

**Case Information**

Case	Pravastatin Sodium case
Court, case No.	The second petty bench of the Supreme Court (2012 (Ju) 1204, 2012 (Ju)2658)
Date of judgment	June 5, 2015
Parties	Appellant :Teva Gyogyszergyar Zartkoruen Mukodo Reszvenytarsasag Appellees: Kyowa Hakko Kirin Co.,Ltd. (2012 (Ju) 1204) Appellees: Tohri Company., Ltd. (2012 (Ju)2658)

**FACTS**

In the present cases where a patent has been granted for an invention of a product, the appellant (Teva), who has a patent right with regard to so-called product-by-process (PBP) claim which recites the manufacturing process of the product in the claims, filed the cases against the appellees (Kyowa Hakko Kirin in the first case and Tohri in the second case, respectively), asserting that each appellee's acts of manufacturing/importing and selling the product infringe upon the appellant's patent right.

The appellant has the patent right of the invention entitled "Pravastatin sodium substantially free of pravastatin lactone and epi-pravastatin, and compositions containing the same" (Patent No. JP 3737801). Claim 1 (PBP claim) of the subject patent is as follows:

"Pravastatin sodium prepared by a process comprising the steps of:

- 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 pravastatin sodium; and
- e) isolating pravastatin sodium;  
wherein the pravastatin sodium contains less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava."

A Grand Panel of the Intellectual Property High Court (IP High Court) judged the

first case and made decision to dismiss the demand of the appellant, Kyowa Hakko Kirin.

(1) Technical scope of a patented invention regarding the PBP claim in a patent infringement lawsuit

In the case where the scope of claims with regard to the patented “invention of a product” recites a manufacturing process of the product, the technical scope of the invention should be definitely determined as being limited to products manufactured by said manufacturing process (in relation to this case, such claims are referred to as “Genuine Product-by-Process Claims” for convenience), unless there exist circumstances where it is impossible or difficult to directly specify the product by means of the structure or feature of the product at the time of filing an application (in relation to this case. Such claims are referred to as “Inauthentic Product-by-Process Claims” for convenience).

In the case of “Genuine Product-by-Process Claims”, the technical scope of the patented invention should be recognized as covering “product” in general, not limited to product manufactured through the manufacturing process stated in the scope of claims. Contrarily, for “Inauthentic Product-by-Process Claims”, the technical scope of the patented invention is interpreted as being limited to “products manufactured through the manufacturing process stated in the scope of claims,

(2) Interpretation of the PBP claim in determining the validity

In the case where the patented claim of the “invention of a product” recites a manufacturing process of the product, and validity of the patent is at issue as an invalidity defense under Article 104-3 of the Patent Act, the claim should be interpreted in the same manner as described the above item (1), being limited to products manufactured by said manufacturing process, unless there exist circumstances where it is impossible or difficult to directly specify the product by means of the structure or feature of the product at the time of filing an application.

In the second case, which IP High Court decision was rendered after the Grand Panel decision, the issue at the appeal court (IP High Court) was only the invalidity of the patent. The IP High Court also made the decision to dismiss the demand of the appellant in this case based on the above described claim construction established by the Grand Panel of the IP High Court.

The appellant appealed both cases to the Supreme Court, and the Supreme Court

decided to review the cases.

## ISSUE

(1) Technical scope of the invention regarding the PBP claim in a patent infringement lawsuit (first case)

(2) Interpretation of the PBP claim in determining the validity (second case)

Note: Clarity regarding the PBP claim is not an issue in dispute, however, the Supreme Court focused on a clarity issue of a product-by-process claim in the judgment as shown below.

## HOLDING

(Main text of the judgment in both cases)

The original decision is reversed.

The case is remanded to the IP High Court.

(Essential summary of the majority opinion in each case)

(1) “[E]ven if a scope of claims with regard to the patented “invention of a product” recites a manufacturing process of the product, the technical scope of the patented invention should be determined as products that have the same structure and feature, etc. as those of the product made in accordance with the manufacturing process” (first case).

(2) “[E]ven if a scope of claims with regard to the patented “invention of a product” recites a manufacturing process of the product, the said invention should be determined as products that have the same structure and feature, etc. as those of the product made in accordance with the manufacturing process” (second case).

(3) “[W]hen a scope of claims with regard to the patented “invention of a product” recites a manufacturing process of the product, the claims would satisfy the requirement of “the invention ... is clear” according to Article 36(6)(ii) of the Patent Act, only if there exist circumstances where it is impossible or utterly impractical to directly specify the structure or feature of the product at the time of filing an application” (both cases).

The Supreme Court made a judgment as described in the main text, in the opinion of the judges unanimously.

It is noted that Justice Katsumi Chiba has a supporting opinion, and Justice Tsuneyuki Yamamoto has an opinion.

Justice Chiba mentioned the definition of the terms “impossible” and “utterly impractical” in the above requirement of clarity (Article 36(6)(ii) of the Patent Act) established as the majority opinion to recognize PBP claim as follows: “impossible” means a case in which it is impossible mainly from a technical point of view for those skilled in the art to analyze and specify the structure or feature of the claimed product at the time of filling an application.; “utterly impractical” means, for example, a case in which it may require an impractical amount of time and cost which is not commercially-viable for those skilled in the art to carry out to specify the structure or feature of the claimed product at the time of filling an application, so that it is too severe to require such a work to specify when obtaining a patent where technology is rapidly evolving and competition is intense on an international scale.

Justice Chiba criticizes the IP High Court’s construction of a PBP claim, which uses product per se construction for “genuine” PBP and limited-by-the process construction for “inauthentic” PBP, so that it contradicts precedents of Supreme Court and such construction by courts would be unpredictable by a third party.

Justice Yamamoto agrees that both cases should be remanded to the IP High Court, however, he expressed the reason thereof is different from that of the majority opinion. For example, Justice Yamamoto criticizes the majority opinion such that there are many cases where PBP claim is clearer compared with the claim forcibly described by the structure or feature. Nevertheless, claim interpretation according to the majority opinion that invokes the requirement of clarity against the PBP claim and does not allow to get the patent from the beginning in the first place, goes beyond bounds.

June 2015

Original document (Japanese):

[http://www.courts.go.jp/app/files/hanrei\\_jp/145/085145\\_hanrei.pdf](http://www.courts.go.jp/app/files/hanrei_jp/145/085145_hanrei.pdf)

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English translation:

N/A