

## Supreme Court Decisions on Product-by-Process Claims

— Supreme Court Decisions on Nos. 2012 (ju) 1204 and (ju) 2658 (June 5, 2015) —\*

by Toshio Nakamura\*\*

### 1 Introduction

The Japan Supreme Court, as the final appellate court for the Grand-Panel decision on product-by-process claims (PBP claims) issued by the Intellectual Property High Court (IP High Court, 2010 (Ne) No. 10043 (January 27, 2012)), made a decision on June 5, 2015, together with a related case (Supreme Court decisions on Nos. 2012 (ju) 1204 and (ju) 2658). The Supreme Court decisions overruled the Grand-Panel decision, and presented a new guideline. In response to the Supreme Court decisions, the Japan Patent Office released interim handling procedures for examinations and appeals/trials involving PBP claims on July 6, 2015 to change the handling of examinations, and revised the Examination Guidelines in October. For the Grand-Panel decision of the IP High Court, please refer to my report in NEWS LETTER Vol. 2 (July 2012).<sup>1</sup>

### 2 Background of PBP Claims

A PBP claim means a claim concerning an invention of a product which is at least partially defined by a manufacturing process. PBP claims are accepted in many countries to protect an invention of a product which is to be subject to patent protection

but cannot be defined by the structure, physical properties, or the like of the product without resort to a manufacturing process thereof.

How the gist of PBP claims (novelty aspect) and the technical scope of the same (infringement aspect) should be interpreted has been discussed in Japan and other countries and can be based on either "product identity theory" or "manufacturing process limitation theory".

<Product identity theory> Following this theory, what is defined by a PBP claim is a product itself, manufactured by a manufacturing process recited in the PBP claim. When a product manufactured by a different manufacturing process is identical to the product manufactured by the manufacturing process recited in the PBP claim, that product is included in the PBP claim.

<Manufacturing process limitation theory> Following this theory, what is defined by a PBP claim is only the product manufactured by the manufacturing process recited in the PBP claim. A product manufactured by a different manufacturing process is not included in the PBP claim even though it is identical to the product manufactured by the manufacturing process recited in the PBP claim.

### 3 IP High Court Grand-Panel Decision

The summary of the IP High Court Grand-Panel decision, which is the original decision reviewed by the Supreme Court decisions, will be described.

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According to the Grand-Panel decision, PBP claims include two types, that is, authentic PBP claims and unauthentic PBP claims. When a PBP claim involves circumstances in which "it is impossible or difficult to directly define a product by its structure or characteristics at filing an application (impossible or difficult circumstances)", the PBP claim is regarded as an authentic PBP claim, and both the gist and the technical scope thereof are interpreted by "product identity theory". When a PBP claim involves impossible or difficult circumstances, the PBP claim is regarded as an unauthentic PBP claim, and both the gist and the technical scope thereof are interpreted by "manufacturing process limitation theory".

## 4 Supreme Court Decisions

The Supreme Court decisions on the two cases related to infringement lawsuits based on the same patent right to different defendants, and the technical scope (infringement aspect) was at issue in one case, and the gist (invalidity aspect) was at issue in the other case. The two Supreme Court decisions indicated the following two points.

### (1) Gist and Technical Scope of PBP Claims

The Supreme Court decisions indicated that both the gist and the technical scope should be based on "product identity theory", stating as follows:

"A patent is to be granted for an invention of a product, an invention of a method, or an invention of a process of producing a product. If a patent has been granted for an invention of a product, the patent right 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."

### (2) Clarity

The Supreme Court decisions indicated that a PBP claim lacks clarity unless it involves circumstances in which it is impossible or utterly impractical to directly define a product based on its structure or characteristics at filing

an application (impossible or impractical circumstances), stating as follows:

"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 process, or whether the gist of the invention is limited to products manufactured by the process, and this would prevent those who read the claim from clearly understanding 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, depending on the specific content, nature, etc. of the invention, there may be cases where it is technically impossible to analyze the structure or characteristics of the product at filing the application, or where it is utterly impractical in light of the nature of a patent application that needs to be handled speedily, etc., to require the applicant to define the product in such manner when the work to define the product would require excessive economic cost and time. Assuming so, it is inappropriate to prohibit reciting a manufacturing process in a claim of a patent for an invention of a product in any case, but rather when there are such circumstances as mentioned above, it would not be unfairly prejudicial to a third party's interest to identify the gist of the invention as referring to a product having the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim."

### (3) Chief Judge Chiba's Concurring Opinion and Judge Yamamoto's Opinion

Two opinions are attached to the Supreme Court decisions. Chief Judge Chiba's concurring opinion provides an analysis of the situation in the U.S. and the Examination Guidelines in Japan on the interpretation of PBP claims, as well as a suggestion on examinations of impossible or impractical circumstances. Judge Yamamoto opposes the majority opinion, and stresses

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that it should be done cautiously to determine a PBP claim as indefinite only based on its claim format, because a patent applicant can determine freely how to claim their invention under their responsibility after the revision in 1994 of former Article 36(5)(ii) of the Patent Law, and the claim should be rejected only by Article 49 of the Patent Law.

## 5 Interim Handling Procedures for Examinations and Appeals/Trials

In response to the Supreme Court decisions, the Japan Patent Office released interim handling procedures for examinations and appeals/trials on July 6, 2015 and put the procedures into effect on the same date.

The interim handling procedures apply to all patent applications and granted patents including PBP claims in the past, present, and future. The gist of a PBP claim is recognized by "product identity theory" as before. When a PBP claim involves impossible or impractical circumstances, the PBP claim is determined as indefinite, and grounds of rejection are notified. The interim handling procedures include examples indicating whether a claim falls within a PBP claim, and examples indicating whether the PBP claim involves impossible or impractical circumstances. The procedures also describe that, in response to the Notice of Grounds of Rejection, the applicant can (1) delete any claim concerned, (2) amend any claim concerned into a claim of a product defined by its structure, characteristics, etc., (3) amend any claim concerned into a claim of a manufacturing process, and (4) make a counterargument.

Thereafter, in October, the Examination Guidelines were revised and the above handling procedures were formally put into effect.

## 6 Discussion

(1) Difference between the Supreme Court Decisions and the IP High Court Grand- Panel Decision

Both decisions stated that, when a PBP claim involves impossible or impractical circumstances (or impossible or difficult circumstances), the PBP claim is valid, and the gist and technical scope thereof can enjoy a broad patent scope by "product identity theory". In contrast, when a claim does not involve impossible or impractical circumstances, the IP High Court Grand-Panel decision stated that the gist and technical scope thereof should be interpreted narrowly by "manufacturing process limitation theory", whereas the Supreme Court decisions overruled that decision and instead ruled to reject/invalidate the PBP claim as lacking clarity.

### (2) Clarity of PBP Claims

The majority opinion and Judge Yamamoto's opinion conflict over the clarity of PBP claims. My consideration on this point is provided below.

#### i) Whether PBP Claims Are Definite

How is the gist of the PBP claim "water generated by reacting hydrogen with oxygen" recognized? The gist of the invention significantly varies depending on what characteristic is chosen, such as water, water not containing minerals, neutral water, or tasteless odorless water. The applicant can freely change the gist of the invention and make a counterargument depending on prior art, while maintaining the same claim. Similarly to indefiniteness of the gist of the invention, in the case of infringement, it is indefinite how to determine the structure, characteristics, etc. of the water derived from the manufacturing process, and this may result in a big issue between the patentee and an alleged infringer. Therefore, I believe that PBP claims are basically indefinite in many cases, as described in the majority opinion.

#### ii) Examination Guidelines

Both the Examination Guidelines corresponding to the revised Patent Law in 1994, and the previous Examination Guidelines in 2015, prescribed to conduct examinations on impossible or impractical circumstances.

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<Examination Guidelines (before 2000), Part I, chapter 1, 3.3.1>

The following typical examples do not comply with Article 36(5)(ii) of the Patent Law (clarity):

8) An invention of a product, which technical means are expressed by a method. However, this shall not apply when there is no appropriate expression other than expressing it by the method and the product can be defined by such expression.

9) An invention of a chemical substance, which is not defined by its name or chemical structural formula. However, when it is impossible to define the substance by its name or formula, the substance may be defined by its physical or chemical properties. Further, when it is still impossible to define the substance by its physical or chemical properties, the substance may be defined by a manufacturing process as a portion of defining means, only when it can be defined by adding the manufacturing process.

<Previous Examination Guidelines in 2015, Part I, 2.2.2.4 (2) (1)(i) >

The product subject to the invention may be defined by the manufacturing process, where it is impossible, difficult or inappropriate for some reasons to directly define the constitution of the invention by means of its properties, etc. independent of the manufacturing process.

(Opposite interpretation of this statement provides the basis for lack of clarity.)

iii) Considering i) and ii) above and the situations in the major foreign countries described below in (3), I think it reasonable to consider PBP claims as indefinite unless they involve impossible or impractical circumstances, as described in the majority opinion.

### (3) Situations in Major Foreign Countries

Handling of the gist, the clarity requirement, and the technical scope of PBP claims in major foreign countries is shown in the table.

		Japan	U.S.	EPO	Germany	U.K.	China	Korea
Patentability Determination	Gist of invention	PIT	←	←	←	←	←	←
	Impossible or impractical circumstances	required	not required	required	required	required	required	required
Infringement Determination	Technical scope	PIT	MPLT	-	PIT	determined	determined	PIT

※product identity theory and manufacturing limitation theory are abbreviated respectively as PIT and MPLT.

As described in the table, clarity based on impossible or impractical circumstances is examined in all countries except for the U.S. This seems to be based on the concept to accept a PBP claim as an exception only when it involves impossible or impractical circumstances. I believe it preferable in view of harmonization that the Supreme Court decisions indicated the clarity requirement. It should be also noted that, as described in my previous report, "necessity requirement" which is a similar provision based on a board decision in 1891, had been examined in the U.S., but the relevant description was deleted in the revision of MPEP in 1974.

Regarding patentability, the gist of the invention is determined by "product identity theory" in all countries. On the other hand, in infringement, the technical scope of the invention is determined by "product identity theory" in Japan, Germany, and Korea, whereas it is determined by "manufacturing process limitation theory" in the U.S.

### (4) Problem of Correction

A registered PBP claim not involving impossible or impractical circumstances becomes invalid due to violation of the clarity requirement. Chief Judge Chiba's concurring opinion points out the issue that "this situation results from the present examination practice under which PBP claims have been loosely examined and permitted, and it is not attributable to the applicants alone. ... procedures such as a request for correction and a request for a trial for correction may be helpful. How these procedures will actually be handled is an issue to be addressed in the future."

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In Europe, a correction to change a PBP claim to a manufacturing process claim was accepted (T 423/89), whereas in Japan, an amendment to change a PBP claim to a manufacturing process claim which was filed at filing a Notice of Appeal was rejected on the grounds that it was exactly a change in the scope of claims, and did not comply with Article 17-2(4)(i) to (iv) (IP High Court, 2006 (Gyo-Ke) No. 10494 (September 20, 2007)).

The interim handling procedures for examinations and appeals/trials released by the Japan Patent Office describe that an amendment to change a PBP claim to a manufacturing process claim which was filed after a final Notice of Grounds of Rejection, etc. falls within the clarification of an ambiguous statement (Article 17-2(5)(iv)). However, there is also a requirement that a correction after patent registration should not substantially expand or change the scope of claims (Article 126(6)). In addition, questions and answers on the appeal/trial system released on August 7, 2015 do not present a clear viewpoint, merely stating that, as for a correction to change a PBP claim to a manufacturing process claim, analysis of examples will be advanced and judgment will be made for each case based on laws and regulations. It will be necessary to watch the trend of future appeal decisions.

## 7 Future Measures

Based on the Supreme Court decisions, impossible or impractical circumstances are examined on all PBP claims. The extent of the impossible or impractical circumstances is not clear at present, and many countries adopt interpretation of the technical scope by "manufacturing process limitation theory". Therefore, to obtain a global patent, it will be more effective to pursue a patent using a product claim defined by structure, characteristics, etc., or a manufacturing process claim, than a PBP claim.

### Note:

1) **The Grand-Panel Decision issued by the Intellectual Property High Court relating to the product-by-process claims — the pravastatin sodium case — (Digest)**

The Intellectual Property High Court heard as its sixth Grand-Panel case, a pravastatin sodium case relating to product-by-process claims (PbP claims) (IP High Court Decision, Heisei 22 (Ne) No. 10043), and delivered the Decision on January 27, 2012. The present Decision includes several noteworthy points which differ from conventional decisions, and will greatly affect principles in filing an application and patent infringement issues in the future.

### <Summary of the Grand-Panel Decision>

The Court categorized PbP claims into two types: authentic PbP claims (with special circumstances); and unauthentic PbP claims (without special circumstances), and held the technical scope, the gist of the invention, and the burden of proof (the English Abstract of the Decision is available on the web page of the Intellectual Property High Court). The present Grand-Panel Decision held four points below:

- (a) The technical scope and the gist of authentic PbP claims shall be interpreted based on a "universal-product theory";
- (b) With regard to PbP claims, how to interpret the technical scope and how to interpret the gist shall be the "same";
- (c) The technical scope and the gist of unauthentic PbP claims shall be interpreted based on a "manufacturing-process-limitation theory"; and
- (d) The patentee (s) shall bear the burden of proving special circumstances.

Points (a) and (b) seem to be reasonable, because it appears extremely unbalanced that, as in the current practice in the United States, a patent right only within the scope limited by a manufacturing process is obtained whereas all prior art documents relating to the same product are of interest in determining novelty and the like.

Point (c) indicates existence of a double standard; that is, existence of two types of PbP claims based on the "universal-product theory" and PbP claims based on the "manufacturing-process-limitation theory" in spite of the fact that they are the same PbP claims. In my opinion, there was also an option to rule that a claim which is not an authentic PbP claim shall not be granted a patent and all PbP patent claims shall follow the universal-product theory. A ground for not granting a patent may be, for example, "lack of clarity which is caused by presence of a manufacturing process," "lack of novelty," and "addition of requirements for special circumstances." (The European Patent Office requires "special circumstances". The United States Patent and Trademark Office also previously required "necessity" as defined in MPEP §706.03 (e). Although this section of MPEP was deleted in 1974, an opinion for the necessity requirements was expressed in SmithKline Beecham. Apotex (2006).)

Point (d) is arguable in that how to show special circumstances is unclear.

### <Precautionary Measures>

As precautionary measures that can be taken in the event that the present Grand-Panel Decision is made final, it is suggested (1) to avoid PbP claim form, (2) to draft claim (s) directed to a manufacturing process, (3) to be ready to show special circumstances.