegation of the plaintiff to the effect that Exhibits Ko No. 12 and No. 13 correspond to the examples stated in the Description lacks credibility.

B. The purity of the pravastatin sodium stated in the Description is up to 99.9%, and pravastatin sodium with a higher purity, that is, pravastatin sodium containing 0 to 0.1% of impurities, is not stated therein. It is stated in 4.(4) in the aforementioned written opinion (Exhibit Otsu No. 3-10) that if the purity of pravastatin sodium is 99.9%, the mixed content of pravastatin lactone

is about 0.06% and that of epiprava is about 0.03%. However, pravastatin sodium containing less pravastatin lactone and epiprava than this is supported neither by the description originally attached to the application for the Patent nor by experiment.

C. Consequently, with regard to the content of impurities stated in the Description, a sufficient number of concrete examples throughout the claims are not shown. Even by referring to the statement of the detailed explanation of the invention and in light of the common general technical knowledge as of the filing of the application for the Patent, the concrete examples cannot be expanded or generalized to the whole numerical range stated in the claims. Therefore, Invention 1 goes beyond the scope stated in the detailed explanation of the invention.

Consequently, the statements in Claim 1 of the Patent and those in Claims 2 to 9 citing said claim do not comply with the requirement set forth in Article 36, paragraph (6), item (i) of the Patent Act, and the statement of the detailed explanation of the invention in the Description does not comply with the requirement set forth in paragraph (4) of said Article.

In addition, there is the following statement in "2.2.1.1 Typical Examples of Violation of Article 36(6)(i)" in Chapter 1 in the Examination Guidelines": "Example 10: In an invention which is going to specify a product (…) by limiting function and characteristic etc. numerically, sufficient numbers of concrete examples throughout the whole numerical range described in the claim are not shown, and furthermore by referring to other description in the detailed description of the invention or in the light of the common general technical knowledge as of the filing, it could not be said that the relevant concrete examples could be expanded or generalized to the whole numerical range described in the claim." This case falls under the case mentioned therein, and it is obvious that the statement of the scope of claims does not comply with Article 36, paragraph (6), item (i) of the Patent Act.

(2) Non-compliance with the description requirements (ii)

Claim 1 of the Patent does not state the purity of pravastatin sodium itself, and includes pravastatin sodium that becomes of low purity due to the mixture of side products other than pravastatin lactone and epiprava and other causes.

However, the Description does not support such low purity pravastatin sodium, and such pravastatin sodium also conflicts with the statement of the detailed explanation of the invention, such as the statement in paragraph [0007] in the Description, "manufacturing substantially pure pravastatin sodium." In this manner, the statement of the scope of claims goes beyond the scope stated in the detailed explanation of the invention. This does not comply with Article 36, paragraph (6), item (i) of the Patent Act.

(Allegations of the plaintiff)

(1) Regarding non-compliance with the description requirements (i)

A. The Correction is supported by the Description and the working examples.

As mentioned below, it is obvious that Claim 1 after the Correction is supported by the Description, irrespective of the adequacy of the defendant's allegation that the content ratio between pravastatin lactone and epiprava is two to one.

As the claims after the Correction are supported by the Description, the claims before the Correction are needless to say supported thereby.

(A)a. The Correction is supported by the statement in paragraph [0031] in the Description, "Pravastatin sodium further may be isolated with less than 0.2% (w/w) pravastatin lactone and 0.1% (w/w) epiprava by adhering to the preferred embodiments of the invention, two of which are exemplified in Examples 1 and 3."

Based on this statement in paragraph [0031], it is obvious that the content of pravastatin lactone and that of epiprava stated therein are based on the working examples. Moreover, the aforementioned statement in paragraph [0031] should be considered as a concrete statement equivalent to the working examples. Therefore, the Correction is also supported by the working examples (this was also confirmed in a trial for patent invalidation (Exhibit Ko No. 10) and an action to seek rescission of a JPO decision rendered on said trial (Exhibit Ko No. 11) wherein the invalidity of a patent for a subsequent application was disputed while deeming this case as the earlier application).

Furthermore, it is also possible to confirm based on the detailed purification table (Exhibit Ko No. 12) and the sample information (Exhibit Ko No. 13) that this statement in paragraph [0031] is based on the working examples. Based on a high consistency of Exhibits Ko No. 12 and No. 13 with the statements of the working examples in the Description, it is obvious that Exhibits Ko No. 12 and No. 13 were obtained from the experiment note that served as the basis for the working examples stated in the Description. Exhibits Ko No. 12 and No. 13 are not intended to supplement the matters not stated in the Description.

b. The expression, "may be," in paragraph [0031] is a very common expression that is generally used to indicate the scope of an invention in a more extensive manner. It is thus unreasonable to inordinately take up this expression and have it stand for a special meaning.

(B)a. Moreover, it is stated in paragraph [0051] of Example 5 in the Description that the purity of the manufactured pravastatin sodium was about 99.9%. This inevitably supports the requirement after the Correction, that is, the mixed amount of pravastatin lactone is less than 0.2% and the mixed amount of epiprava is less than 0.1%.

Furthermore, it is stated in paragraph [0045] of Example 1 and paragraph [0047] of Example 3 in the Description that the pravastatin sodium has a "purity of about 99.8%." Although the content of pravastatin lactone and that of epiprava are not stated in these working examples, the content of pravastatin lactone is less than 0.2%, taking into account that other impurities are also possibly contained. Corrected Invention 1 is also supported by this.

b. Although the defendant alleges that the upper limit of the purity of pravastatin sodium can be 101%, the purity of pravastatin sodium and the content of impurities are measured in the Description by using not a quantitative method wherein the upper limit is 101% but by an area percentage method wherein the upper limit is 100%. The Description does not clearly state that an area percentage method was used, but it is common general technical knowledge as of the priority date to use an area percentage method in the case of measuring the content of each of multiple impurities (Exhibits Ko No. 24 to No. 26 (including blanch numbers for each)) and the same numerical values as those in the Description are also clearly indicated with the unit "area %" in the experiment note (Exhibit Ko No. 12).

Incidentally, Exhibit Otsu No. 6 Document indicates the product specification, and it is common to use values measured by a quantitative method as component values in a product specification. Therefore, it is impossible to say, based on the statements in Exhibit Otsu No. 6 Document, that the Description is based on a quantitative method.

(C) Therefore, it is obvious that the statement of Claim 1 after the Correction is supported by the Description.

B. Regarding the indication that pravastatin sodium with a purity of over 99.9% is not stated in the Description

It was recognized in a trial for patent invalidation and a judgment on an action to seek rescission of a JPO decision rendered on said trial that the aforementioned statement in paragraph [0031] in the Description is based on the working examples, as mentioned above.

Also, the detailed purification table (Exhibit Ko No. 12) states, in Example 5, "pravastatin sodium containing less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava," including pravastatin sodium containing 0.01% of epiprava and less than the detection limit of pravastatin lactone. Therefore, the working examples provide sufficient support.

In addition, as it is possible to reduce the content of pravastatin lactone and that of epiprava to close to 0% by repeating salting-out crystallization, the enablement requirement is also fulfilled.

C. Consequently, the Patent does not violate Article 36, paragraph (6), item (i) of the Patent Act and paragraph (4) of said Article.

Although the Examination Guidelines pointed out by the defendant are applied in general terms, the properties of individual inventions must be taken into consideration in applying the Examination Guidelines to specific cases. The Examination Guidelines should not be interpreted in an unjustifiably limited manner. This point is also indicated in the Examination Guidelines as a point to be noted.

(2) Non-compliance with the description requirements (ii)

The defendant points out that Claim 1 of the Patent includes low purity pravastatin sodium.

However, the Inventions are intended to provide highly pure pravastatin sodium, as it is obvious from the statements in paragraphs [0006], [0007], etc. in the Description. In addition to this, taking into account that the subject matter of Invention 1 is not "pravastatin sodium composition" but "pravastatin sodium," it is appropriate to consider that Invention 1 refers to highly pure pravastatin sodium wherein the content of impurities is reduced.

Moreover, it is reasonable and natural that the focus is placed on pravastatin lactone and epiprava out of all impurities, and their contents are stipulated in the HPLC chart in the sample information (Exhibit Ko No. 13), because the finally obtained purified product contains almost no other impurities than pravastatin lactone and epiprava, except for 6-α-OH isocompactin acid, etc., and because it is very difficult to obtain pravastatin sodium wherein both the content of pravastatin lactone and that of epiprava are reduced at the same time.

Furthermore, the Inventions achieved highly pure pravastatin sodium by overcoming a special difficulty that differs from the difficulty of removal of impurities from chemical substances in general. Therefore, even if the claims do not stipulate the purity of pravastatin sodium, if the claims stipulate that the content of pravastatin lactone and that of epiprava were reduced, it is obvious, in light of the fact that the subject matter of the Inventions is highly pure pravastatin sodium, that the claims stipulate highly pure pravastatin sodium.

Consequently, Claim 1 of the Patent can be regarded as one stated in the detailed explanation of the invention, and complies with the requirement set forth in Article 36, paragraph (6), item (i) of the Patent Act.

8. Regarding Issue 3 (whether the Correction is proper)

(Allegations of the plaintiff)

Regarding Claim 1 of the Patent, the plaintiff filed a request for correction (Exhibit Ko No. 7) to [i] correct the statement concerning the mixed amount of pravastatin lactone and that of epiprava to "Pravastatin sodium containing less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava" and to [ii] correct the statement, "(e) conducting pravastatin sodium isolation," to "(e) isolating pravastatin sodium" (Exhibit Ko No. 7).

Correction [i] is intended to restrict the scope of claims (Article 134-2, paragraph (1), item (i) of the Patent Act), and Correction [ii] is intended to correct an error in the description (item (ii) of said paragraph). Neither of them enlarges or alters the scope of claims (paragraph (5) of said Article and Article 126, paragraph (4) of said Act).

Moreover, as mentioned below, the Corrected Inventions are stated in paragraph [0031] in the Description, and Exhibit Otsu No. 1 Document, etc. does not state those that fall under the scope after the Correction. Therefore, the Corrected Inventions are recognized as having both novelty and an inventive step, and eliminate the grounds for invalidation of the Patent. They thus fulfill the requirement for correction set forth in Article 126 of the Patent Act.

Furthermore, the Defendant's Product falls under the technical scope of the Corrected Inventions.

Consequently, the Patent is not one that should be invalidated by a trial for patent invalidation if the Correction is accepted and becomes final and binding. Therefore, the exercise of the Patent Right is not at all restricted.

(1) Novelty of the Corrected Inventions

A. The pravastatin sodium disclosed in Exhibit Otsu No. 1 Document contains 0.02 to 0.06% of pravastatin lactone and 0.19 to 0.65% of epiprava, and the pravastatin sodium disclosed in Exhibit Otsu No. 6 Document contains 0.11% of epiprava. Therefore, both of them differ from the "pravastatin sodium containing less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava" claimed in the claims after the Correction in the structure. Therefore, the novelty of the Corrected Inventions is affirmed.

B. As mentioned above, Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample are secret matters. Therefore, they do not constitute public working or description in a publication.

In addition, Exhibit Otsu No. 1 Document and mevalotin tablets as well as Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample do not state a manufacturing process to obtain the pravastatin sodium disclosed in the Corrected Inventions. It is also difficult to obtain said pravastatin sodium by prior art. Therefore, Exhibit Otsu No. 1 Document and mevalotin tablets as well as Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample cannot be cited references that disclose "inventions" as mentioned in Article 29, paragraph (1), items (ii) and (iii) of the Patent Act.

(2) Inventive step of the Corrected Inventions

A. Regarding Exhibit Otsu No. 1 Document and mevalotin tablets as well as Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample

Exhibit Otsu No. 1 Document and mevalotin tablets as well as Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample cannot be used in determining the novelty of the Corrected Inventions, as mentioned above. They can also not be used in the determination of an inventive step thereof, which is to be made based on the same cited inventions as those used in the determination of the novelty.

B. Regarding an inventive step

A difference in the structure which reduces the content of epiprava, an impurity, from 0.19% to 0.1 wt% in a chemical substance purified to over 99% purity is extremely large, and a person ordinarily skilled in the art could not have easily achieved it.

The essence of the Corrected Inventions exists in the reduction of impurities, and the inventive step of the Corrected Inventions is affirmed if [i] difficulty of increasing the level of purity of pravastatin sodium or [ii] a prominent effect of the obtained pravastatin sodium is

proven.

(A) Difficulty of increasing the level of purity

First of all, the difficulty of increasing the level of purity by removing impurities is as follows.

a. As neither Exhibit Otsu No. 1 Document nor Exhibit Otsu No. 6 Document state the purification process, it is difficult for a person ordinarily skilled in the art to obtain the structure of the Corrected Inventions.

b. It is difficult to remove impurities, in particular, from a highly pure chemical substance.

c. Pravastatin lactone and epiprava are very difficult to separate and remove from pravastatin sodium due to their close similarity to pravastatin sodium in the structure and their similarity thereto in the physical and chemical property (it is obvious from the experiments of Exhibits Ko No. 33 and No. 34 that it was difficult to do so by prior art). Moreover, there is the possibility that impurities will be generated through the intramolecular reaction of pravastatin that also occurs in the purification process or through the dissolution of pravastatin.

d. Even Company D, which is on the cutting-edge of the industry in the development of pravastatin sodium, also could not reduce the content of epiprava to less than 0.19%. In addition, a patent application was filed for an invention characterized by reducing the content of epiprava to less than 0.1% and was patented once though the patent was invalidated on the grounds of existence of the Patent as an earlier application. Taking this into consideration, it is obvious that the Corrected Inventions that reduce the content of pravastatin lactone to less than 0.2 wt% in addition to reducing the content of epiprava to less than 0.1 wt% are patentable.

e. Pravastatin lactone is generated through intermolecular reaction of pravastatin in the purification process. Therefore, it is necessary to reduce the content of epiprava to less than 0.1 wt% while restricting the generation of pravastatin lactone to less than 0.2 wt%. The purification of pravastatin sodium thus involves a special difficulty that differs from the difficulty of the purification of chemical substances in general.

f. The step of the Corrected Inventions wherein pravastatin is crystalized by salting-out in the form of ammonium salt, which is the step of reducing epiprava without increasing pravastatin lactone, is very unique as a step in the purification process of pravastatin. The Corrected Inventions made this step possible for the first time, and the step has not at all been suggested in prior art and could not have been easily conceived of by a person ordinarily skilled in the art.

g. Even if it becomes possible to obtain a new product by a new process for the first time, once the new product is obtained, it has patentability as an invention of a product per se without being limited by its manufacturing process. This is an established practice in the chemical field.

h. There is no evidence showing the existence of prior art that indicates that the mixed amount of epiprava can be reduced to less than 0.1 wt%, which is the amount after the Correction, while

restricting the increase of pravastatin lactone and keeping the mixed amount thereof less than 0.2 wt%, which is the amount after the Correction.

(B) Prominent effect

In general, it is considered that the fewer impurities and higher purity a medicine has, the fewer the side effects and the greater utility that it has. It is thus obvious that the pravastatin sodium pertaining to the Corrected Inventions has an excellent effect as a medicine.

C. Regarding the purification test of pravastatin conducted by the defendant (Exhibits Otsu No. 8 and No. 9)

(A) The pravastatin sodium used for the purification test of pravastatin (Exhibit Otsu No. 8; hereinafter referred to as "Exhibit Otsu No. 8 Test") conducted by the defendant (Exhibit Otsu No. 9; hereinafter the document stating such pravastatin sodium is referred to as "Exhibit Otsu No. 9 Document," and the sample stated therein is referred to as "Exhibit Otsu No. 9 Sample") is one that Company C obtained in July 2000. It was impossible to confirm whether said pravastatin sodium is identical with the pravastatin sodium stated in Exhibit Otsu No. 6 Document, and said pravastatin sodium is highly likely to be a different one. If they are identical with each other, said pravastatin sodium is subject to confidentiality and its disclosure in an action should be prohibited. Therefore, the submission of Exhibit Otsu No. 8 Test is impermissible.

In addition, the content of epiprava and that of pravastatin lactone in Exhibit Otsu No. 9 Sample as of July 2000 are unclear.

Furthermore, Exhibit Otsu No. 8 Test was conducted in October 2008, and the starting material used therein is a product that was obtained in July 2000 and had been stored in Company C for eight years since then.

Moreover, it is impossible to discuss the existence of an inventive step on the premise of Exhibit Otsu No. 6 Sample (pravastatin sodium containing 0.03% of pravastatin lactone and 0.11% of epiprava) because a person ordinarily skilled in the art could not reproduce Exhibit Otsu No. 6 Sample as of the priority date of the Patent.

(B) The analysis result of Exhibit Otsu No. 8 Test does not prove the technical level as of the priority date of the Patent, as mentioned below. Therefore, it is impossible to deny the inventive step of the Corrected Inventions based thereon.

a. First of all, as mentioned above, the composition of the sample used for Exhibit Otsu No. 8 Test as of July 2000 is unclear. In addition, as Figure 2 in Exhibit Otsu No. 8 shows existence of many peaks of unidentifiable impurities, the composition of the sample used for Exhibit Otsu No. 8 Test seems to have significantly changed from its original composition during the eight-year storage. Therefore, it is impossible to accomplish the task of proving the technical level as of the priority date by using a product that existed as of the priority date by purifying

such sample that denatured over time as the starting material.

b. The process which the defendant used in Exhibit Otsu No. 8 Test is the HPLC method stated in Exhibit Otsu No. 11, wherein the concentration of the sample, the column temperature, and the flow rate of the mobile phase were changed. The HPLC method stated in Exhibit Otsu No. 11, which is a cited reference prior to the priority date of the Patent, was not used as it was. Said changes are those intended to further increase the separation performance of HPLC. Therefore, Exhibit Otsu No. 8 Test does not prove the technical level as of the priority date of the Patent.

The defendant alleges that these changes of the conditions were made to reproduce the retention time. However, it is common general technical knowledge to adjust only one of the parameters, which has almost no effect on the separation capacity, to the minimum extent necessary in order to adjust the retention time. In addition, it is impossible to equate the reproduction of the retention time and that of the separation capacity, and even if the retention time is reproduced, that cannot serve as evidence proving that the separation capacity is also reproduced.

Despite that, the defendant significantly changed the three parameters that affect the separation capacity, at the same time, as mentioned above. It is thus obvious that these changes were intended to improve the peak separation capacity of HPLC. On the other hand, in the reproduction test (Exhibit Ko No. 20) of Exhibit Otsu No. 8 Test conducted by the plaintiff, the plaintiff changed only the flow velocity of the mobile phase, and this change is a mere slight change of a parameter that has almost no effect on the separation capacity.

c. The Corrected Inventions are intended to measure the content of impurities in solid pravastatin sodium (in the case of an industrial use, pravastatin sodium is used in the solid powder state; therefore, the content of impurities is measured in the solid state in the Corrected Inventions). On the other hand, in Exhibit Otsu No. 8 Test, [i] drying is finished at the stage of sorted enriched liquid, and epiprava and pravastatin lactone therein were measured, and [ii] as acetic acid is used in the HPLC method stated in Exhibit Otsu No. 11, pravastatin lactone is further produced if the sorted enriched liquid is dried and solidified (this is also obvious in the experiment (Exhibit Ko No. 20) conducted by the plaintiff), and the sorted enriched liquid falls short of being used as a technical product for manufacturing a medicine even if it is dried. Therefore, Exhibit Otsu No. 8 Test does not serve as a ground for denying the inventive step of the Corrected Inventions.

Moreover, such sorted enriched liquid is highly likely to contain many impurities (see Exhibit Ko No. 20). There had been no crystallization method that could reduce pravastatin lactone and epiprava at the same time prior to the priority date of the Patent. In addition, it is impossible to remove salt other than pravastatin sodium by using a freeze-drying method though it is possible to remove solvent thereby. Therefore, it is also impossible to obtain the pravastatin

sodium pertaining to the Corrected Inventions even by using such a method.

d. First of all, a person ordinarily skilled in the art does not have motivation to divert the HPLC method that is clearly indicated as an analysis method to a purification or manufacturing process. In addition, as mentioned above, as acetic acid is used in the HPLC method stated in Exhibit Otsu No. 11, the content of pravastatin lactone is increased. Therefore, it is impossible to obtain highly pure pravastatin sodium by said method.

Consequently, a person ordinarily skilled in the art who intends to acquire highly pure pravastatin sodium will never apply the HPLC method stated in Exhibit Otsu No. 11 to purification of pravastatin sodium. There is thus no motivation to apply the HPLC method stated in Exhibit Otsu No. 11 for purification of pravastatin sodium (see Exhibit Ko No. 21).

(C) In the first place, Exhibit Otsu No. 11 merely stipulates the HPLC method, which is prior art. Even if the HPLC method is applied, it is impossible to obtain highly pure pravastatin sodium like that stipulated by the Corrected Inventions (Exhibits Ko No. 9 and No. 34). In addition, even if the HPLC method is repeated, there is a limit to the purity that can be achieved thereby. Consequently, it is impossible to obtain highly pure pravastatin sodium in the same way.

(3) Article 36 of the Patent Act

As mentioned above, the content of the scope of claims after the Correction is stated in the Description.

(4) Whether the Defendant's Product fulfills the constituent features of the Corrected Inventions

The Defendant's Product contains nearly 0.04 wt% of pravastatin lactone and nearly 0.02 wt% of epiprava. Therefore, it falls under the technical scope of the Corrected Inventions.

(Allegations of the defendant)

(1) Novelty of the Corrected Inventions

A. As mentioned above, around early [in] April 2000, prior to the priority date of the Patent, Biogal distributed its own pravastatin sodium to a pharmaceutical manufacturer in Japan through a trading company, and it is clearly stipulated in the "Related substances" column in Exhibit Otsu No. 6 Document, which was distributed as an attached document showing the results of specification testing along with the distribution of the sample, that the content of epiprava is 0.11% and that the content of pravastatin lactone is 0.03%.

B. It is obvious that the content of pravastatin lactone in Exhibit Otsu No. 6 Document falls under the content thereof in Corrected Invention 1, "less than 0.2 wt%."

On the other hand, the content of epiprava in Exhibit Otsu No. 6 Document is 0.11% and exceeds the content thereof in Corrected Invention 1, "less than 0.1 wt%." However, the fact that figures up to the first decimal place alone are stipulated in Corrected Invention 1 without questioning figures in the second decimal place and thereafter means that the accuracy of figures in the second decimal place and thereafter does not matter. In addition, the content of

epiprava in Exhibit Otsu No. 6 Document and the content thereof in Corrected Invention 1 differ only by 0.01%, and this difference is nothing more than a difference caused by a measurement error and cannot be regarded as a substantial difference. Therefore, Exhibit Otsu No. 6 Document should be regarded as substantially indicating the value equivalent to the content of epiprava in Corrected Invention 1, "less than 0.1 wt%."

In addition, Exhibit Otsu No. 6 Document and Exhibit Otsu No. 6 Sample were distributed prior to April 6, 2000, as mentioned above. Corrected Invention 1 thus falls under Article 29, paragraph (1), items (ii) and (iii) of the Patent Act.

C. The same as Corrected Invention 1 applies to Corrected Inventions 2 to 9 as they are inventions for the product finally obtained.

(2) Inventive step of the Corrected Inventions

A. Trying to increase the level of purity of a useful chemical substance used for a medicine, etc. and thereby reduce the mixed amount of impurities is what a person ordinarily skilled in the art commonly attempts.

Thus, Exhibit Otsu No. 1 Document and Exhibit Otsu No. 6 Document disclose highly pure pravastatin wherein the mixed amount of pravastatin lactone, epiprava, etc., which are the related substances of pravastatin, are reduced. If there is actually a difference of around 0.01% between the mixed amount of epiprava in Exhibit Otsu No. 6 Document and that in Corrected Invention 1, these kinds of pravastatin are closely similar to each other in their physicality. Therefore, it is obvious that the invention of a "product" per se is not recognized as having an inventive step if said difference is not recognized as having a technical meaning or a meaning as a limit.

Moreover, as it is obvious that purity is increased if a purification step is repeated, the content of Corrected Invention 1 as alleged by the plaintiff only means that the purification step was repeated. Corrected Invention 1 is thus an invention made through exertion of the ordinary creative ability of a person ordinarily skilled in the art.

Furthermore, it is not stated in the Description that the corrected content produces a prominent technical effect that goes beyond the prediction of persons ordinarily skilled in the art. Therefore, the pravastatin sodium of Corrected Invention 1 is not considered as producing a prominent technical effect that goes beyond the prediction of persons ordinarily skilled in the art in comparison with the highly pure pravastatin sodium stated in Exhibit Otsu No. 1 Document or Exhibit Otsu No. 6 Document.

Therefore, Corrected Invention 1 is one that a person ordinarily skilled in the art could have easily conceived of, and thus has no inventive step.

Corrected Inventions 2 to 9 are also inventions of products per se. Therefore, Inventions 2 to 9 have no inventive step for the same reason as that for Corrected Invention 1.

B. Regarding Exhibit Otsu No. 8 Test

(A) It was possible to obtain pravastatin sodium containing 0.14% of pravastatin lactone and no epiprava from pravastatin sodium (Exhibit Otsu No. 9 Sample) manufactured by Biogal containing 0.35% of pravastatin lactone and 0.10% of epiprava, which was distributed by Biogal as a sample and was obtained by Company C on July 10, 2000, prior to the priority date of the Patent, by purifying Exhibit Otsu No. 9 Sample by the HPLC method (Exhibit Otsu No. 11), which was publicly known as of said priority date (Exhibit Otsu No. 8).

This proves that it was easy for a person ordinarily skilled in the art to obtain pravastatin sodium wherein the content of pravastatin lactone and that of epiprava are within the numerical range stated in Corrected Invention 1 based on the state of the art as of the priority date of the Patent.

(B) Regarding the allegations of the plaintiff concerning Exhibit Otsu No. 8 Test

a. The purpose of Exhibit Otsu No. 8 Test is to prove that it was also easy for a person ordinarily skilled in the art to obtain pravastatin sodium wherein the content of pravastatin lactone and that of epiprava are around the amount stated in Corrected Invention 1 based on the state of the art as of the priority date of the Patent. Therefore, there is no need to use pravastatin sodium that is free of denaturation over time.

That is, the content of pravastatin lactone and that of epiprava in Exhibit Otsu No. 9 Sample are as mentioned above. The content of pravastatin lactone and that of epiprava in Exhibit Otsu No. 9 Sample are almost equivalent to or more than those in Exhibit Otsu No. 6 Sample, which was publicly known as of the priority date of the Patent. Even in the case of using such Exhibit Otsu No. 9 Sample, a person ordinarily skilled in the art could easily obtain pravastatin sodium wherein pravastatin lactone and epiprava are reduced to around the values stated in Corrected Invention 1 by using a process that was publicly known as of the priority date of the Patent. Therefore, it is obvious that it is even easier to obtain such pravastatin sodium in the case of using Exhibit Otsu No. 6 Sample.

b. The conditions for the HPLC method stated in Exhibit Otsu No. 11, such as the concentration of the sample, the column temperature, and the flow rate, were changed in Exhibit Otsu No. 8 Test. These changes are intended to reproduce the retention time (21 minutes) of the objective substance. It is very common to change conditions, such as the flow velocity of a mobile phase and column temperature, accordingly for such purposes, and there is no need for a trial and error process. Such changes are not to obtain higher separation capacity than as stated in Exhibit Otsu No. 11.

ActuallyIn fact, 21-minute retention time of pravastatin sodium was achieved, and the relative retention time of Impurity A (epiprava) stated in Exhibit Otsu No. 11, specifically, 0.6, was also achieved.

c. The plaintiff points out that pravastatin sodium after purification was not dried in Exhibit Otsu No. 8 Test. However, Corrected Invention 1 is not bound by the requirement that pravastatin sodium is limited to that in the solid state or the requirement relating to the content of related substances other than pravastatin lactone and epiprava, impurities other than the related substances, water, etc. Therefore, the allegation of the plaintiff is unreasonable. Even if the content of pravastatin lactone increases due to drying, it is very easy to reduce the content of pravastatin lactone to less than 0.2 wt% through conversion of pravastatin lactone into pravastatin sodium by adding sodium hydroxide thereto (Exhibit Otsu No. 22), which was common general technical knowledge as of the priority date of the Patent.

In addition, even if acetic acid, etc. is mixed in the pravastatin sodium obtained by Exhibit Otsu No. 8 Test, it is common general technical knowledge to obtain solid pravastatin sodium from which the acetic acid, etc. is removed by using a publicly known process, such as a crystallization method and freeze-drying method.

d. The plaintiff alleges that there is no motivation to divert the HPLC method stated in Exhibit Otsu No. 11, which is an analysis method, to a purification process. However, even if the HPLC method is clearly indicated as an analysis method, it is impossible to unambiguously say that it is a method not intended for subsequent collection. In terms of the HPLC chart, it is common sense among persons ordinarily skilled in the art to think that a highly pure objective substance can be sorted if the objective substance is separated from other impurities to a sufficient extent. Whether or not a practical scale can be obtained is originally not a constituent feature.

Regarding use of acetic acid in Exhibit Otsu No. 11, if the process is one that increases impurities, it is originally impossible to conduct a correct analysis. Such a process must not be placed in the European Pharmacopoeia. Therefore, said use of acetic acid has no effect on the motivation to use the process stated in Exhibit Otsu No. 11. Even if pravastatin lactone increases when pravastatin sodium is solidified, pravastatin lactone can be easily converted into pravastatin sodium, as mentioned above.

C. Consequently, it is possible to easily obtain the pravastatin sodium pertaining to Corrected Invention 1 by using Exhibit Otsu No. 9 Sample or the pravastatin sodium stated in Exhibit Otsu No. 1 Document or Exhibit Otsu No. 6 Document as a starting material and by purifying it by using the process stated in Exhibit Otsu No. 11. Therefore, Corrected Invention 1 is an invention that a person ordinarily skilled in the art could have easily made based on the invention that was publicly worked or the invention stated in Exhibit Otsu No. 1 Document, Exhibit Otsu No. 6 Document or Exhibit Otsu No. 9 Document and well-known art or the invention stated in Exhibit Otsu No. 11.

Corrected Inventions 2 to 9 are also inventions that a person ordinarily skilled in the art could have easily made in the same manner as Corrected Invention 1.

(3) Non-compliance with Article 36 of the Patent Act

A. As mentioned above, the Description does not state the actual measured values of pravastatin lactone and epiprava. The purity stated in the Description as the working examples, etc. is up to 99.9%, and pravastatin sodium with purity higher than 99.9% is not stated therein. Therefore, Corrected Invention 1 also goes beyond the scope stated in the detailed explanation of the invention.

B. In addition, it is obvious that the statement in the scope of claims after the Correction, "containing less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava," does not comply with the support requirement set forth in Article 36, paragraph (6), item (i) of the Patent Act because no concrete example is disclosed in the detailed explanation of the invention to the extent that a person ordinarily skilled in the art can recognize that the problem to be solved of the invention can be solved and because it cannot be said that the content disclosed in the detailed explanation of the invention can be expanded or generalized to the scope of the invention stated in the scope of claims even in consideration of the common general technical knowledge of a person ordinarily skilled in the art as of the filing of the application for the Patent.

(4) Whether the Defendant's Product fulfills the constituent features of the Corrected Inventions

A. The defendant does not dispute the point that the Defendant's Product is pravastatin sodium containing less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava.

B. As mentioned above, the part relating to the manufacturing process should be taken into consideration in the interpretation of the scope of right of the Patent, and the process to manufacture the Defendant's Product differs from the process of Corrected Invention 1. Therefore, the Defendant's Product does not fall under the technical scope of Corrected Invention 1.

In addition, as Corrected Inventions 2 to 9 are inventions citing Corrected Invention 1, the Defendant's Product also does not fall under the technical scope of these inventions.

No. 4 Decision concerning the issues

1. Regarding Issue (1)A. (whether the manufacturing process should be taken into consideration in relation to the technical scope of the Inventions)

(1) The claims in the scope of claims of the Patent are those that state the process to manufacture the product in relation to an invention of a product (i.e. product-by-process claims).

The technical scope of a patented invention shall be determined based upon the statements in the scope of claims (Article 70, paragraph (1) of the Patent Act). Therefore, if a process to manufacture a product is daringly stated in relation to an invention of a product even though it is possible to specify the invention as a product without stating said process in the scope of claims, it is considered unreasonable to interpret the technical scope of the patented invention with no

consideration for the statements concerning the manufacturing process. On the other hand, it is impossible to technically deny the possibility of existence of the cases, like the cases of certain chemical substances, etc., where it is difficult to concretely state a relevant product by specifying the structure of the product and there is no other choice but to specify the product stated in the scope of claims by the process to manufacture the product. In such cases, it is considered that there is no need to interpret the technical scope of the patented invention by limiting it to the product manufactured by said manufacturing process.

Consequently, for an invention of a product, if a process to manufacture the product is stated in the scope of claims, the statements concerning the process to manufacture the product stated in the scope of claims should not be, in principle, excluded on the grounds that the invention is an "invention of a product." The technical scope of the patented invention should be considered as being limited to the product manufactured by said manufacturing process. It is reasonable to understand that products which are manufactured by a different manufacturing process from said manufacturing process but are recognized as being identical with said product are also included in the technical scope of said patented invention only where there are special circumstances such as where it is difficult to specify the product by stating the structure thereof and there is no other choice but to specify the product stated in the scope of claims by the process to manufacture the product.

(2) Therefore, whether there are the "special circumstances" mentioned in (1) above in this case is considered.

A. Necessity for the specification of a product

According to pieces of evidence (Exhibits Ko No. 2, No. 36, and No. 37 and Exhibit Otsu No. 1) and the entire import of argument, the pravastatin sodium disclosed in the Inventions per se is recognized as having been a publicly known substance among persons ordinarily skilled in the art as of the priority date of the Patent. The structure of "pravastatin sodium containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava," which is a "product" stated in Claim 1 of the Patent, is physically specified by that statement itself. It is not recognized in this case that there is no other choice but to state a process to manufacture the product in order to specify the product.

That is, the "product" stated in Claim 1 of the Patent, "pravastatin sodium containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava," is recognized as one that does not require the statement of a process to manufacture it in order to specify the product (incidentally, the parties agree that there is no need to take the manufacturing process into consideration in order to specify the product).

B. Prosecution history

According to pieces of evidence (Exhibits Ko No. 1 and No. 2 and Exhibit Otsu No. 3

(including branch numbers thereof)) and the entire import of argument, the background to the filing of the application for the Patent and the explanations, etc. made by the plaintiff in the application process are recognized as follows.

(A) The plaintiff filed an international application for the Patent on October 5, 2001, and submitted translations that are deemed to be the description submitted with the application on November 27, 2002. The scope of claims in the translations included claims that do not include statements concerning a manufacturing process, as mentioned below (Exhibit Otsu No. 3-1).

"[Claim 1] Substantially pure pravastatin sodium.

[Claim 2] Pravastatin sodium stated in Claim 1 containing less than 0.5% of pravastatin lactone.

[Claim 3] Pravastatin sodium stated in Claim 1 containing less than 0.2% of epiprava.

[Claim 4] Pravastatin sodium stated in Claim 1 containing less than 0.5% of pravastatin lactone and less than 0.2% of epiprava.

[Claim 5] Pravastatin sodium stated in Claim 1 containing less than 0.2% of pravastatin lactone.

[Claim 6] Pravastatin sodium stated in Claim 1 containing less than 0.1% of epiprava.

[Claim 7] Pravastatin sodium stated in Claim 1 containing less than 0.2% of pravastatin lactone and less than 0.1% of epiprava.

[Claim 8] Substantially pure pravastatin sodium which is prepared by a process comprising the steps of: (a) forming an enriched organic solution of pravastatin, (b) precipitating pravastatin as its ammonium salt, (c) purifying the ammonium salt by recrystallization, (d) transposing the ammonium salt to pravastatin sodium, and (e) isolating pravastatin sodium substantially free of pravastatin lactone and epiprava.

(subsequent claims are omitted)"

(B) In the explanation of circumstances concerning the accelerated examination (Exhibit Otsu No. 3-5) that the plaintiff submitted to the JPO on January 29, 2004, the plaintiff stated as follows as explanations through comparison with the three documents cited in an international search report under the Patent Cooperation Treaty (Cited Document 1: the description of U.S. Patent No. 4346227; Cited Document 2: the description of U.S. Patent No. 5202029; Cited Document 3: WO 00/17182).

a. Aforementioned Cited Document 1

"Cited Document 1 discloses new statin compounds, and does not state a process to purify them to a high purity level."

b. Aforementioned Cited Document 2

"Cited Document 2 states a process to purify HMG-CoA reductase inhibitor to a high purity level, but this process is characterized by the use of silica-gel chromatography and differs from the process of the invention claimed in the patent application. In addition, this cited document concretely states the purification of lovastatin, and does not state the purification of pravastatin

sodium."

c. Aforementioned Cited Document 3

"Cited Document 3 states a process to purify pravastatin, etc., but this process is one using sophisticated liquid chromatography and thus differs from the process of the invention claimed in the patent application."

(C) In relation to the application for the Patent, the JPO gave a notice of reasons for refusal (Exhibit Otsu No. 3-8) dated March 17, 2004 on such grounds as that the invention pertaining to the application is an invention described in a publication, etc. or an invention that could have been easily made based thereon and thus lacks novelty and an inventive step.

In response to this, the plaintiff, who is the applicant, submitted a written opinion and a written amendment (Exhibits Otsu No. 3-10 and No. 3-11) dated September 24, 2004. The following are statements in the written opinion and the written amendment.

a. Statements in the written opinion (page 3 and thereafter of Exhibit Otsu No. 3-10)

"7. Regarding Reasons 6 and 7 (Article 29, paragraph (1), item (iii) of the Patent Act and paragraph (2) of said Article)

(1) Regarding the invention claimed in the patent application

As already explained, it is very difficult to obtain highly pure pravastatin sodium, and it was impossible to obtain highly pure pravastatin or pravastatin sodium, for example, those with a purity over 99.5%, by prior art. The major reason therefor is the fact that pravastatin lactone and epiprava that are inevitably generated in the process of generating pravastatin are very similar to pravastatin in their physical and chemical properties. The invention consists of [i] extracting pravastatin from the fermentation broth by using butyl acetates or propyl acetates as the step before purification and [ii] [a] destroying pravastatin lactone and epiprava by acid treatment and/or treatment by base or [b] removing pravastatin lactone and epiprava by repeating the crystallization of the ammonium salt of pravastatin."

b. Statements in the written amendment (Exhibit Otsu No. 3-11)

"[Claim 1] Pravastatin sodium containing less than 0.5 wt% of pravastatin lactone.

[Claim 2] Pravastatin sodium containing less than 0.2 wt% of epiprava.

[Claim 3] Pravastatin sodium containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava.

[Claim 4] Pravastatin sodium containing less than 0.2 wt% of pravastatin lactone.

[Claim 5] Pravastatin sodium containing less than 0.1 wt% of epiprava.

[Claim 6] Pravastatin sodium containing less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava.

[Claim 7] Pravastatin sodium containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava which is prepared by a process comprising the steps of: (a) forming an

enriched organic solution of pravastatin, (b) precipitating pravastatin as its ammonium salt, (c) purifying the ammonium salt by recrystallization, (d) transposing the ammonium salt to pravastatin sodium, and (e) conducting pravastatin sodium isolation.
(subsequent claims are omitted)"
(D) The plaintiff received an examiner's decision of refusal (Exhibit Otsu No. 3-13) for the application for the Patent dated April 22, 2005 for the following reasons: "The sodium salt of pravastatin with an HPLC purity of 99.7 to 99.8% is stated in Cited Reference 2 (Working Examples 1 to 3). Although the content of pravastatin lactone or epiprava is not stated in Cited Reference 2, it is common general technical knowledge that a compound used as a medicine is more favorable as it has a higher purity. A person ordinarily skilled in the art can easily achieve the more highly pure pravastatin sodium of the invention, etc. containing less pravastatin lactone or epiprava by repeating the purification of the sodium salt of pravastatin." In this examiner's decision of refusal, Claim 7 (which has the same content as Invention 1) in (C)b. above that stated the manufacturing process is not cited as a claim involving a reason for refusal.
(E) In response to this, the plaintiff, who is the applicant, filed a request for a trial against the examiner's decision of refusal (Exhibit Otsu No. 3-14) on July 25, 2005, and submitted a written amendment on the same day. In the written amendment, the plaintiff made an amendment (Exhibit Otsu No. 3-15) that deletes all the claims concerning pravastatin sodium that specify the product only by indicating the content of pravastatin lactone and that of epiprava without stating the manufacturing process (that is, claims that state the product alone) and made those claims identical with the statement of the scope of claims as stated in the aforementioned facts, etc. undisputed by the parties. As a result of reconsideration by an examiner before appeal, the plaintiff received an examiner's decision to the effect that a patent is to be granted (Exhibit Otsu No. 3-18) dated September 16 of the same year.
(3)A. As mentioned above, Claim 1 of the Patent physically specifies the product by stating it as "pravastatin sodium containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava." Therefore, there is no need to state the manufacturing process to specify the product. However, the manufacturing process is daringly stated. Taking into account this fact and the background to the filing of the application on which such statement of the scope of claims was adopted (in particular, although the scope of claims attached to the initial application included claims pertaining to both a product for which its manufacturing process is not stated and a product for which its manufacturing process is stated, the plaintiff deleted all the claims that do not state the manufacturing process in response to receipt of an examiner's decision of refusal on the grounds that claims that do not state the manufacturing process have no inventive step; as a result, the plaintiff received an examiner's decision to the effect that a patent is to be

granted), it is not recognized in relation to the Patent that there are special circumstances where the technical scope of the patented invention is not limited to the product manufactured by the manufacturing process stated in the scope of claims (it can rather be said that there is an affirmative circumstance where the technical scope of the patented invention should be limited to the product manufactured by said manufacturing process).

Therefore, the technical scope of Invention 1 should be interpreted by limiting it to the product manufactured by the manufacturing process stated in Claim 1 of the Patent. Accordingly, said technical scope is understood as follows.

"Pravastatin sodium containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava, which is prepared by a process comprising the steps of: (a) forming an enriched organic solution of pravastatin, (b) precipitating pravastatin as its ammonium sault, (c) purifying the ammonium sault by recrystallization, (d) transposing the ammonium salt to pravastatin sodium, and (e) conducting pravastatin sodium isolation."

B. The plaintiff alleges that as the plaintiff filed a request for correction of the Patent, the prosecution history for the claims before the Correction makes no sense in relation to the claims after the Correction.

However, correction of a patented invention is conducted on the premise that a patent has been granted in light of certain prosecution history after the filing. Therefore, it is obvious that the prosecution history before the obtainment of a patent does not then make no sense through correction. In particular, in this case, the plaintiff deleted Claim 6 ("Pravastatin sodium containing less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava), which is substantially identical with Claim 1 after the Correction in terms of the structure of the product stated, through amendment after receiving the examiner's decision of refusal (Exhibit Otsu No. 3-13) on the grounds that said claim lacks an inventive step. Taking this into account, it should be said that such prosecution history cannot be still further ignored.

In addition, a correction is accepted only in the case of the restriction of the scope of claims, the correction of errors or incorrect translations, or clarification of an ambiguous description (Article 126, paragraph (1) and Article 134-2, paragraph (1) of the Patent Act). A correction that substantially enlarges the scope of claims is not accepted (Article 126, paragraph (4) and Article 134-2, paragraph (5) of said Act). Where the technical scope of the invention claimed in a claim before correction is considered as being limited by the manufacturing process, if the prosecution history comes to make no sense through the correction and the technical scope of the invention claimed in the claim after the correction is considered as not being limited by the manufacturing process, it means accepting the substantial enlargement of the technical scope of the patented invention through the correction. This is not reasonable.

Therefore, the aforementioned allegation of the plaintiff is unacceptable. The technical

scope of Corrected Invention 1 should be interpreted by limiting it to the product manufactured by the manufacturing process stated in Claim 1 after the Correction.

2. Regarding Issue (1)B. (whether the Defendant's Product fulfills the constituent features)

As stated in the aforementioned facts, etc. undisputed by the parties, the Defendant's Product is pravastatin sodium containing less than 0.2 wt% of pravastatin lactone and less than 0.1 wt% of epiprava. Therefore, it fulfills one of the constituent features of Invention 1 and Corrected Invention 1, "pravastatin sodium containing less than 0.5 (0.2 after the Correction) wt% of pravastatin lactone and less than 0.2 (0.1 after the Correction) wt% of epiprava."

However, as mentioned in 1. above, the technical scope of Invention 1 and Corrected Invention 1 is considered as being limited to the product manufactured by the manufacturing process stated in the scope of claims. Consequently, whether the Defendant's Manufacturing Process fulfills Plaintiff's Steps (a) to (e) is considered below.

(1) Regarding the Defendant's Manufacturing Process

A. According to pieces of evidence (Exhibit Ko No. 38 and Exhibit Otsu No. 5), the process to manufacture the Defendant's Product is stated as follows.

(A) Statements in the Defendant's Application for Approval (Exhibit Otsu No. 5)

"●(omitted)●"

(B) Statements of the "current process" in Attachment 1 of the document titled "Japanese Pharmacopoeia: Pravastatin sodium; Regarding the result of change control" (Exhibit Ko No. 38)

"(1) ●(omitted)● process ●(omitted)●

(2) ●(omitted)● process ●(omitted)●

(3) ●(omitted)● process ●(omitted)●

(4) ●(omitted)● process and thereafter ●(omitted)●"

B. In light of the above statements and entire import of argument, the process to manufacture the Defendant's Product is recognized as one that is divided into the following steps:

(A) a step wherein ●(omitted)● pravastatin is generated;

(B) a step wherein a reaction liquid containing this pravastatin is ●(omitted)●;

(C) a step wherein ●(omitted)● pravastatin is ●(omitted)●;

(D) a step wherein ●(omitted)● pravastatin is eluted by ●(omitted)●; and

(E) a step wherein the eluate is enriched, crystallized, and purified to obtain pravastatin sodium.

Incidentally, it is recognized that Defendant's Step (E) is further divided into the following steps:

(E)-1 a step wherein the eluate is ●(omitted)● to obtain ●(omitted)●;

(E)-2 a step wherein ●(omitted)● pravastatin ●(omitted)● is obtained; and

(E)-3 a step wherein pravastatin ●(omitted)● is dissolved and purified by ●(omitted)● to obtain

pravastatin sodium (hereinafter the Defendant's Manufacturing Process pertaining to this finding is referred to as the "Recognized Defendant's Manufacturing Process" and each step thereof is referred to as "Recognized Defendant's Step (A), etc.," respectively).

C. The following is stated in the document titled "Japanese Pharmacopoeia: Pravastatin sodium; Regarding the result of change control" (Exhibit Ko No. 38) prepared by the defendant under its name: [i] "Japanese Pharmacopoeia: The change of the manufacturing process was examined to improve the productivity of pravastatin sodium … quality evaluation was terminated"; and [ii] an application for the registration of change is started as soon as possible if the defendant can gain approval of the change of the manufacturing process from customers. Based on this, the plaintiff alleges that the Defendant's Manufacturing Process was changed.

However, this document is a document for seeking the approval of the change of the Defendant's Manufacturing Process and is not a notice of the change. Therefore, based on the document, it is impossible to recognize that the Defendant's Manufacturing Process has already been changed.

(2) Whether the Recognized Defendant's Manufacturing Process fulfills Plaintiff's Step (a)

The plaintiff alleges that the end product obtained by Recognized Defendant's Step (D) wherein "●(omitted)● pravastatin is eluted by ●(omitted)●" or that obtained by Recognized Defendant's Step (E)-2 wherein "●(omitted)● pravastatin●(omitted)● is obtained" falls under an "enriched organic solution" in Plaintiff's Step (a). Therefore, whether an "enriched organic solution" in Plaintiff's Step (a) is formed in the Recognized Defendant's Manufacturing Process is examined after considering the meaning of an "enriched organic solution" in Plaintiff's Step (a).

A. Meaning of an "enriched organic solution" in Plaintiff's Step (a)

(A) With regard to an "enriched organic solution," the following is stated in the Description (Exhibit Ko No. 2).

a. "[0008] A preferred embodiment of this process involves extraction of pravastatin from an aqueous fermentation broth into an organic solvent, back-extraction of pravastatin into a basic aqueous solution and re-extraction into an organic solvent, resulting in an organic solution that is enriched in pravastatin relative to the initial concentration of pravastatin in the fermentation broth. The pravastatin may be obtained from the enriched solution by precipitation as its ammonium salt and then purification by recrystallization of the ammonium salt."

b. "[0010] Enzymatic Hydroxylation of Compactin

The enzymatic hydroxylation broth from which pravastatin is isolated can be any of the aqueous broths known for industrial scale fermentation of compactin … Preferably, the enzymatic hydroxylation is conducted using a living culture of Steptomyces, with a nutrient mixture of compactin and dextrose. If the broth is neutral or basic upon completion of the fermentation,

then an acid is added to it to bring the broth to a pH of between about 1 and 6, preferably between 1 and 5.5 and more preferably between 2 and 4. … Acidification of the fermentation broth converts any pravastatin carboxylate salts in the broth to the free acid and/or lactone."

c. "[0011] Isolation of Substantially Pure Water (note: "Pure Water" is an error in the description; correctly, "Pure") Pravastatin Sodium

Pravastatin is first isolated from an aqueous fermentation broth in a relatively highly concentrated organic solution by a sequence of extraction and back-extraction steps.

[0012] In the first step, pravastatin is extracted from the fermentation broth. C_2-C_4 alkyl formates and C_1-C_4 alkyl esters of C_2-C_4 carboxylic acids are capable of efficient extraction of pravastatin from an aqueous fermentation broth. … Preferred esters include ethyl formate … Of these preferred organic solvents, we have found that ethyl acetate, i- butyl acetate, propyl acetate and ethyl formate are especially well suited. The most preferred extraction solvent is i-butyl acetate. Other organic solvents may be substituted for the esters. …

[0013] Pravastatin is optionally back-extracted into a basic aqueous solution of pH from about 8.0 to about 9.5. … The extraction solvent is preferably contacted with the basic aqueous solution until the amount of pravastatin in the organic phase has been substantially depleted as determined by thin layer chromatography or any other method including the subjective judgment that sufficient contacting has occurred for complete extraction. Multiple back-extractions may be performed for optimal recovery. … Back-extraction may be used to concentrate the pravastatin by using a volume of aqueous base that is less than the volume of the organic extract. Preferably, the back-extraction is conducted with a volume of basic aqueous solution that is less than one third of the volume of the organic extract, more preferably less than one fourth and most preferably, about one fifth of the volume of the organic extract.

[0014] The aqueous solution is preferably acidified with an acid … to a pH of about 1.0 to about 6.5, more preferably about 2.0 to about 3.7.

[0015] Pravastatin is preferably re-extracted into one of the organic solvents previously described as suitable for extracting pravastatin from the fermentation broth. … In this re-extraction, further enrichment of pravastatin may be accomplished by re-extracting into an amount of organic solvent that is preferably less than about 50% (v/v) of the aqueous extract, more preferably from about 33% (v/v) to about 20% (v/v) and still more preferably about 25% (v/v) of the volume of the aqueous extract. Pravastatin may be concentrated from 100 L of fermentation broth to 8 L of enriched organic solution in 89% yield from the initial organic extract. It will be understood by persons ordinarily skilled in the art that a higher yield of purified pravastatin may be attained by performing multiple extractions where only a single extraction has been described in this preferred mode for working this invention. This preferred mode achieves a balance of solvent economy and high product yield. … Before proceeding to

obtain pravastatin from the enriched organic solution by "salting out," the enriched organic solution is preferably dried, which may be done using a conventional drying agent … and optionally decolorized with activated carbon. A dried and/or decolorized enriched organic solution is preferably then separated conventionally, as for instance by filtration or decanting.

[0016] In the next step, pravastatin may be salted out from the enriched organic solution with ammonia or an amine. … Regardless of the absence, presence or multiplicity of substitution on nitrogen, a salt formed by reaction of ammonia or an amine is hereafter referred to as an ammonium salt. Its meaning is intended to encompass salts of amines as well as a salt of ammonia.

[0017] Precipitation of the ammonium salt of pravastatin may also be induced by addition of an ammonium salt either alone or in combination with the ammonia or amine. … Ammonium salts and high boiling liquid and solid amines may be added by conventional means, preferably in an area with good ventilation, either as solids, neat liquids or solutions in aqueous or organic solvent. … In an especially preferred embodiment, pravastatin is obtained from the enriched organic solution as the pravastatin salt of ammonia by addition of gaseous ammonia and NH_4C1 to the enriched organic solution."

d. Working examples

"[0039] Examples

Example 1

Purification of Pravastatin

The fermentation broth (100 L) was acidified from about 2.5 to about 5.0 by addition of sulfuric acid. The acidified fermentation broth was extracted with i-butyl acetate (3 x 50 L). … The combined i-butyl acetate phases were then extracted with water (35 L) at a pH of about 7.5 to about 11.0 by addition of concentrated ammonium hydroxide. The resulting aqueous pravastatin solution was then reacidified to a pH of about 2.0 to about 4.0 by addition of 5M sulfuric acid and back-extracted with i-butyl acetate (8 L). The resulting solution of pravastatin in i-butyl acetate was partially dried over Perlite and Na_2SO_4. The pravastatin solution was decanted and then filtered from the drying agents and decolorized over activated charcoal (1.7 g). The solution was then filtered to remove the charcoal and transferred to a flask equipped with a gas inlet.

[0040] Ammonia gas was then introduced into the headspace above the solution with rapid stirring. The precipitated crystals of ammonium pravastatin carboxylate salt were collected by filtration and washed with i-butyl acetate and then acetone, which yielded pravastatin ammonium salt in about 94 % purity as determined by HPLC coupled with UV absorbance measured at λ=238nm."

"[0049]

Example 5

Following the procedure of Example 1, the fermentation broth (100 L) was acidified to a pH of about 2.5 to about 5.0. by addition of sulfuric acid. The acidified fermentation broth was extracted with i-butyl acetate (3 x 50 L). The combined i-butyl acetate phases were then extracted with water (35 L) having been basified to a pH of about 7.5 to about 11.0 by addition of concentrated ammonium hydroxide."

[0050] Instead of reacidifying the aqueous extract and conducting extraction with i-butyl acetate to obtain a further enriched organic solution as was done in Example 1, the aqueous extract was concentrated to 140 g/L under reduced pressure. The resulting concentrated solution was then acidified to a pH of about 4.0 to about 7.5 by addition of 1M HC1.

[0051] Ammonium chloride crystals (405 g) were then added to the concentrated solution and the pravastatin ammonium salt was allowed to crystallize at ambient temperature. The crystals were then isolated by filtration and washed with a saturated solution of ammonium chloride. The crystals were then added to water (1 L) at 40°C. After dissolution, the temperature was reduced to 30°C and ammonium chloride (330 g) was added to the solution. The solution was then stirred for 15 hours at ambient temperature and crystals of pravastatin ammonium salt were recovered by filtration and washed with i-butyl acetate and after that with acetone and dried. The resulting crystals were then further purified by recrystallization wherein they are transposed to the sodium salt and isolated as described in Example 1. Pravastatin sodium was obtained in about 99.9% purity and 67.7% yield."

(B) Regarding the fact that pravastatin ammonium salt is precipitated from the "enriched organic solution of pravastatin" in the Plaintiff's Manufacturing Process

According to the statements concerning Plaintiff's Steps (a) and (b) and the statements in the Description, it is recognized that in Invention 1, Plaintiff Step (b) is a step wherein pravastatin in an enriched organic solution formed in Plaintiff's Step (a) is converted into ammonium salt with ammonia or an amine and precipitated. This step is considered as a step wherein pravastatin in the enriched organic solution is precipitated as ammonium salt by using the properties of ammonium salt, i.e. being soluble in water but insoluble in an organic solution.

In that case, it is obvious that ammonium salt of pravastatin is difficult to precipitate if the organic solution in Plaintiff's Step (a) contains water. From a technical perspective, it is not reasonable to speculatively consider that the "organic solution" contains water.

Therefore, it is reasonable to consider that the "organic solution" in which pravastatin ammonium salt is precipitated, that is, the "enriched organic solution" in Plaintiff's Step (a), is an organic solution that does not contain water.

(C) In addition, it is considered that a person ordinarily skilled in the art has a common understanding of the term, "organic solution," as meaning one that does not contain water, and it

is also not stated in the Description that the "enriched organic solution" mentioned in Invention 1 may be one that contains water.

Rather, as mentioned above, it is only stated in the Description that the process to form an "enriched organic solution" in Plaintiff's Step (a) involves acidification of the fermentation broth of pravastatin and a sequence of extraction, back-extraction, and re-extraction steps, such as extraction of pravastatin into an organic solution, back-extraction of pravastatin into a basic aqueous solution and re-extraction into an organic solution. It is also considered that the "extraction" in the Plaintiff's Manufacturing Process is conducted by using the property of pravastatin, which is acid, i.e. being more soluble in an organic solution than water. Therefore, it is considered that the possibility that an "enriched organic solution" that is formed by such steps contains water is not envisaged in the Plaintiff's Manufacturing Process.

(D) According to the above, it is reasonable to consider that the "enriched organic solution of pravastatin" mentioned in Plaintiff's Step (a) is one that does not contain water.

(E) Incidentally, the plaintiff alleges that, in Example 5 in the Description, the enriched solution formed by concentrating the aqueous extract under reduced pressure is salted out by addition of ammonium chloride.

However, taking into account that 100 L of fermentation broth was extracted with 150 L (3 x 50 L) of i-butyl acetate in Example 5, i-butyl acetate solution after the extraction is recognized as not falling under an "enriched" organic solution of pravastatin.

In addition, taking into account that in Example 5, this i-butyl acetate solution was extracted with basified water and this aqueous extract (basified water from which pravastatin was extracted) was concentrated under reduced pressure and then acidified, the "aqueous extract" to be concentrated does not contain organic solvent and is thus recognized as not falling under an enriched "organic solution."

Consequently, an "enriched organic solution of pravastatin" is not formed in the steps of Example 5. Therefore, Example 5 is recognized as not being a working example of Invention 1, which includes formation of such an enriched organic solution as Plaintiff's Step (a).

Therefore, Example 5 cannot serve as a ground for considering that the "enriched organic solution" mentioned in Plaintiff's Step (a) also includes one that contains water.

B. Whether an "enriched organic solution of pravastatin" is formed in the Recognized Defendant's Manufacturing Process

(A)a. Whether the product obtained by Recognized Defendant's Step (D) wherein "●(omitted)● pravastatin is eluted by ●(omitted)●" falls under an "enriched organic solution of pravastatin"

As mentioned in (1)B. above, in Recognized Defendant's Step (D), ●(omitted)● pravastatin is eluted by ●(omitted)●. Therefore, the solution eluated thereby is recognized as one that

contains water.

Therefore, the solution eluated by ●(omitted)● is recognized as not falling under an "enriched organic solution of pravastatin" in Plaintiff's Step (a), which is considered as an organic solution that does not contain water as mentioned above.

b. Whether the product obtained by Recognized Defendant's Step (E)-2 wherein "●(omitted)● pravastatin ●(omitted)● is obtained" falls under an "enriched organic solution of pravastatin"

As mentioned in (1)B. above, Recognized Defendant's Step (E)-2 is a step wherein ●(omitted)● of pravastatin is dissolved by ●(omitted)● and is ●(omitted)●, and is then ●(omitted)●. Therefore, ●(omitted)● solution is recognized as one that contains water.

Consequently, ●(omitted)● solution is recognized as not falling under an "enriched organic solution of pravastatin" in Plaintiff's Step (a), which is considered as an organic solution that does not contain water as mentioned above.

c. In light of each piece of evidence in this case, it is not recognized that the Recognized Defendant's Manufacturing Process involves a step of forming an "enriched organic solution of pravastatin."

d. According to the above, it is recognized that the Recognized Defendant's Manufacturing Process does not involve a step of forming an "enriched organic solution of pravastatin" of Plaintiff's Step (a).

(B) The plaintiff alleges that the Defendant's Product is presumed to have been produced by the Plaintiff's Manufacturing Process through application or mutatis mutandis application of Article 104 of the Patent Act to the Inventions.

However, the Inventions are inventions of products although a limitation by the manufacturing process is imposed thereon. Therefore, Article 104 of the Patent Act will never apply thereto. In addition, there is also no statutory provision on the mutatis mutandis application of said Article. Consequently, said Article will also never apply mutatis mutandis to the Inventions.

Even if the "mutatis mutandis application" as alleged by the plaintiff means that Article 104 of the Patent Act analogically applies to an invention of a product for which its manufacturing process is stated, such as those in this case, there is no room for the application of presumption under said Article without the need for examination of other requirements because, as mentioned in (A) above, the Recognized Defendant's Manufacturing Process is recognized as not involving a step of forming an "enriched organic solution of pravastatin" of Plaintiff's Step (a) and because the Defendant's Product is recognized as not having been produced by a manufacturing process identical with the Plaintiff's Manufacturing Process.

C. Summary

According to the above, the Defendant's Product is not recognized as fulfilling Plaintiff's

Step (a). Therefore, the Defendant's Product is not recognized as falling under the technical scope of Invention 1, without the need for a ruling on other issues.

D. Regarding other allegations of the plaintiff

The plaintiff alleges that the disclosure of the Defendant's Manufacturing Process by the defendant is insufficient.

However, although the disclosure of the Defendant's Manufacturing Process by the defendant is not the concrete disclosure of all manufacturing steps, the defendant discloses the manufacturing steps to a considerable extent as mentioned in (1) above. In addition, as recognized in B. above, the Recognized Defendant's Manufacturing Process, which is recognized from the manufacturing steps disclosed by the defendant, is recognized as not fulfilling at least Plaintiff's Step (a). Moreover, there is no objective evidence suggesting or leading people to presume that a manufacturing step that fulfills Plaintiff's Step (a) exists in any part of the manufacturing process which the defendant does not concretely disclose. Consequently, even if the defendant does not concretely disclose the whole of its manufacturing process, that fact does not affect the aforementioned holding.

(3) Regarding Inventions 2 to 9

As stated in the aforementioned facts, etc. undisputed by the parties, all of Inventions 2 to 9 are those that directly or indirectly cite Invention 1. Therefore, as long as the Defendant's Product is not recognized as falling under the technical scope of Invention 1, it is also not recognized as falling under the technical scope of Inventions 2 to 9.

3. Conclusion

Consequently, there is no reason for any of the plaintiff's claims without the need for a ruling on other issues. Therefore, these plaintiff's claims shall be dismissed. The judgment shall be rendered in the form of the main text.

Tokyo District Court, 29th Civil Division

Presiding judge: SHIMIZU Misao

Judge: SAKAMOTO Saburo

Judge: IWASAKI Shin

(Attachment)

List of the Parties

Hungary <hereinafter omitted>

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