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Case Number

2012 (Ju) 1204

Reporter

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Title

Judgment concerning how to determine the technical scope of the patented invention based on a claim of a patent for an invention of a product when the claim is what is generally referred to as a "product-by-process claim," which recites the manufacturing process of the product

Case name

Case to seek an injunction against infringement of a patent right

Result

Judgment of the Second Petty Bench, quashed and remanded

Court of the Second Instance

Intellectual Property High Court, Judgment of January 27, 2012

Summary of the judgement

1. Even in the case of what is generally referred to as a "product-by-process claim," that is, when a claim of a patent for an invention of a product recites the manufacturing process of the product, the technical scope of the patented invention should be determined as referring to products that have the

same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim.

2. In the case of what is generally referred to as a "product-by-process claim," that is, when a claim of a patent for an invention of a product recites the manufacturing process of the product, the recitation of the claim should be held to meet the requirement that the claimed invention is clear as prescribed in Article 36, paragraph (6), item (ii) of the Patent Act, only if there are circumstances where it was impossible or utterly impractical to directly define the product subject to the invention by means of its structure or characteristics at the time of the filing of the application.

(There are a concurring opinion and an opinion concerning 1 and 2.)

References

(Concerning 1) Article 70, paragraph (1) of the Patent Act; (Concerning 2) Article 36, paragraph (6), item (ii) of the Patent Act

Patent Act

Article 70

(1) The technical scope of a patented invention shall be determined based upon the statements in the scope of claims attached to the application.

Article 36

(6) The statement of the scope of claims as provided in paragraph (2) shall comply with each of the following items:

(ii) the invention for which a patent is sought is clear;

Main text of the Judgment

The judgment in prior instance is quashed.

The case is remanded to the Intellectual Property High Court.

Reasons

Concerning Reasons I, II, IV, and V for petition for acceptance of final appeal argued by the appeal counsel, UETANI Kiyoshi, et al.

1. In this case, the appellant of final appeal, who holds a patent right for an invention of a product based on a claim which recites the manufacturing process of the product, generally referred to as a "product-by-process claim," alleges that the medicine manufactured and sold by the appellee of final

appeal infringes the appellant's patent right, and seeks an injunction against the appellee to stop it from manufacturing and selling the medicine in question and demands the disposal of the same. The appellee contends, inter alia, that the appellee's medicine does not fall within the technical scope of the invention covered by the appellant's patent. The point at issue in this case is how to determine the technical scope of the patented invention in the case where a claim of a patent for an invention of a product recites the manufacturing process of the product.

2. The outline of the facts determined by the court of prior instance is as follows.

(1) The patent in question

The appellant holds a patent for an invention titled "pravastatin sodium substantially free of pravastatin lactone and epipravastatin, and compositions containing the same" (Patent No. 3737801; the number of claims: 9; hereinafter referred to as the "Patent").

(2) The invention in question

Claim 1 of the Patent (hereinafter referred to as the "Claim") is as described below (hereinafter the invention described in the Claim is referred to as the "Invention").

"Pravastatin sodium 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,

and containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava."

(3) The appellee's product

A. The appellee manufactures and sells medicine named pravastatin Na tablets, 10mg, "KH" (former name: pravastatin Na tablets, 10mg, "Merck"; hereinafter referred to as the "appellee's product").

B. The appellee's product contains pravastatin sodium that contains less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava. The manufacturing process of the appellee's product does not contain, at least, the step of "a) forming an enriched organic solution of pravastatin," which is stated in the Claim.

3. The court of prior instance dismissed the appellant's claim, holding as follows.

(1) When a claim of a patent for an invention of a product recites the manufacturing process of the product, the technical scope of the invention should be determined as being limited to products manufactured by the manufacturing process recited in the claim, except when there are circumstances where it was impossible or difficult to directly define the product subject to the invention by means of its structure or characteristics at the time of the filing of the application.

(2) Since such circumstances mentioned in (1) above cannot be found with regard to the Invention, the technical scope of the Invention should be determined as being limited to products manufactured

by the manufacturing process recited in the Claim. The manufacturing process of the appellee's product does not contain, at least, the step of "a) forming an enriched organic solution of pravastatin," which is stated in the Claim, and hence the appellee's product does not fall within the technical scope of the Invention.

4. However, we cannot affirm the criterion mentioned in 3.(1) above, which was presented by the court of prior instance, and then, we also cannot affirm the determination mentioned in 3.(2) above, which was made by the court of prior instance based on that criterion. The reasons for this conclusion are as follows.

(1) The recitation of a claim attached to a patent application plays a role of the basis for determining the technical scope of a patented invention (Article 70, paragraph (1) of the Patent Act), and also for identifying the gist of the invention claimed in a patent application, which serves as the premise for examining the requirements of patentability prescribed in Article 29 of said Act (see 1987 (Gyo-Tsu) No. 3, judgment of the Second Petty Bench of the Supreme Court of March 8, 1991, Minshu Vol. 45, No. 3, at 123). A patent is to be granted for an invention of a product, an invention of a process or an invention of a process of producing a product. If a patent has been granted for an invention of a product, a patent right relating to that patent is effective against any products that have the same structure, characteristics, etc. as those of the product subject to the invention, irrespective of the manufacturing processes of these products.

Consequently, it is appropriate to construe that even when a claim of a patent for an invention of a product recites the manufacturing process of the product, the technical scope of the patented invention should be determined as being limited to products that have the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim.

(2) Under Article 36, paragraph (6), item (ii) of the Patent Act, the recitation of a claim must meet the requirement that the claimed invention is clear. The patent system is designed to grant a patent right, which is an exclusive right, to a person who has disclosed his or her invention, thereby protecting the invention for the interest of the patentee, while enabling a third party to understand the content of the patented invention, with the ultimate purpose of promoting the utilization of inventions to encourage inventions, and thereby contributing to the development of industry (see Article 1 of the Patent Act). The provisions of Article 36, paragraph (6), item (ii) of said Act can be understood as requiring clarity of the claimed invention because of such purpose of the patent system. From this viewpoint, in cases where a claim of a patent for an invention of a product recites the manufacturing process of the product, without exception, if the technical scope of the patented invention is determined on the assumption that a patent right relating to that patent is effective against any products that have the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim, this could be unfairly prejudicial to

the interest of a third party and would be problematic. More specifically, when a claim of a patent for an invention of a product recites the manufacturing process of the product, it is generally unclear what structure or characteristics of the product are represented by the manufacturing process, or whether the technical scope of the patented invention is limited to products manufactured by the manufacturing process, although the subject matter of the invention is the product, and this would prevent those who read the recitation of the claim, etc. from clearly understanding the content of the invention and make it impossible for them to predict the scope of the exclusive right to be conferred to the patentee, leading to an inappropriate situation.

On the other hand, in a claim of a patent for an invention of a product, the applicant is usually supposed to directly define the product by clearly reciting its structure or characteristics. However, there may be cases where, depending on the specific content, nature, etc. of the invention, it is technically impossible to analyze the structure or characteristics of the product at the time of the filing of the application, or where it is utterly impractical to require the applicant to define the product in such manner because, in light of the nature of a patent application that needs to be handled speedily, etc., the work to define the product could require excessive economic costs and time. Assuming so, it is inappropriate to prohibit reciting the manufacturing process of a product in a claim of a patent for an invention of a product in any case, but rather it must be said that if there are such circumstances as mentioned above, it would not be unfairly prejudicial to the interest of a third party to determine the technical scope of the patented invention as referring to products that have the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim.

According to the above, it is appropriate to construe that when a claim of a patent for an invention of a product recites the manufacturing process of the product, the recitation of the claim should be held to meet the requirement that the claimed invention is clear as prescribed in Article 36, paragraph (6), item (ii) of the Patent Act, only if there are circumstances where it was impossible or utterly impractical to directly define the product subject to the invention by means of its structure or characteristics at the time of the filing of the application.

5. Contrary to this conclusion, the court of prior instance determined that when a claim of a patent for an invention of a product recites the manufacturing process of the product, the technical scope of the patented invention should be determined as being limited to products manufactured by the manufacturing process recited in the claim, while generally permitting a claim in this form. This determination involves violation of laws and regulations that apparently affects the judgment. The appeal counsel's arguments are well-grounded, and the judgment in prior instance should inevitably be quashed. We remand the case to the court of prior instance to have it determine the technical scope of the Invention in the manner as instructed in this judgment, and further examine issues including whether or not the recitation of the Claim meets the requirement that the claimed invention

is clear and therefore it is acceptable based on the assumption that there are such circumstances as mentioned in 4.(2) above.

Therefore, the judgment has been rendered in the form of the main text by the unanimous consent of the Justices. There are a concurring opinion by Justice CHIBA Katsumi, and an opinion by Justice YAMAMOTO Tsuneyuki.

The concurring opinion by Justice CHIBA Katsumi is as follows.

In addition to the majority opinion, I would like to give my opinion as follows with regard to how to grasp a claim that is generally referred to as a "product-by-process claim."

1. First, I understand the basic framework for the construction and handling of a product-by-process claim as follows.

(1) The amendment to the Patent Act in 2004 introduced a new clause as Article 104-3, which allows a defense of invalidity of a patent to be raised in an infringement suit. As a result, the issue of identifying the gist of the invention as the premise for determining whether the defense of invalidity under said Article is established (whether the invention has novelty and an inventive step) and the issue of determining the technical scope of the patented invention as the cause of action in an infringement suit are addressed in the same litigation proceedings. In that case, since it is unreasonable if these issues are addressed within different basic frameworks for the construction and handling of a product-by-process claim, a uniform framework should be applied. This is what is to be expected under the Japanese patent law system, and on the premise of this view, the majority opinion examines the case according to the product identity theory).

(2) Meanwhile, in the United States, as a framework for the construction and handling of a product-by-process claim, the part reciting a process in the claim is not considered to be a particular problem in the patent examination, and an application with such a claim is accepted according to the product identity theory as long as the scope of the patent is not unclear. However, at the stage of determining the existence or absence of patent infringement, it has been an issue whether or not such part reciting a process should be regarded as a factor for limiting the claim. As is well known, the United States Court of Appeals for the Federal Circuit (CAFC) presented inconsistent views, i.e. a view that rejected the limitation in *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir.1991), and a view that supported the limitation in *Atlantic Thermoplastics Co. v. Faytex Corp.*, 970 F.2d 834 (Fed.Cir.1992). Then, in its en banc decision in *Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282 (Fed. Cir. 2009), the CAFC finally adopted the latter view, and decided that the scope of a right based on a product-by-process claim is limited to products manufactured by the manufacturing process recited in the claim. This means that in an infringement suit, the CAFC will not adopt the view that a product-by-process claim should be construed according to the product identity theory broadly, without being limited by the manufacturing process recited in the claim.

Regarding this last mentioned case (=566 F.3d 1282)], the Supreme Court of the United States denied certiorari, and the CAFC decision became final and binding.

(3) Thus, in the United States, as a framework for the construction and handling of a product-by-process claim, the existence of such circumstances as pointed out in the majority court, i.e., it was impossible or utterly impractical to directly define the product subject to the invention by means of its structure or characteristics at the time of the filing of the application (hereinafter such circumstances are referred to as "impossible or impractical circumstances"), is not strictly required, and the gist of the invention is identified according to the product identity theory. However, when infringement is claimed, that is, when the technical scope of the patented invention needs to be determined, the gist of the invention is construed strictly in the end, being limited to the manufacturing process recited in the claim. In the present case, since this court adopts a uniform framework for determination to be applied to both stages of identifying the gist of the invention and examining whether the allegedly infringing product falls within the technical scope of the patented invention, the outcome would inevitably be different in some aspects from the operation of the patent system in the United States. Having said that, looking at the operation in the United States as described above, when infringement is claimed, the entire scope of a product-by-process claim would end up being limited to the manufacturing process recited therein, in which case the significance of admitting the concept of a product-by-process claim as a patent for an invention of a product would be greatly undermined, ending up having to admit a double standard. Hence, as long as the United States maintains such operation, harmonization with the operations in Japan and European countries under different law systems will never be achieved.

(In *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120 (2014), which was concluded on June 2, 2014, the Supreme Court of the United States revoked the CAFC judgment and remanded the case, holding as follows: with regard to the definiteness of a claim, which is one of the descriptive requirements of a claim, although the CAFC determined that a claim should be judged to be indefinite only when it is not amenable to construction or when the claim is insolubly ambiguous, a claim should be judged to be indefinite if, when read in light of the specification and prosecution history, it fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention, and in this respect, the CAFC's determination would diminish the definiteness requirement's public-notice function. This decision by the Supreme Court is worthy of note in that it shows the court's attitude of strictly requiring a high level of definiteness.)

2. Next, I would point out the following with regard to the JPO's current criteria for examination of a product-by-process claim.

(1) According to the JPO's Examination Guidelines for Patent and Utility Model (Part I, Chapter 1, 2.2.2.4(2), Part II, Chapter 2, 1.5.2(3)), the JPO still examines a product-by-process claim according to the product identity theory, in a manner as outlined below.

The product subject to the invention may be defined by the manufacturing process thereof when there are circumstances where it is impossible or difficult to directly define the constitution of the invention by means of its properties, etc. (e.g. structure, etc.) independently of the manufacturing process, or it is inappropriate to do so for some reasons (for example, when defining the product in such manner would not be impossible or difficult but would increase the degree of difficulty in understanding) (such circumstances are hereinafter referred to as "impossible, difficult or inappropriate circumstances"). When a part of a claim is written to define the product by means of the manufacturing process, such claim is construed as referring to the product itself that is finally obtained.

If a claim contains expressions intended to define the product by means of the manufacturing process, in the examination on the clarity of the claim (Article 36, paragraph (6), item (ii) of the Patent Act) before examining the novelty and involvement of an inventive step in the invention according to the product identity theory, the JPO rarely conducts substantive examination as to whether or not there are any such impossible, difficult or inappropriate circumstances as mentioned above because the applicant has filed the application with a claim in said form in the first place on the grounds of the existence of such circumstances. If the applicant files an application with a claim in said form, the JPO finds the existence of any impossible, difficult or inappropriate circumstances by making reference to what is recited in the claim, and regards the claim as a product-by-process claim and examines whether the product itself has novelty and an inventive step according to the product identity theory.

(2) However, when an application is filed for a patent for an invention of a product, the subject matter should in principle be directly defined by means of the structure or characteristics of the product itself as recited in a claim. If the scope of the subject matter to be defined by means of the manufacturing process of the product is determined too broadly, the scope of the right to be conferred by a patent would be expanded to cover any products that have the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim, which could impede fair competition and be unfairly prejudicial to the interest of a third party as pointed out in the majority opinion. To avoid such a situation, a product-by-process claim should be permitted only exceptionally, and strict consideration should be made as to whether or not there are circumstances due to which a product-by-process claim should be permitted. The examination of such a claim should be handled virtually in line with such consideration.

3. According to the view explained above, I would examine the details of exceptional circumstances due to which a product-by-process claim should be permitted.

(1) In the present case, this court (majority opinion) states that such circumstances can be found if "there are circumstances where it is impossible or utterly impractical" to define the product subject to the invention, and the details of these circumstances are explained in the majority opinion. The

term "impossible" referred to therein means the case where it is impossible mainly from a technical perspective for a person ordinarily skilled in the art at the time of the filing of the application to define the product subject to the invention by analyzing its structure or characteristics (the term "characteristics" as used here means characteristics that are appropriate and significant in distinguishing the product in question from other products in the course of determining the novelty and involvement of an inventive step in the invention). The term "utterly impractical" referred to in the majority opinion assumes the case where, rather than from a technical perspective, the work to define the product could force a person ordinarily skilled in the art at the time of the filing of the application to spend time and costs to an extent that is impractical in terms of profitability and therefore it would be too cruel to require such person to perform such work while trying to obtain a patent in the face of the rapid advancement of technology and fierce competition on a global scale. Although the meaning of the latter term is not firmly established, the guideline for considering what case would actually fall under the meaning of the latter term will be made clear as court cases addressing this issue are accumulated in the future.

(2) The third criterion adopted in the JPO's current examination practice, i.e., "where it is inappropriate," covers too broad a range because it relies too much on an aspect of value judgment and its substance is unclear. Furthermore, even when it is not so difficult to define the product by means of its structure, etc., this criterion could lead to allowing the applicant to recite the manufacturing process in the claim merely for the purpose of making it easier to understand the constitution of the invention. At any rate, applying this criterion could result in the outcome being inconsistent with the purpose of admitting the concept of a product-by-process claim, and therefore it cannot be held to be reasonable.

If the applicant intends to make it easier to understand the constitution of the invention, it would be sufficient to describe the manufacturing process in the "detailed explanation of the invention," rather than reciting it in a claim, and the applicant should take this approach.

4. I would comment on the patent practice in the future and the conventional handling of a product-by-process claim.

(1) Conventionally, in the examination of a product-by-process claim at the time of the filing of an application, the JPO has permitted the application with such claim by loosely applying the requirement of impossible, difficult or inappropriate circumstances, without conducting substantive examination on this point. In the future, on the contrary, if a claim recites the manufacturing process, the JPO is expected in the examination process to first confirm that the application contains a product-by-process claim, and then request the applicant to allege and prove that there are impossible or impractical circumstances, and if the applicant fails to submit sufficient allegation and proof on this point, the JPO is to issue a decision to refuse the application. If the applicant wishes to avoid the refusal, the applicant would need to apply for a patent for the same invention as an

invention of a process for producing a product as well (Article 2, paragraph (3), item (iii) of the Patent Act).

(2) In this respect, according to the criterion presented in the judgment of the Grand Panel of the Intellectual Property High Court, which is the court of prior instance of the present case, it is assumed that the JPO, in its examination practice, does not reject a product-by-process claim by reason of the failure to meet the clarity requirement irrespective of whether or not there were circumstances where it was impossible or difficult at the time of the filing of the application to directly define the scope of the invention of the product by means of the structure, etc. of the product (hereinafter referred to as "impossible or difficult circumstances"), and based on this assumption, the JPO adopts the approach that categorizes a product-by-process claim into two types, in that, both when identifying the gist of the invention and when determining the technical scope of the patented invention, the JPO in principle follows the manufacturing process limitation theory by regarding the claim as a pseudo product-by-process claim, whereas the JPO follows the product identity theory if the claim is a genuine product-by-process claim for which impossible or difficult circumstances exist. This approach, in light of the spirit of Article 1, etc. of the Patent Act, permits a claim that defines a product by means of its manufacturing process, and treats such claim as not violating Article 36, paragraph (6), item (ii) of said Act. It can be described as representing the JPO's view reached through its elaborate efforts to pursue a realistic way of handling a product-by-process claim in accordance with both the principle of said Act and the JPO's examination practice.

However, this view is somewhat inconsistent with the precedents of this court in which the court seems to have adopted the product identity theory to construe a product-by-process claim (1997 (Gyo-Tsu) No. 120, judgment of the Third Petty Bench of the Supreme Court of September 9, 1997, not officially published, 1997 (Gyo-Tsu) No. 121, judgment of the Third Petty Bench of the Supreme Court of September 9, 1997, not officially published, 1998 (O) No. 1579, judgment of the Third Petty Bench of the Supreme Court of November 10, 1998, not officially published). Furthermore, while whether the product-by-process claim in question is a genuine or pseudo one remains unclear until the court presents its view on this point, the scope of the claim would greatly differ depending on this distinction and might disagree with what the applicant intended. The scope of a right to be conferred by a patent would also greatly differ depending on whether the invention is defined by a genuine or pseudo product-by-process claim, but this point remains unclear, making it difficult for a third party to predict the scope of the right appropriately. This problem is ultimately attributed to the scope of the patent being unclear and unspecific, which should be held to be in violation of Article 36, paragraph (5), and paragraph (6), item (ii), etc. of the Patent Act. Moreover, according to the JPO's view, it would be necessary in the examination practice to make a clear distinction as to whether the product-by-process claim is a genuine or pseudo one before permitting the patent application because the scope of the claim, etc. could differ depending on this distinction.

As a result, the JPO would have to be very careful in carrying out the examination and hence would have to bear a greater burden, and this would be highly likely to cause delay in examination.

(3) In light of the abovementioned problems posed by the court of prior instance, the majority opinion presents a view that will help establish the examination practice in which the JPO will strictly consider whether there are circumstances where a product-by-process claim should be permitted, while taking into account the principal purpose of the concept of this type of claim, and will advise the applicant to apply for a patent for an invention of a process for producing a product if the application with a product-by-process claim is likely to be refused due to the absence of such circumstances. This will change the conventional examination practice in that the JPO will be expected to substantively examine the requirement for permitting a product-by-process claim as a patent for substance. However, the applicant would doubt how common it has been to apply for a patent with a product-by-process claim rather than an ordinary patent with regard to an invention of a product even when the product can be defined by means of its structure (when impossible or impractical circumstances do not exist), and if it is truly "impossible" or "utterly impractical" to define the product by means of its structure, etc., the applicant would not find a great burden in alleging and proving this point (for example, in the field of life science, a claim which recites a cell, etc. created by a new genetic engineering technique would not be rejected on the grounds of the absence of circumstances where it is impossible or utterly impractical to define such a cell, etc. by its structure, etc. at the time of the filing of the application). In the examination process, since there is a limit due to the nature of the task to the applicant's potential to prove the existence of such circumstances voluntarily and strictly, the JPO will not be able to strictly require the applicant to do so and would be very likely to find the existence of such circumstances unless there is a reasonable doubt. In this meaning, it is very likely that the applicant would not have to worry so much.

(4) Next, it is also expected that requests for invalidation trials will be filed or the defense of invalidity will be raised in infringement suits in relation to patents with product-by-process claims that have already been granted and registered without, in principle, going through the test in terms of the existence of impossible or impractical circumstances in the examination process. However, if the applicants of these patents were unable to establish the existence of impossible or impractical circumstances at the time of the filing of the applications (which means that the applicants easily chose to file product-by-process claims in which the products were defined by the manufacturing processes although the products could have been defined by their structure, etc.), it is inevitable that their patents would later be invalidated. However, this situation results from the conventional examination practice in which the JPO has loosely examined and permitted product-by-process claims, and it is not attributable to the applicants alone. To avoid such a situation, procedures such as a request for correction (Article 134-2 of the Patent Act) in a patent invalidation trial and a request for a trial for correction (Article 126 of said Act) may be helpful. How these procedures will actually

be handled is an issue to be addressed in the future.

The opinion by Justice YAMAMOTO Tsuneyuki is as follows.

I agree with the decision to remand the case to the court of prior instance, for reasons different from those given in the majority opinion. I would explain the reasons in the sections below.

1. In view of the background for the amendment to the Patent Act in 1994, a patent applicant is considered to be basically free to choose what to recite in a claim. Article 36, paragraph (5), item (ii) of the Patent Act prior to said amendment provided that a claim should recite "only such matters that are essential to the constitution of the invention for which a patent is sought." However, the Industrial Property Council explained this issue in its report as follows: "(1) Necessity to permit a function or process claim...basically, in the case of an invention of a 'product,' 'matters that are essential to the constitution of the invention' are required to be expressed in the form of a 'product,' and a function and process are not considered as matters that are essential to the constitution of the invention. Accordingly, the following approaches of reciting a function or process in a claim are not permitted: [i] where the matters recited in a claim consist of a single technical means, and the technical means is recited in the form of a function or process; and [ii] where a claim relates to an invention of a product, and a technical means incorporated therein is recited in the form of a process. However, as a result of greater emphasis being placed on technologies for intangible infrastructure along with the development of information-related technologies (electronics, communication, information technologies), etc., it is more often the case that inventions of devices developed in these fields can be expressed more appropriately by defining the relevant device by means of its function or operating method, rather than by reciting the physical structure of the device or the specific means incorporated therein as matters that are essential to the constitution of the relevant invention. (2) Necessity to respect what is recited in a claim...the applicant should take responsibility for deciding what to claim for a patent. Therefore, it is inappropriate for the examiner to direct the applicant to modify the scope of a claim as long as the claimed invention is described in the detailed explanation of the invention in a manner to enable a person ordinarily skilled in the art to easily work the invention, and the invention meets the requirements of patentability including novelty and involvement of an inventive step...However, due to the provisions requiring a claim to "recite only such matters that are essential to the constitution of the invention" remaining in the existing law, when a notice of reasons for refusal is issued with respect to such a claim reciting a function or process as mentioned above, the applicant would have to revise the claim in the form of a generic concept (function or process) and recite a more limited, specific means, which would result in forcing the applicant to limit the claim..." (the Council's report of September 1994, from pages 23 to 24). Thus, the Industrial Property Council declared that the applicant should take responsibility for deciding what to claim. In order to make this point clear, Article 36, paragraph (5) of the Patent Act was amended in full, with the term "only" deleted from the phrase "only such matters that are

essential...," thereby respecting what is recited in a claim as expressed by the applicant of his or her own will. The reasons for this amendment are naturally true not only with a function claim but also with a claim that is designed to define a product by means of its manufacturing process (generally referred to as a "product-by-process claim"). I understand that this patent practice follows the trend of international harmonization of patent systems and basically conforms to the practices at the major patent offices in the world.

2. What patent practice is acceptable on a global scale? I would explain this point based on my understanding, taking the patent practice in Japan as an example.

As a result of the abovementioned amendment to the Patent Act, the patent practice at the JPO has changed so that an examiner will not refuse an application by reason of the failure to conform to the provisions of the amended clause, based on the idea that it is inappropriate for an examiner to examine whether all the matters necessary for defining an invention are recited in a claim, against the will of the applicant who drafted the claim at his or her own discretion. Accordingly, under the existing system of the Patent Act, it is up to the applicant to choose a function claim, product-by-process claim or whatever form of claim to define the invention for which a patent is sought, whereas the invention defined by such claim will not be patented if it falls under any of the items of Article 49 of the Patent Act (reasons for refusal), and even where it is patented, the patent will be invalidated if it falls under any of the items of Article 123 of said Act (grounds for invalidation). Consequently, according to the purpose of the legal amendment in 1994, it seems to me that the JPO has been very careful about refusing an application or invalidating a patent by assessing what is recited in a product-by-process claim to be unclear on the grounds of, in a sense, procedural matters---whether the claim in question meets the formal definition of a product-by-process claim, or what kind of product-by-process claim it is---, inasmuch as the applicant him/herself chose this type of claim. I consider that this practice at the JPO reflects correct interpretation and application of law.

To my understanding, according to the JPO's Examination Guidelines, an application with a product-by-process claim may be refused in the following two cases.

Case 1 is that a product-by-process claim fails to meet the clarity requirement and is rejected due to violation of Article 36, paragraph (6), item (ii) of said Act (referred to in Article 49, item (iv) and Article 123, item (iv) of said Act) (Examination Guidelines, Part I, Chapter 1, page 15, [2] Typical examples where the claimed invention is considered to be unclear). More specifically, an application with a product-by-process claim may be refused if [i] the claimed invention is unclear because the manufacturing process (e.g. starting material, manufacturing steps) recited in the claim cannot be understood, or [ii] the claimed invention is unclear because the characteristics of the product (e.g. structure and nature) recited in the claim cannot be understood (for example, when the description includes only process-related characteristics (e.g. high yield or efficiency in manufacturing can be

achieved by the manufacturing process in question)). In these cases, it cannot be said that the invention of a product is defined by a product-by-process claim. In other cases, as long as the invention of a product is defined by a product-by-process claim, the examiner permits the claim as-is and then examines the requirements of patentability such as novelty and involvement of an inventive step. This practice applies even when part of what is recited in a product-by-process claim is unnecessary. I understand that it is common practice on a global scale.

Case 2 is that a product-by-process claim fails to meet the novelty requirement and is rejected due to violation of Article 29, paragraph (1), item (iii) of said Act (Examination Guidelines, Part II, Chapter 2, page 8). In this case (where it is clear that the invention claimed in a patent application is a product because it is recited in a product-by-process claim which is composed in the form of a noun that refers to a "product"), what is recited in the claim is construed as referring to the product itself that is finally obtained. Accordingly, the novelty of the claimed invention is denied when the same product can be manufactured by any manufacturing processes other than the one recited in the claim and this product is publicly known.

In brief, in Case 1 [i], an application with a product-by-process claim is refused if the invention is unclear because the matters necessary for defining the invention cannot be understood from what is recited in the claim, as in the case of other forms of claim. In Case 1 [ii], an application with a product-by-process claim is refused if the invention is unclear when viewed as an invention of a product because the claim only recites process-related characteristics, such as high yield or efficiency in manufacturing achieved by the process in question, and the characteristics of the product in question are unclear (which means that the invention should have been claimed as an invention of a process). In Case 2, an application with a product-by-process claim is refused due to lack of novelty and an inventive step because the product itself is publicly known or can be easily invented from publicly known art.

As explained above, although the applicant is free to choose what to recite in a claim, an application with a product-by-process claim that should have been refused is eventually refused through the necessary and sufficient application of the clarity and novelty requirements. If such a claim is patented by mistake, the patent will be invalidated under the same criteria as those described above. I consider that the same should be applied to the cases under Article 104-3 of said Act.

3. However, the majority opinion in this judgment could result in fundamentally undermining the abovementioned interpretation of the Patent Act and patent practice. I would have no particular objection if it is in the right direction, but to me, it does not at all seem to be right. The majority opinion (4.(2)) explains that a product-by-process claim regarding an invention of a product must be clearly written, in reference to the purpose of Article 1 of the Patent Act and the provisions of Article 36, paragraph (6), item (ii) of said Act. This is right as a general theory. However, it is often the case that an invention of a product cannot be clearly recited in a claim other than a

product-by-process claim. In particular, in the case of an invention of a product that has novelty, it would be very easy to understand the invention if the applicant describes the process by which the product is made. However, if the applicant tries to describe the product by means of its structure or characteristics, the description would, no doubt, need to be expressed with complicated concepts and terms. In that case, the applicant would have to spend unnecessary time and cost and would miss the chance to file an application at the right time, and what is more, such description would rather be hard to understand not only for the examiner but also for a person ordinarily skilled in the art, which is contrary to the clarity requirement. For example, with regard to an invention relating to a new cell in the field of life science, if this invention is described by a product-by-process claim in such a manner as "a cell produced by a certain method of injecting a certain gene into a certain cell," the description of the claim would be very easy to understand for a person ordinarily skilled in the art. If, to the contrary, the cell produced by such process is required to be described based on its structure or characteristics, although it may not be completely impossible to do so by spending considerable cost and time, the description of the claim regarding the cell that has been finally elaborated through such effort might in most cases be dry-as-dust, pointless and incomprehensible to anyone. It is easy to imagine that an application with such a claim will be refused due to the failure to meet the clarity requirement. Such a consequence goes further away from the ideal of the Patent Act, i.e., the achievement of harmonization between protection of inventions and public use thereof.

On this point, the majority opinion states, "there may be cases where ... it is technically impossible to analyze the structure or characteristics of the product at the time of the filing of the application, or where it is utterly impractical to require the applicant to define the product in such manner because, in light of the nature of a patent application that needs to be handled speedily, etc., the work to define the product could require excessive economic costs and time," thus it appears to intend to permit a product-by-process claim although in an extremely limited manner. However, it concludes, "the claim should be held to meet the requirement that the claimed invention is clear as prescribed in Article 36, paragraph (6), item (ii) of the Patent Act only if there are circumstances where it was impossible or it was utterly impractical to directly specify the product subject to the invention by means of its structure or characteristics at the time of the filing of the application." If this interpretation applies, there would be almost no chance for a product-by-process claim to be permitted.

This issue reminds me of recent important inventions in the field of life science, which relate to stem cells produced by new genetic engineering techniques. In most cases, when a patent application is filed for such an invention by claiming it as an invention of a product, the claim would be in the form of a product-by-process claim. Then, according to the majority opinion mentioned above, the applicant, when drafting a claim, would first need to consider if it is possible to directly define the product by means of its structure or characteristics, for fear that the application or patent with that

claim would be refused or invalidated just because the claim is in the form of a product-by-process claim. However, it is not at all easy for the applicant to perform the work to define the product and prove the fact as required according to the criterion presented by the majority opinion, that is, "there are circumstances where it was impossible or it was utterly impractical to directly define the product subject to the invention by means of its structure or characteristics at the time of the filing of the application" (hereinafter referred to as the "criterion of impossible or impractical circumstances"). It seems to be rather unrealistic just to imagine such work or proof, but there is no evidence, either, that it is impossible to do so. Meanwhile, while taking much time to do such a thing, the applicant would lag behind in fierce global competition with other applicants under the first-to-file principle, so the applicant would feel pressed to file a patent application. Presumably, the applicant in such a situation would take the decision to file an application with a product-by-process claim because of being unable to express the product by means of its structure or characteristics, although he or she is not firmly confident whether or not such decision was right. Then, in the examination or trial procedure, the application or patent with a product-by-process claim would be tested as to whether it should be refused or invalidated by reason of the failure to conform to the criterion of impossible or impractical circumstances. However, since this criterion of impossible or impractical circumstances is too ambiguous and vague to grasp, it seems to me to be very difficult to interpret and apply the criterion in a stable and uniform manner. Moreover, seeing that matters such as how an assessment as to circumstances where "it was impossible or utterly impractical" would be made by whom and by what criteria have not been clearly indicated at all, I would say that the concept of circumstances where "it was impossible or utterly impractical" is almost equal to referring to circumstances where it was "impossible." I am concerned that, as a result, most patent applications claiming inventions of products with product-by-process claims would be refused by reason of the failure to meet the clarity requirement. This could bring about what is called the chilling effect, driving all product-by-process claims out of Japanese patent applications even when these claims are truly necessary, and impeding protection of inventions. I am also concerned that since the failure to conform to the criterion of impossible or impractical circumstances could be the ground for invalidating the existing patents, the validity of a number of patents with product-by-process claims that have already been granted would be challenged more frequently in litigation. When these patents were granted, there was no room for the applicants to be conscious of the criterion of impossible or impractical circumstances. Such background should be taken into careful consideration in such litigation.

4. It is true that the perspective of preventing the interest of a third party from being unfairly prejudiced is as important as the perspective of protecting inventions, as pointed out in the majority opinion. The essential nature of patents can be described as residing in balance between these two perspectives. However, there is the risk that the application of the criterion of impossible or impractical circumstances presented in the majority opinion would lead to the complete failure to

achieve the protection of inventions, which is what I am most concerned about.

In the current patent practice, when each claim in a patent application is composed in the form of a noun that refers to a "product" rather than a "process," it is clear that protection by a patent for an invention of a product is sought even if the relevant claim is a product-by-process claim. Then, the application is eventually refused if the product finally obtained by the process recited in the claim is found to lack novelty and an inventive step, that is, it is a publicly known product. Accordingly, a third party would have to pay attention only to patent applications that claim new products, in which case the third party's burden of caution would be mitigated to a considerable degree. In other words, in cases such as where a person ordinarily skilled in the art would have been unable to assume the specific product manufactured by the manufacturing process recited in the claim even by taking into consideration the common general technical knowledge available at the time of the filing of the application, it would suffice to treat this as the premise for determining the novelty and involvement of an inventive step in the claimed invention. Contrary to this, according to the majority opinion, when a claim is composed in the form of a product-by-process claim that fails to meet the criterion of impossible or impractical circumstances, the application or patent with such claim would be refused or invalidated without exception on the grounds of the failure to meet the clarity requirement because of this claim form. I consider that this consequence is far outside the range of the conventional interpretation of Article 36, paragraph (6), item (ii) of the Patent Act and it obviously constitutes misinterpretation of law.

5. Conventionally, the issue of identifying the gist of the invention and the issue of determining the technical scope of the patented invention were addressed separately, the former by the JPO and the latter by the court. Since these issues, when brought to litigation, were dealt with in separate cases, I presume that it did not appear to be so strange even if these cases ended up with inconsistent conclusions. However, as a result of the introduction of Article 104-3 to the Patent Act through the amendment in 2004, it has become possible to raise the defense of invalidity of a patent in the litigation proceedings in which patent infringement is claimed. Accordingly, it has come to be considered to be unreasonable for the same claim to be construed differently, and the double standard that previously existed is now being eliminated. This is the right direction. The "gist of the invention" involved in determining patentability and the "technical scope of the patented invention" involved in determining infringement must be consistent with each other as claim construction.

Having said that, if the "technical scope of the patented invention" is assumed as the first place to start, and in the stage of identifying the "gist of the invention," emphasis is placed on a sort of a procedural issue, i.e. whether the claimed invention meets the criterion of impossible or impractical circumstances, and a patent is refused from the beginning by applying the clarity requirement, such practice has gone too far as claim construction. In light of the purpose of the amendment to the Patent Act in 1994, if the claimed invention can be defined based on the content of a claim that the

patent applicant has chosen him/herself, a patent should be granted as long as the invention has novelty and an inventive step. This is irrelevant to whether a product-by-process claim is contained in a patent application. This is the stage of identifying the gist of the invention.

In such case, a question may be raised as to the interpretation of Article 70 of the Patent Act in connection with the handling of a product-by-process claim. In this respect, I consider that the manufacturing process recited in a claim of a patent for an invention of a product (a claim composed in the form of a noun that refers to a "product") should be construed as being recited with a view to defining the product itself that is made by the manufacturing process, rather than as being recited to limit the scope of the patent by means of the manufacturing process. Such claim construction is made on the basis of the wording of the claim. In other words, when the manufacturing process is recited in a claim of a patent for an invention of a product, this fact can be construed as the applicant's intention to seek protection for the invention of the product itself, and such manner of construction should be the principle.

Next, with regard to a product-by-process claim, it is necessary to admit that there may be exceptional cases where the issue of determining the technical scope of the patented invention cannot be considered in the same manner as considering the issue of identifying the gist of the invention addressed in response to the defense of the invalidity of the patent. Claim construction performed by the court in an infringement suit is intended for the purpose of determining the scope of legal protection of a patent right already granted. On the other hand, claim construction performed by the JPO in the examination and trial procedures is intended for the purpose of assessing whether or not to grant a patent for the claimed invention (in the examination procedure) or assessing whether or not a patent already granted should have been granted at all (in the trial procedure). Thus, purposes are different between claim construction by the court and that by the JPO, and it may be inevitable that the court and the JPO reach different constructions. In this sense, a product-by-process claim should be regarded as an exceptional case where the technical scope of the patented invention determined in an infringement suit may be inconsistent with the gist of the invention identified by the JPO. This view could lead to the consequence that for some product-by-process claims, the technical scope of the patented invention determined by the court, within which a patent may be enforced, is narrower than the gist of the invention identified by the JPO. However, this results from the applicant having chosen a product-by-process claim, and hence it is an inevitable consequence. Therefore, as is currently done in some actual cases, a reasonable conclusion may be drawn by construing the technical scope of the patented invention, which is based on a patent for an invention of a product expressed in the form of a product-by-process claim, as being substantially limited to the manufacturing process, by applying the doctrines of claim construction already established, such as the doctrine of estoppel and the doctrine of intentional exclusion.

6. The court of prior instance determined that when a claim of a patent for an invention of a product is expressed as a product-by-process claim, the technical scope of the patented invention should in principle be determined as being limited to products manufactured by the manufacturing process recited in the claim, while generally permitting a claim in this form. However, although a product-by-process claim may be generally permitted, the criterion of impossible or difficult circumstances, which is applied to distinguish cases where this claim form is permitted from those where it is not permitted, is extremely ambiguous and is subject to the same criticism as that of the criterion of impossible or impractical circumstances presented in the majority opinion.

In addition, the court of prior instance held that if this claim form is not permitted, the technical scope of the patented invention should be determined as being limited to products manufactured by the manufacturing process recited in the claim. In this respect, as pointed out in the majority opinion, I consider that when a claim of a patent for an invention of a product recites the manufacturing process of the product, the technical scope of the patented invention should be determined as referring to products that have the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim.

The Invention based on the Patent held by the appellant relates to a product expressed by a product-by-process claim (pravastatin sodium that contains less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava). On the other hand, the appellee's product has been found to contain pravastatin sodium that contains less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava. Thus, as long as the Patent remains valid, the appellee's product would be held to fall within the technical scope of the patented invention in question, but this is yet to be proved to be true. Therefore, I agree to remand the case to the court of prior instance, for the purpose of having it examine that point as well as issues including whether it is possible to construe the technical scope of the patented invention in question in a limited manner in light of the prosecution history of the patent application concerned.

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Presiding judge

Justice CHIBA Katsumi

Justice ONUKI Yoshinobu

Justice ONIMARU Kaoru

Justice YAMAMOTO Tsuneyuki

(This translation is provisional and subject to revision.)