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## *Japan Supreme Court finally eliminates confusion of Product-by-Process claim in Pravastatin Sodium judgments*

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On June 5, 2015, the Supreme Court of Japan handed down two judgments: *Teva vs. Kyowa Hakko Kirin*, and *Teva vs. Tohri* (Supreme Court, Nos. 2012(ju)1204 and 2012(ju)2658) in relation to the product-by-process claim in the same patent JP 3737801, in which the following two legal principles are explained.

Firstly, the Supreme Court ruled that a product-by-process claim covers the product that has the same structure and characteristics, etc. as those of the product made by the process in the claim, in determining both infringement and patentability. Namely, a product-by-process claim extends to broadly cover even the products made by other methods as long as it has the same structure and characteristics, etc.

Secondly, a new requirement of clarity for a product-by-process claim was created, by which the product-by-process claim is rejected or invalidated due to lack of clarity, in the case that the product-by process claim could have been expressed by its structure and characteristics, etc.

After declaring the two principles above, the Supreme Court reversed the original judgments of the IP High Court, and remanded the cases to the IP High Court to consider clarity of the product-by process claim.

### 1. Background

A product-by-process claim was construed mainly by two ways in Japan. One is to construe the claim narrowly to cover only the product made by the process ("Narrow Interpretation"), and the other is to construe the claim broadly to cover any products that have the same structure and characteristics, etc. as those of the product made by the process in the claim ("Broad Interpretation"). Formerly, when determining patentability of a product-by-process claim, the Japan Patent Office and courts took the Broad Interpretation in most of the cases, but when determining infringement, there were many contradicting judgments under Narrow and Broad Interpretations.

Under these circumstances, the IP High Court chose the case *Teva vs. Kyowa Hakko Kirin* as a Grand Panel case (IP High Court, No. 2010(ne)10043), and handed down the judgment on January 27, 2012, which is the original judgment of the above Supreme Court judgment (Supreme Court, No. 2012(ju)1204).

### 2. The Grand Panel judgment of the IP High Court

In *Teva vs. Kyowa Hakko Kirin* (IP High Court, No. 2010(ne)10043), the IP High Court first expressed a general interpretation of a product-by-process claim as follows.

In the case that it was not impossible or difficult at the time of filing to directly identify the product by its structure or characteristics, the scope of the product-by process claim is limited to the product made by the process in the claim (Narrow Interpretation) in determining both infringement and patentability.

In the case that it was impossible or difficult at the time of filing to directly identify the product by its structure or characteristics, the scope of the product-by-process claim covers broadly any products that have the same structure and characteristics, etc. as those of the product made by the process in the claim (Broad Interpretation) in determining both infringement and patentability.

The patent at issue is JP 3737801, claim 1 of which is as follows:

*“Pravastatin sodium containing less than 0.5 wt% of pravastatin lactone and less than 0.2 wt% of epiprava, 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 the pravastatin sodium.”*

Since it was not impossible or difficult at the time of filing to directly identify the pravastatin sodium by its structure or characteristics, the scope of the invention of claim 1 should be limited to only pravastatin sodium prepared by the process (Narrow Interpretation). The process of Kyowa Hakko Kirin does not involve at least "a) forming an enriched organic solution of pravastatin" in claim 1, therefore pravastatin sodium of Kyowa Hakko Kirin does not fall within the scope of the present invention.

### 3. The judgments of the Supreme Court

The Supreme Court first expressed two legal principles as follows.

When a patent is granted on a product invention, the effect of the patent covers any products that have the same structure and characteristics, etc. as those of the patented product without any regard to the manufacturing process. Therefore, the technical scope of a product-by-process claim should be determined to cover a product that has the same structure and characteristics, etc., as those of the product made by the process.

It is generally unclear what structure or characteristics of the product in the product-by-process claim are represented by the process. Readers of the product-by-process claim cannot clearly understand the content of the invention, and it makes unpredictable what scope of monopoly the patent proprietor has. However, depending on the nature, property, etc. of the product, it may be technically impossible to analyze its structure or characteristics at the time of filing, or it may require an outrageously large economic expenditure or time to carry out work necessary to identify. Therefore, it should be made possible to recite a manufacturing process in a claim directed to a product invention. Accordingly, in order that a product-by-process claim satisfies the requirement of clarity under Article 36(6)(ii) of the Japan Patent Law, circumstances must exist under which it was impossible or utterly impractical to directly identify the structure or characteristics of the product at the time of filing.

Back to the present cases, the determination of the original judgments contain a clear violation of law which affects the conclusion of the judgments. The Supreme Court reversed the judgments of the IP High Court, and remanded the cases to the IP High Court to consider clarity of the product-by-process claim.

#### 4. Announcements of the Japan Patent Office

On June 10, 2015, the Japan Patent Office made an announcement that study on revision of the Examination Guidelines, Part I, Chapter 1 “Requirements for Description and Claims” has been started, and that examination of all applications including product-by-process claims will be suspended until early July.

#### < The Reporter’s Comments >

The principles introduced by the Supreme Court are similar to the practice before the European Patent Office, the German courts and the British courts\*). In that sense, harmonization will be accomplished regarding interpretation of product-by-process claims. However, the new principles have not permeated throughout Japan, the Japan Patent Office and the courts. Since the Examination Guidelines will be revised to follow the opinion of the Supreme Court in early July, we hope the revised Examination Guidelines clarify sufficiently examination of product-by-process claims.

- \*) Guidelines for Examination in the EPO, Part F, Chap. IV, 4.12; "Case Law of the Boards of Appeal of the EPO" 7th ed., Part II, Chap. A, 7; Kirin-Amgen v. Hoechst Marion Roussel, House of Lords, [2004] UKHL 46.

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