

Date	January 27, 2012	Court	Intellectual Property High Court, Special Division
Case number	2010 (Ne) 10043		
<p>– A case in which, with regard to how to define the technical scope of a claim that is generally referred to as a product-by-process claim, the court ruled that if there are no such circumstances as that it is impossible or difficult to directly specify the technical scope of a product-by-process claim by means of the structure or feature of the product at the time of filing an application, the technical scope is limited to products manufactured through the manufacturing process stated in the claim</p> <p>– A case in which, with regard to a defense under Article 104-3 of the Patent Act, the court ruled that, in the process of recognizing the gist of a claim that is generally referred to as a product-by-process claim, if there are no such circumstances as that it is impossible or difficult to directly specify the constitution of the product by means of the structure or feature of the product at the time of filing an application, the gist of the invention is recognized as being limited to products manufactured through the manufacturing process stated in the claim</p>			

References:

Article 29, paragraphs (1) and (2), Article 100, and Article 104-3 of the Patent Act

(Summary)

The appellant, who has a patent right for the invention entitled "Pravastatin sodium substantially free of pravastatin lactone and epi-pravastatin, and compositions containing the same" (Patent No. 3737801), filed this case against the appellee, asserting that the appellee's products infringe the appellant's patent right. The appellant sought an injunction against the manufacturing and sale of the appellee's products and disposal of the appellee's products in stock.

Claim 1 in the scope of claims of the patent (Invention 1) states a process to manufacture an invention of a product (this type of claim is generally referred to as a "product-by-process claim").

The major issues of this case are (i) whether the appellee's products fall within the technical scope of the inventions in question and (ii) whether the patent should be invalidated by a trial for patent invalidation. In particular, interpretation of a product-by-process claim became an issue.

In the judgment in prior instance, the Tokyo District Court made a determination on the aforementioned issue (i) alone. The court held that, for an invention of a product, when the scope of claims states a process to manufacture the product, it is impermissible to interpret the technical scope excluding said manufacturing process

unless there are special circumstances such as difficulty in stating the constitution of the product, and determined that the process to manufacture the appellee's products does not fulfill the requirements for the manufacturing process of Invention 1. Based on these holdings, the court dismissed the appellant's claims.

The Intellectual Property High Court indicated the methods of defining the technical scope of a product-by-process claim and recognizing the gist of the invention as follows, and held that the technical scope of the patent and the gist of the claimed invention are limited to products manufactured in accordance with the requirements for the manufacturing process stated in Claim 1 of the patent. Accordingly, the court determined that the judgment in prior instance is justifiable in terms of the conclusion, and dismissed the appeal.

#### 1. Regarding the technical scope of the inventions in question

(1) Regarding the definite determination of the technical scope of a patented invention in a patent infringement lawsuit

A. With regard to the definite determination of the technical scope of a patented invention in a patent infringement lawsuit, Article 70, paragraph (1) of the Patent Act provides that "The technical scope of a patented invention shall be determined based upon the statements in the scope of claims attached to the application." Paragraph (2) of said Article provides that "In the case of the preceding paragraph, the meaning of each term used in the scope of claims shall be interpreted in consideration of the statements in the description and drawings attached to the application."

Therefore, where a claim for an injunction or damages has been made on the grounds of infringement of a patent right, statements in the "scope of claims" should be used as standards in definitely determining the technical scope of a patented invention, based on which such claim has been made. The statements in the scope of claims should be understood as specifically demarcating the technical scope of the patented invention. If this idea is denied, and a specific "wording" used in the scope of claims is interpreted as not intending to limit the technical scope of the invention, this will undermine the trust of third parties who acted in accordance with the statements in the "scope of claims" appearing in the patent gazette, which will result in impairing legal stability.

Assuming so, where the scope of claims of an "invention of a product" states a "process to manufacture" the product, as it happens in this case, the technical scope of the invention should be interpreted or definitely determined as being limited to products manufactured by said manufacturing process. It is, in principle, impermissible

to interpret or definitely determine the technical scope of the invention as including other manufacturing processes beyond said manufacturing process stated in the scope of claims.

In the case of an "invention of a product," like with the one disputed in this case, it is desirable that the scope of claims is stated and defined by means of the structure or feature of the product. However, if there are 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, it is also permissible to specify the product by means of a process to manufacture the product in light of the purpose of Article 1, etc. of the Patent Act, i.e. encouraging inventions and thereby contributing to the development of industry, and such manner of specifying the product does not seem to go against Article 36, paragraph (6), item (ii) of the Patent Act.

Where there are such circumstances, even if a specific manufacturing process is stated in the scope of claims, such manufacturing process is regarded as being stated for the purpose of specifying the product, and the technical scope is to be interpreted and definitely determined as not being limited to products manufactured through the manufacturing process stated in the scope of claims but also covering "products" in general.

B. Where, for an invention of a product, a process to manufacture the product is stated in the scope of claims, such a claim is generally called a "product-by-process claim." In light of the perspective mentioned in A. above, product-by-process claims as mentioned above fall into two types, specifically: (i) claims "in which a product is specified by means of a process to manufacture the product because there are 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 "Authentic Product-by-Process Claims" for convenience)"; and (ii) claims "in which a process to manufacture the product is stated in addition to a product, though it cannot be said that there are circumstances where it is impossible or difficult to directly specify the product subject to the invention 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 "Unauthentic Product-by-Process Claims" for convenience)." The court examines product-by-process claims based on this distinction.

According to A. above, for Authentic Product-by-Process Claims, the technical scope of the invention is interpreted as "not being limited to products manufactured through the manufacturing process stated in the scope of claims but also covering any

"products" that are identical to the products manufactured through said process." Contrarily, for Unauthentic Product-by-Process Claims the technical scope of the invention is interpreted as being limited to "products manufactured through the manufacturing process stated in the scope of claims."

In addition, from the perspective of distribution of the burden of proof in a patent infringement lawsuit, where a manufacturing process is stated in the scope of claims of an invention of a product, the statement is in principle to be interpreted literally. Therefore, a person who asserts that the claim falls under Authentic Product-by-Process Claims should bear the burden of proving that "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." If such a person is unable to fully prove this, it is reasonable to regard the claim as an Unauthentic Product-by-Process Claim and to interpret or definitely determine the technical scope of the invention as stated in the scope of claims.

(2) Regarding Invention 1, there are no "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." Therefore, Invention 1 should be understood as being stated in an Unauthentic Product-by-Process Claim as mentioned above, and the technical scope thereof is limited to products manufactured in accordance with the requirements for the manufacturing process.

(3) The appellee's manufacturing process does not fulfill process (a) out of the requirements for the manufacturing process of Invention 1.

According to the above, the appellee's products are recognized as not falling within the technical scope of Invention 1, without needing to determine other points.

2. Regarding whether the patent should be invalidated by a trial for patent invalidation

According to 1. above, the appellee's products manufactured and sold by the appellee (defendant) do not fall within the technical scope of Invention 1. However, by way of caution, the court also makes a determination on the issue of whether "the patent should be invalidated by a trial for patent invalidation," argued by the appellee as a defense.

(1) Recognition of the gist of the invention

Article 104-3 of the Patent Act provides that "Where, in litigation concerning the infringement of a patent right or an exclusive license, the said patent is recognized as one that should be invalidated by a trial for patent invalidation, the rights of the patentee or exclusive licensee may not be exercised against the adverse party." However, the gist of the invention, which serves as a premise in determining the

validity of a defense under Article 104-3 of the Patent Act, should be recognized in the same manner as recognizing the specific content of the claims, which the Japan Patent Office, the decision-making entity, should understand in the aforementioned procedure of a request for a trial for patent invalidation.

More specifically, regarding the gist of the invention in the case of a product-by-process claim as mentioned above (where the scope of claims of an "invention of a product" states a "process to manufacture" the product), like with the one disputed in this case, the same reasons as those explained in connection with the aforementioned method of defining the technical scope of a patented invention in a patent infringement lawsuit would apply, that is: (i) if there are circumstances where it is impossible or difficult to directly specify the constitution of the product subject to the invention by means of the structure or feature of the product, without referring to the manufacturing process, at the time of filing an application, the gist of the invention should be recognized as covering "products" in general, not limited to products manufactured through the manufacturing process stated in the scope of claims (Authentic Product-by-Process Claim); (ii) if it cannot be said that there are such circumstances as mentioned in (i) above, the gist of the invention should be recognized as being limited to products manufactured through the manufacturing process stated in the scope of claims (Unauthentic Product-by-Process Claim).

In this case, it is reasonable to understand that a claim should be handled as an Unauthentic Product-by-Process Claim mentioned in (ii) above when it is not found that there are circumstances as mentioned in (i) above.

Examining the present case from the aforementioned perspective, as described above, there are no such circumstances as mentioned in (i) above (impossibility of or difficulty in specifying the product) with regard to the patent. Therefore, the procedure to recognize the gist of the invention in the process of a request for a trial for patent invalidation should be carried out while regarding the claimed invention as relating to products manufactured through the manufacturing process as stated in the scope of claims. Consequently, the same understanding should also apply to a defense under Article 104-3 of the Patent Act.

(2) Invention 1 is recognized as an invention that a person ordinarily skilled in the art would have been able to easily make based on the invention disclosed in Exhibit Otsu No. 30, the document of Exhibit Otsu No. 1, and common general technical knowledge as of the priority date. Thus, the patent was granted in violation of Article 29, paragraph (2) of the Patent Act and therefore should be invalidated by a trial for patent invalidation.