

Pravastatin Sodium Case, Product-by-Process Claiming Practice

Dr. Shoichi Okuyama
Patent Attorney, Okuyama & Sasajima

Product-by-process claim drafting and interpretation practice were greatly modified by the *Pravastatin Sodium Case* decisions (the Supreme Court of Japan, June 5, 2015, Second Petty Bench, case Nos. 2012(ju)1204 and 2012(ju)2658). Japan's highest court *reversed* the Grand Panel¹ of the IP High Court. The two decisions upset the current practice and efforts toward international harmonization. Two points were emphasized in the opinion of the Court:

Products made by a Different Process Infringe the Claim: “[E]ven if a patent claim concerning a product invention recites the manufacturing process of a product, the technical scope of the patented invention should be determined to cover products that have the same structure and characteristics, etc., as those of the product made in accordance with the manufacturing process.”

Product-by-Process Claims When Only Way to Define a Product: “[W]hen patent claims concerning a product invention recite the manufacturing process of a product, such claims would satisfy the requirement [that] "the invention be clear" according to Article 36(6)(ii), Patent Act, only if circumstances exist under which it is impossible or utterly impractical to directly identify the structure or characteristics of the product at the time of filing.”

In fact, the Supreme Court adhered to the theory it created years ago that a product claim should be, as a rule, delimited by the structure or

¹ The Grand Panel consists of the heads of the four divisions that exist in the IP High Court plus one judge.

characteristics of the inventive product despite the fact that in 1994, Article 36 of the Patent Act was amended to allow for more flexibility in claim drafting. The Supreme Court allowed the use of product-by-process limitations in the claims only if it is impossible or utterly impractical to define the invention without using such limitations. In order to justify above-mentioned two theses, it created a new category of the lack of clarity under Article 36(6)(ii).

An analysis follows, with an English translation of the majority opinion at the end of this paper.

The Supreme Court *Lipase Decision* (1991): The Supreme Court in this decision recognized the importance of the public notice function of patent claims. Citing the *Lipase Decision*, the Court in the *Pravastatin Sodium Case* reiterated the public notice function of patent claims. In the earlier *Lipase Decision* the Supreme Court rejected the idea of reading a limitation from the specification into pending claims. The Tokyo High Court (now IP High Court) read "lipase" in the claim as the species "Ra lipase" because all examples in the specification were for Ra lipase. The *Lipase Decision* was an appeal from a JPO decision to reject the application.

The Supreme Court stated that:

When the patentability requirements according to Article 29(1) and (2), Patent Act; that is, the novelty and inventive step of an invention found in a patent application are reviewed, the gist of the invention in the application has to be determined in order for the invention to be compared with prior art defined in Article 29(1). Unless special circumstances exist, this determination of the gist has to be made based on the recitations in the claims. Only if special circumstances exist such as when the technical meaning of

a recitation in the claim cannot be understood without ambiguities, or when it is apparently clear that such recitation is an error with reference to the detailed description of the invention in the specification, it is permitted to refer to the detailed description of the invention in the specification.

Justice Yamamoto's Sharply Worded Concurrence: Justice Tsuneyuki Yamamoto, who started his career as a bureaucrat at the Ministry of International Trade and Industry (now the Ministry of Economy, Trade and Industry), concurred with the Judgement but strongly criticized the majority opinion.

He pointed out that the Patent Act was amended in 1994 with respect to Article 36(5)(ii), which required that patent claims must "set forth only the features indispensable for the constitution the invention." The corresponding provision after the amendment is in Article 36(5), which requires that claims must set forth "all matters which an applicant for a patent considers necessary in defining an invention." Noting discussions made in the report of the council responsible for the amendment and also quotations from the current examination guidelines published by the Japan Patent Office, he noted that the amendment and current JPO practice allow functional and process limitations in claims, while product-by-process claims are also subject to other patentability requirements such as clarity of claims and novelty.

He noted that the majority opinion would upset such interpretation of the Patent Act and also the current examination practice. He also pointed out that, in a large number of cases, if the format of product-by-process claims is not used, claims become rather unclear. He gave an

exemplary claim which recites that "a cell produced by introducing a certain gene into a certain cell in a certain way." He argued that such a claim is very easy to understand for a skilled person. On the other hand, if the cell has to be defined in terms of structure or characteristics, the resulting claim would be understandable to no one. This is against the ideal of the Patent Act which aims at a proper balance between the protection of inventions and public use.

He also cautioned that if product-by-process claims are allowable only "if circumstances exist under which it is impossible or utterly impractical to directly identify the structure or characteristics of the product at the time of filing" as in the majority opinion, it would become practically impossible to use process-by-process limitations.

He also questioned the expansive interpretation of Article 36(6)(ii) (clarity requirement) by stating that: "According to the majority opinion, if product-by-process claims are refused or invalidated as violating the clarity requirement when such claims do not satisfy the requirement that it is impossible or impractical to specify the claimed product without a process limitation goes far beyond the traditional interpretation of Article 36(6)(ii), and such new interpretation is clearly wrong."

Justice Yamamoto agreed with the majority opinion in that the product-by-process claim should also cover products that are not made by the recited process. He also agreed to remand the case back to the IP High Court.

Two Decisions: The two Supreme Court decisions were handed down on the same day. A Hungarian subsidiary of Teva Pharmaceutical Industries, Ltd. separately sued two Japanese companies, Kyowa Hakko Kirin Co., Ltd. and Tohri Company Ltd., for infringement of a Japanese patent it owns, patent No. 3737801. The first case involving Kyowa Hakko Kirin resulted in the Grand Panel decision of the IP High Court, which addressed the issue of infringement of the product-by-process claim. The other case involving Tohri led to another IP High Court decision rendered by an ordinary panel of three judges. The main issue in the second decision was an invalidity defense - the lack of inventive step. The second decision (case No. 2012(ju)2658) is just a paraphrased version of the first decision (case No. 2012(ju)1204), and they are substantially the same. In this paper, we base our analysis on the first decision involving Kyowa Hakko Kirin.

Supreme Court Reference to American Court Decisions: In the supporting opinion, Justice Chiba discussed the *en banc* decision of the Federal Circuit in *Abbott Labs. v. Sandoz, Inc.* (2009), and the *Nautilus* United States Supreme Court decision.

Implications for Product-by-Process Claiming: Under these new Supreme Court decisions, the Japan Patent Office now has to examine patent applications containing product-by-process claims to determine whether or not any circumstances exist under which it was impossible or impractical to directly identify the structure or characteristics of the product at the time of filing. The burden rests on the applicant to show such circumstances existed as of the filing date. It is generally not easy

to show that something is impossible to accomplish while it may be easier to show the contrary. Also, the applicant may have to make sure that the structures or characteristics of, say, antibiotics, microorganisms or modified cells are described in detail in the patent application, although claims identifying such structures or characteristics may be more difficult to understand. Also, the scope of these decisions may not be limited to biotech and pharmaceutical fields. Inventions in such fields like metals, alloys, semiconductors, or even mechanical engineering may face problems if claims contain some language that suggests use of a process.

Questioning the Validity of Existing Patents: The validity of existing patents that have product-by-process limitations in the claims may have to be questioned.

Interim Guidelines published on July 6, 2015: On July 6, 2015, the Japan Patent Office published a document entitled "Interim Handling Procedures for Examinations and Appeals/Trials involving Product-by-process Claims." According to this document, if the applicant argues in writing that it was impossible or impractical to identify the invention in terms of its structure or characteristics at the time of filing, the examiner is encourage to take the face value of the argument and allow the application as a rule. An English summary version was also prepared and published by the JPO. The following is an excerpt from the English version.

Based on the opinion of the judgments by the Supreme Court on the above-mentioned cases, an outline of the interim handling of

examinations is provided below:

When a claim concerning an invention of a product recites a manufacturing process of the product, the examiner will notify any reasons for refusal whenever the invention of that product is not clear. However, this will not be the case when the examiner can find that the invention involves "impossible or impractical circumstances".

The term "impossible or impractical circumstances" means any circumstances in which it is impossible or utterly impractical to define the product based on its structure or characteristics at the time the subject application for such product was filed.

The reasons for refusal will be notified to give the applicant an opportunity to assert and prove the existence of "impossible or impractical circumstances", and also an opportunity to make an argument and/or an amendment thereof. These opportunities are given in order to avoid situations in which an already granted patent could include grounds for invalidation, or in which interests of third parties could be unfairly harmed.

The applicant can file other responses as arguments against a notice of reasons for refusal in order to resolve such reasons, including:

- (i) deleting any claim concerned,
- (ii) amending any claim concerned into a claim concerning an invention of a process for producing a product,
- (iii) amending any claim concerned into a claim concerning an invention of a product which does not include a manufacturing process, and/or
- (iv) asserting and proving the existence of "impossible or impractical circumstances" based on a written argument.

When the applicant asserts and proves the existence of "impossible or impractical circumstances", the examiner will, normally, conclude that "impossible or impractical circumstances" do exist. However, this will not be the case when the examiner has doubts, based on a tangible reason, about the existence of "impossible or impractical circumstances".

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Pravastatin Sodium Case
Case No. 2012 (ju) 1204
Patent infringement case demanding injunction
June 5, 2015
Ruling of the Second Petty Bench

A Translation of the Majority Opinion*

Judgement

The original decision is reversed.
The case is remanded to the Intellectual Property High Court.

Reason

Concerning the first, second, fourth, and fifth points raised in the Petition for Acceptance of Final Appeal by appeal attorney Kiyoshi Kamiya.

1 In the present case, the appellant, who has a patent including a so-called product-by-process claim which recites the manufacturing process of a product while the patent is granted on a product invention, asked for an injunction on the manufacture and sale of pharmaceutical products the appellee produces and the disposal of such products, because the appellee's pharmaceutical products allegedly infringe on the appellant's patent. The appellee asserts, for example, that such pharmaceutical products do not fall under the technical scope of the patented invention of the appellant. An issue in dispute is how the technical scope of a patented invention should be determined when the manufacturing process is recited

* This is an English Translation of the Majority Opinion of the Supreme Court of Japan in Case No. 2012(ju)1204 as published on the web site of the Supreme Court (Supporting Opinion by Justice Katsumi Chiba and Opinion by Justice Tsuneyuki Yamamoto are not included. Underlining is shown as it appears in the decision.)

in a patent claim directed to a product invention.

2 Summary of the original court decision and determined facts are as follows.

(1) The present patent

The appellant has a patent on an invention entitled "Pravastatin sodium substantially free of pravastatin lactone and epi-pravastatin, and compositions containing same," (patent No. 3,737,801, and the number of claims is nine. Hereinafter, it is called "the subject patent.")

(2) The present invention

Claim 1 among the claims of the subject patent (hereinafter referred to as "the subject claim") is as follows (hereinafter referred to as "the present invention"):

"Pravastatin sodium in which a mixed amount of the pravastatin lactone is less than 0.5 % by weight, and a mixed amount of epiprava is less than 0.2% by weight, prepared by a process comprising the following steps:

- a) forming a concentrated organic solution of pravastatin;
- b) precipitating pravastatin as an ammonium salt thereof;
- c) purifying the ammonium salt by recrystallization;
- d) transposing the ammonium salt to the pravastatin sodium; and
- e) isolating pravastatin sodium."

(3) The appellee's product

A. The appellee manufactures and sells pravastatin Na salt tablets 10mg of the drug "KH" (formerly known as pravastatin Na salt tablets 10mg "Merck", hereinafter referred to as "the appellee's product").

B. The appellee's product contains pravastatin sodium that has less than 0.5 wt% of mixed pravastatin lactone and less than 0.2 wt% of mixed epiprava. Its method of manufacture, at least, does not involve "a) forming a concentrated organic solution of pravastatin" recited in the subject claim.

3 The original decision dismissed the demand of the appellant and made determinations as follows:

(1) The technical scope of a patented invention, when the manufacturing process of a product is recited in a patent claim directed to a product invention, the technical scope of such invention should be limited to products manufactured according to the manufacturing process described in the claim, unless there exist circumstances in which it is impossible or difficult at the time of filing to directly identify the product by its structure or characteristics.

(2) Since no such circumstances as in (1) above do not exist for the present invention, the technical scope of the present invention should be limited to those manufactured by the production process. The process for making the appellee's product does not involve at least "a) forming a concentrated organic solution of pravastatin" recited in the subject claim, the appellee's products do not fall within the technical scope of the present invention.

4 However, we cannot accept the criteria indicated in 3(1) above discussed in the original decision, and we cannot accept the determination made on the basis of such criteria discussed in 3(2) above. The reasons for this are as follows:

(1) The claims attached to the application has the function of defining the technical scope of the patented invention based on statements in the claims (Article 70(1), Patent Act), and also based on statements in the claim, the gist of the invention in the patent application is determined for the purpose of examination of patentability requirements such as those prescribed in Article 29 of the same Act² (Supreme Court decision of March 8, 1991, Ccse No. 1987(gyotsu), the ruling of the Second Petty Bench, published in *Minshu*, Vol. 45, No. 3, page 123). While patents are granted on product inventions, method inventions, and inventions of processes for producing products, when a patent is granted on a product invention, the effect of the patent covers products that have the same structure and characteristics, etc. as those of the patented product without any regards to the manufacturing process.

Therefore, *even if a patent claim concerning a product invention recites the manufacturing process of a product, the technical scope of the patented invention should be determined to cover products that have the*

² The term "technical scope" is used associated with infringement determination, and the term "gist" is used associated with the examination of patentability requirements.

same structure and characteristics, etc., as those of the product made in accordance with the manufacturing process.

(2) By the way, according to Article 36(6)(ii), Patent Act, recitations in the claims have to satisfy the requirement that "the invention be clear". The patent system is to provide protection over inventions for patentees by granting patents that are monopolistic rights to those who disclosed inventions, and encourage the utilization of inventions by letting third parties know of patented inventions, for the purpose of encouraging inventions, and thereby contributing to the development of industry (Article 1, Patent Act). We understand that the requirement of clarity of the invention in the claims according to Article 36(6)(ii) is provided for this purpose. In view of this, in every case where a manufacturing process of a product is described in a patented claim directed to a product invention, if the effect of such patent is determined in such a manner that the technical scope of the patented invention is determined to cover products that have the same structure and characteristics, etc. as those of the product made in accordance with the manufacturing process, it is problematic in that third party interests may possibly be unjustifiably prejudiced. In other words, if the manufacturing process is recited in a patented claim directed to a product invention, it is generally unclear what structures or characteristics of the product are represented by the manufacturing process, or it is unclear whether the technical scope of the claim directed to a product invention is limited to products manufactured by the manufacturing process. The reader of such recitation in the claims cannot clearly understand the content of the invention, making to what extent the proprietor has monopoly unpredictable. This is not appropriate.

On the other hand, in a patented claim directed to a product invention, such product is ordinarily identified by clearly reciting its structure and characteristics in a direct manner. However, depending on the nature, property or the like of the product, it may be technically impossible to analyze its structure or characteristics at the time of filing, or it may require significantly large economic outlay or time to carry out work necessary for identification. In view of the nature of patent applications which requires promptness, etc., it may not be practical to require applicants such identification in some cases. Therefore, it should be made possible to recite a manufacturing process in a claim directed to a product invention. If the above-mentioned circumstances exist, third party interests would not be unjustifiably harmed even if the technical scope of

the patented invention is determined to be products that have the same structure and characteristics, etc. as those of the product made by such manufacturing process.

As we have discussed above, when patent claims concerning a product invention recite the manufacturing process of a product, such claims would satisfy the requirement of "the invention be clear" according to Article 36(6)(ii), Patent Act, only if circumstances exist under which it is impossible or utterly impractical to directly identify the structure or characteristics of the product at the time of filing.

5 Differing from the above, the judgement in the original decision, which says that when a manufacturing process of a product is recited in a claim, while generally allowing such recitation in the claim, to say that the technical scope of the patented invention should be limited, as a rule, to products manufactured according to the manufacturing process described in the claim is a clear violation of law which affects the judgement in the decision. The drift of arguments is reasoned, and the original decision has to be reversed. Then, the case is remanded to the original court, so that in accordance with what is discussed in this decision, proceedings should be completed concerning whether the recitations in the subject claim satisfy the requirement of "the invention be clear" and allowable when the circumstances discussed in section 4(2) above exist, and the technical scope of the subject invention should be determined.

Thus, in the opinion of the justices unanimously, it is ruled as in the Judgment. In addition, Justice Katsumi Chiba has a supporting opinion³, and Justice Tsuneyuki Yamamoto has an opinion⁴.

- The end of the majority opinion -

³ Justice Chiba explained the majority opinion (which is about 5 pages in length) in greater detail in a lengthy discussion (about 8 pages).

⁴ Concurring in judgement, but Justice Yamamoto is very critical of the majority opinion.