

# Handling of Product-by-Process Claims in Examination Procedures (\*)

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*In the judgments of June 5, 2015 with respect to product-by-process claims, the Supreme Court of Japan reversed the Intellectual Property High Court's judgments that had separated the construction of PBP claims by applying the product identity theory for "Authentic PBP claims" and the manufacturing process limitation theory for "Unauthentic PBP claims," and instead uniformly applied the "product identity theory" for "identification of the gist of the invention" and "determination of technical scope of the invention." It held that "in cases where the relevant claim falls under the category of PBP claims (hereinafter referred to as the 'Case'), the invention will be found to comply with the requirements of clarity of inventions only if there are 'impossible or impractical circumstances (hereinafter referred to as the 'Circumstances')' to directly specify the product by its structure or characteristics at the time of filing the application." The Japan Patent Office took these judgments into consideration in revising the Examination Guidelines and Examination Handbook and has stated its intention to enrich case examples for determination on the "Case" and "Circumstance" in the Examination Handbook. In this study, the situations of Japan and other countries (i.e., European Patent Office, the U.K., and Germany) were grasped by conducting surveys on public information, overseas questionnaire surveys, and considerations by experts, and thereby the basic materials were prepared to be used in considering specific case examples that would contribute to such determinations and whether or not to provide such specific case examples in the Examination Handbook.*

## I Introduction

### 1 Background and Purpose of This Study

Following the judgments of the Supreme Court of Japan on June 5, 2015 involving product-by-process claim (i.e., when a claim concerning invention of a product reciting manufacturing processes of the product; hereinafter referred to as "PBP claim")<sup>1</sup>, the Japan Patent Office (JPO) initiated its "Interim Handling Procedures for Examinations involving PBP Claims" on July 6, 2015<sup>2</sup>. In the Handling Procedures, "when a claim concerning an invention of a product recites a manufacturing process of the product" (hereinafter referred to as the "Case"), the Examiner shall determine that the invention of that product is not clear except for the case when the Examiner can find that the invention involves "impossible or impractical circumstances" (hereinafter referred to as the "Circumstances").

Hereby, specific case examples that would contribute to the determination on whether or not to fall under "Case" or "Circumstance" are planned to be further enriched in the Examination Handbook for Patent and Utility Model (hereinafter referred to as the "Examination Handbook") based on future court decisions and JPO's appeal/trial decisions<sup>3</sup>.

Meanwhile, information on such specific case examples not limited to court decisions and appeal/trial decisions would be useful for applicants or others to consider their responses in cases where they receive a notice of reasons for refusal stating that the PBP claim is not clear, or other cases. While there are no such court

decisions or appeal/trial decisions in Japan, it is necessary to grasp the situations in other countries as well as to have the experts consider which specific case examples are applicable to fall under "Case" or "Circumstance", in order to provide such specific case examples to the applicants or others and consider whether or not to include them in the Examination Handbook.

The purpose of this study is, by analyzing the court decisions and appeal/trial decisions concerning PBP claims in foreign countries and having the experts consider, to prepare the basic materials for considering to provide the applicants or others with specific case examples that would contribute to the determination on whether or not to fall under "Case" or "Circumstance", and whether or not to include the specific case examples in the Examination Handbook.

### 2 Methods for Conducting This Study

#### (1) Survey of Public Information

##### (i) Survey of Information Related to This Study

The information on systems and operations in Japan as well as major foreign countries were surveyed, organized, and analyzed by using various publicly available information, such as relevant literature.

##### (ii) Survey of Case Laws

The survey was conducted with respect to literature and other information, including appeal/trial decisions and court decisions, concerning PBP claims rendered by the European Patent Office (EPO) and in the United Kingdom (U.K.) and Germany as well as the

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(\*) This is an English summary by the Institute of Intellectual Property based on the FY2015 JPO-commissioned research study report on the issues related to the industrial property rights system.

commentaries thereof. Also, in compiling the results of analysis of the case laws, we received some advice from an attorney at law/patent attorney who has knowledge on patent laws and regulations and case laws of major foreign countries (Europe).

## **(2) Overseas Questionnaire Survey**

We conducted the questionnaire survey with local law firms, asking about the situations of the EPO, the U.K., and Germany by extracting question items mainly from the points that have not been extracted in the survey of public information.

## **(3) Consideration by the Committee**

A committee was formed of eight members with expert knowledge relating to this study (industry experts, patent attorneys, and attorneys at law) and the meetings were held three times for consideration, analysis and advices from technical standpoints. At the committee, the methods for conducting the surveys of public information and the overseas questionnaire survey were considered, and referring to the results of each survey, the following points were discussed:

### **(i) Relevance of PBP Claims**

\* With respect to the determination concerning the "Case," what specific case examples may fall under type (1-1), (1-2), or (2) of Section 2204 or type (i) or (ii) of Section 2205 in Part II, Chapter 2 of the Examination Handbook or others, respectively;

\* Whether or not there are any specific case examples that are particularly helpful for consideration as to be included in the future as falling under type (2) or (ii) of the Examination Handbook.

### **(ii) Allegation and Proof for Descriptions as a PBP Claim to be Accepted**

\* With respect to the substances of the allegation and proof of the "Circumstances," what matters be contained for the allegation or f to be accepted, such as the characteristics of the art covered by the invention, level of the analysis technology, and the details of the work required to identify the invention by the structure or characteristics

\* Whether or not there are any specific case examples for allegation and proof that are particularly helpful for consideration of future inclusion to the Examination Handbook.

## **II Handling of "PBP Claims" in Japan**

### **1 Outline**

In this study, PBP claims (i.e., where claims concerning inventions of products recite manufacturing processes of the products) were considered. They include

for example such a claim as "Product Y obtained by manufacturing process X." There may be cases where all features of the invention are described only by the "manufacturing process" with the starting material and the reaction thereof, or where some feature of the invention is described as structure or the like and partly characterized by wording of the "manufacturing process."

With respect to the construction of PBP claims (for identifying the gist of the invention and determination of the technical scope of the invention), product identity theory and manufacturing process limitation theory have been known since before. Under the product identity theory, the claim is constructed as to even cover a product obtained by a different manufacturing process, if the product is identical to the product obtained by the manufacturing process described in the claim. On the other hand, under the manufacturing process limitation theory, the claim is literally constructed by limiting to only cover a product obtained by the manufacturing process described in the claims (product Y obtained by manufacturing process X).

## **2 Laws, Regulations and Examination Guidelines or the Like Concerning PBP Claims**

Pursuant to Article 36, paragraph (6) of the Japanese Patent Act, the statement of the "claims" shall "comply with each of the following items."

- (i) the invention for which a patent is sought is stated in the detailed explanation of the invention;
- (ii) the invention for which a patent is sought is clear;
- (iii) the statements for each claim is concise.

Accordingly, pursuant to Article 36, paragraph (6), item (ii), the invention for which a patent is sought must be clear.

Meanwhile, the JPO had been considering, based on the consideration at the first meeting (held on August 22, 2014) of "the Working Group on the Patent Examination Standards, the Patent System Subcommittee, the Intellectual Property Committee of the Industrial Structure Council," under the policy for revising the Examination Guidelines as "summarizing the basic ideas of the application of relevant laws such as the Patent Act" and the Examination Handbook as "including enough case examples, court precedents, and application examples useful in understanding of the basic ideas of the Examination Guidelines, in addition to summarizing procedural matters and points to consider necessary to perform the examination procedures." <sup>4</sup> On June 5, 2015, while the consideration by the Working Group was still continuing, the judgments of the Supreme Court of Japan mentioned above were rendered and the "review and revision of the Examination Guidelines concerning product-by-process claims" became the subject of the sixth meeting (held on July 3, 2015) of the Working Group on the Patent Examination Standards. As a result

of the consideration, the JPO published the "Interim Handling Procedures for Examinations and Appeals/Trials Involving Product-by-Process Claims" on July 6, 2015 based on the judgments of the Supreme Court<sup>5</sup>.

Subsequently, based on the considerations by the Working Group on the Patent Examination Standards, on September 16, 2015, the JPO released the thoroughly revised "Examination Guidelines for Patent and Utility Model,"<sup>6</sup> as well as the thoroughly revised "Examination Handbook for Patent and Utility Model" (hereinafter simply referred to as the "Examination Handbook") on the same date<sup>7</sup>. Operations under these revised "Examination Guidelines for Patent and Utility Model" and "Examination Handbook" are applied to the examinations on or after October 1, 2015.

In this revised "Examination Guidelines for Patent and Utility Models," the parts concerning PBP claims were moved to Part II, Chapter 2, Section 3, 4.3.1 and Part III, Chapter 2, Section 4, 5., and changes have been made to the parts that would be affected by the judgments of the Supreme Court mentioned above.

In addition, the contents of the abovementioned "Interim Handling Procedures for Examinations and Appeals/Trials Involving Product-by-Process Claims" have been reflected in Sections 2203 through 2205 in the Examination Handbook.

This study began amidst the above-mentioned developments. At the committee formed for this study, the contents stated in the Examination Handbook were considered, and based on the results of the consideration described in Chapter V below, the JPO published on its webpages "Reference examples of arguments and verification presented by applicants involving 'impossible or impractical circumstances' concerning product-by-process claims"<sup>8</sup> on November 25, 2015 and "Addition of examples not considered to be product-by-process claims"<sup>9</sup> on January 27, 2016, respectively.

The JPO plans to further consider the handling procedures for PBP claims, including further enrichment of case examples where the "Circumstances" may be found and case examples that would not be considered to be PBP claims and to revise the Examination Handbook by the beginning of April 2016 based on the results of the consideration.

## **2 Court Decisions Related to PBP Claims**

### **(1) Previous Court Decisions**

As overall tendency of previous court decisions before the judgments of the Supreme Court, decisions generally tended to basically stand on the product identity theory in identifying the gist of the invention. In determining the technical scope, many decisions also stood on the product identity theory or the manufacturing process limitation theory if there were special

circumstances while some decisions applied the manufacturing process limitation theory or applied the product identity theory if there were special circumstances.

### **(2) Developments of the Cases Led to the Judgments of the Supreme Court on June 5, 2015**

In case (i) Judgment of the Tokyo District Court of March 31, 2000, Case No. H19(2007) (Wa) 35324, the plaintiff, the patentee of the patent 3737801 "pravastatin sodium substantially free of pravastatin lactone and epipravastatin, and compositions containing the same" alleged that the defendant's specific medicine infringes the plaintiff's patent right and sought injunction of the manufacture and sale of such medicine as well as the disposal of such medicine in stock.

The court held that the "technical scope of the patented invention should be constructed by limiting to the product manufactured by the manufacturing process described in the claim 1 of the patent in dispute."

Furthermore, in case (ii) Judgment of the Tokyo District Court of July 28, 2001, Case No. H20(2000) (Wa) 16895, the plaintiff claimed for injunction against the import and sale of the defendant's relevant medicine as well as the disposal of such medicine in stock. However, unlike in case (i) mentioned above, construction of PBP claims was not particularly disputed and the court dismissed the claim for lack of inventive steps, holding that "the patent in dispute should be invalidated in the course of an appeal/trial for patent invalidation."

Meanwhile, the defendant in case (i) mentioned above filed a request for an appeal/trial for patent invalidation with respect to the patent right mentioned above and the plaintiff in case (i) mentioned above defended against this by filing a request for correction. The JPO, allowing the correction, rendered an appeal/trial decision to dismiss the request for an appeal/trial for patent invalidation in case (iii) appeal/trial decision of August 25, 1999, request for an appeal/trial for patent invalidation No. 2008-800055.

In case (iv) Judgment of the First Division of the Intellectual Property High Court of January 27, 2012, Case No. H21(2009) (Gyo-Ke) 10284, case to seek rescission of the appeal/trial decision (iii) mentioned above, the court, classifying PBP claims into authentic PBP 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", and unauthentic PBP claims for which "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," held that this case was the latter and there was no error in the conclusion of the appeal/trial decision that could not decide the claim invalid, and thereby dismissed the request.

While case (iv) mentioned above was pending, in case (v) Judgment of the Grand Panel of the Intellectual Property High Court of January 27, 2012, Case No. H22(2010) (Ne) 10043, as the appeal for case (i) mentioned above, where the appellant (patentee), claiming the same as in the first instance, sought rescission of the judgment of the prior instance, as with the case (iv) mentioned above, the court classified PBP claims into authentic PBP claims and unauthentic PBP claims, and thereby rendered a decision to dismiss the appeal on the same date as case (iv) mentioned above to seek rescission of the appeal/trial decision.

Later, in case (vi) Judgment of the First Division of the Intellectual Property High Court of August 9, 2012, Case No. H23(2011) (Ne) 10057, as the appeal for case (ii) mentioned above, the court dismissed the appeal on the grounds that no "Circumstances" could be found and that "the gist of the invention is recognized as being limited to products manufactured through the manufacturing process as stated in the claim."

### **(3) Judgments of the Supreme Court**

In the final appeal case (i) Judgment of the Second Petty Bench of the Supreme Court of June 5, 2015; Case No. H24(2012) (Ju) 1204, for case (v) mentioned above, and the final appeal case (ii) Judgment of the Second Petty Bench of the Supreme Court on June 5, 2015, Case No. H24 (2012) (Ju) 2658, for case (vi) mentioned above, respectively, (Presiding judge: CHIBA Katsumi; Judges: ONUKI Yoshinobu, ONIMARU Kaoru and YAMAMOTO Tsuneyuki), the summary of the judgment was stated as follows:

1. Even in the case of what is generally referred to as a "product-by-process claim," that is, when a claim of a patent for an invention of a product recites the manufacturing process of the product, the technical scope of the patented invention should be determined as referring to products that have the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process.

2. In the case of what is generally referred to as a "product-by-process claim," that is, when a claim of a patent for an invention of a product recites the manufacturing process of the product, the recitation of the claim should be held to meet the requirement that "the invention is clear" as prescribed in Article 36, paragraph (6), item (ii) of the Patent Act, only if there are circumstances where it was impossible or utterly impractical to directly define the product subject to the

invention by means of its structure or characteristics at the time of the filing of the application.

In the judgment of the Supreme Court for case (ii), the phrase "the technical scope of the patented invention should be determined..." shall be read as "the gist of the invention should be identified..."

In each of these judgments, there were a concurring opinion by Judge CHIBA and an opinion by Judge YAMAMOTO.

However, since the appellant of the final appeals stated its intention to waive its claim at the Intellectual Property High Court to which the appeal was remanded, the action was closed.

## **III Results of the Surveys of Public Information**

### **1 Survey of Information Related to This Study**

With respect to the "Case" and "Circumstances," the contents discussed with respect to the types, etc. of PBP claims as well as those discussed in relation to the "Circumstances" by the authors were checked in the literature that were relatively easy to acquire among the reference materials listed in the part of reference in the report, and then extracted and listed them in the form of citation or summary.

In many of them, case examples of actual applications or court decisions are discussed.

### **2 Results of the Survey of Case Laws**

#### **(1) Methods for Survey of Case Laws**

The EPO provides a database on its appeal decisions, and when a search was conducted on the term "product-by-process" as a keyword, approximately 84 cases appear as of February 29, 2016. Meanwhile, in the official case law book issued by the EPO, "Case law of the boards of appeal of the European Patent Office," major appeal decisions are introduced from various standpoints in Part II, Chapter A, 7 "Product-by-process claims." Therefore, the appeal decisions listed in the case law book or other decisions were analyzed, referring to the answers obtained in the overseas questionnaire survey.

In the U.K., decisions of the Intellectual Property Office are provided in its database "Results of past patent decisions," while court decisions are provided in the "BAILII Databases." However, no results were obtained from the search conducted on the keyword "product-by-process," and thus the judicial precedents mentioned in papers were analyzed, referring to the answers obtained in the overseas questionnaire survey.

In Germany, the database is provided for each court, such as the Federal Supreme Court and Federal Patent Court as well as the district courts and high courts of each state, and the court decisions in or after 2000 may be

searched. There are also various other databases. However, when the judgments by the Federal Supreme Court of Germany in or after 2000 were searched by the keyword "product-by-process," only four cases show, and when a search was conducted using the keywords "product-by-process" and the German words corresponding to the "Circumstances," no results could be obtained. Thus, the judicial precedents mentioned in papers, etc. concerning PBP claims were analyzed, referring to the answers obtained in the overseas questionnaire survey.

## **(2) Results of the Analysis of Case Laws**

### **(i) Appeal Decision of the EPO**

Among the appeal decisions by the EPO, T 150/82 is one of the established appeal decisions concerning PBP claims. In this appeal decision, it was held that "Claims for products defined in terms of processes for their preparation (known as "product-by-process claims") are admissible only if the products themselves fulfill the requirements for patentability and there is no other information available in the application which could enable the applicant to define the product satisfactorily by reference to its composition, structure, or some other testable parameter." (Also, the appeal decision T 0320/87 with the same effect.)

However, in other appeal decisions concerning PBP claims, there were found many cases where PBP claims were allowed to clarify the difference between the invention in question and prior art in determining the novelty or inventive steps of the invention, while PBP claims were found to be in violation of the requirements of clarity for reasons such that "there is no other information available in the application that could enable the applicant to sufficiently define the product by reference to its composition, structure or some other testable parameter" in relation to the determination on the requirements of clarity.

### **(ii) Court Decisions in the U.K.**

One of the most important court decisions is the judgment for the final appeal case of Kirin-Amgen Inc and others v. Hoechst Marion Roussel Limited and others, [2004] UKHL 46. In this judgment, the court, applying the laws of the EPO in determining the novelty of a PBP claim, held that "impossible or impractical circumstances" are "only if the product is different but the difference cannot in practice be satisfactorily defined by reference to its composition etc."

In the judgment of the Patents Court for the case Hospira UK Limited v Genentech Inc., the court held that "The EPO's approach to overt product by process claims today is settled. They will be permitted (and only permitted) if there is no other way of defining the product open to the patentee," while stating that PBP claims to

which "Circumstances" is applied in a limited extent.

### **(iii) Court Decisions in Germany**

In Germany, there are few cases where decisions were made with respect to the "impossible or impractical circumstances." The judicial precedent that is cited the most is Beschluss v. 06.07.1971, Az.: X ZB 9/70 "Trioxan" wherein the court held that "product claims wherein the chemical material is characterized by the manufacturing process (so-called PBP claims) is admissible, if the structural formula of the chemical material is not known or the chemical material cannot be identified by the characteristics which may be confirmed with certainty" and explained "impossible or impractical circumstances" by stating that "in cases where the complete and exact clarification of the macromolecular substance is impossible at the time of filing, or in practice unreasonable expense is required in relation to economic exploitation, because, for example, in individual case, it is uncertain whether or not the specific structure has a considerable influence on the contemplated characteristics of the claimed polymer, if the applicant is capable of clearly identifying it in another way, macromolecular substance is not excluded from the patent protection;" and "it would not be allowed to ignore the subject matter for which protection is sought in considering the requirement of 'clear identifiability' of the invention. If the macromolecular substance is not yet able to be described at that time with accuracy that is available, for instance, in the field of low-molecular chemistry, only such degree of accuracy can be required that appears as affordable in accordance with the given circumstances by taking into consideration the practical demands and the requirements mentioned above."

## **IV Handling of Product-by-Process Claims in each Country and Region**

This chapter provides the answers obtained from the local agent for the overseas questionnaire survey.

### **1 Claims that would be Determined as PBP Claims**

With respect to (1) determination in examination of whether or not the relevant claim is a PBP claim and (2) a product claim that would not be considered as a PBP claim, at the EPO and in the U.K. and Germany, product claims expressed by the phrase "obtainable by..." and "obtained by..." are considered as PBP claims. Yet, it is mentioned that at least before the EPO, claims using simple definition such as "coated," "connected," "provided," "disposed," "arranged," or "neutralized" would be unlikely considered as PBP claims unless unusual process steps are included, and if it is immediately clear to the Examiner which characteristics of the product are

suggested, objection specific to PBP claims would normally not be raised.

With respect to (3) product claims including wordings that represent the structure and those representing the process ("hybrid claims"), it was answered that they would be considered as PBP claims in all jurisdiction.

With respect to (4) PBP claims in the mechanical, electric/electronics, and chemical fields, various examples were presented.

With respect to (5) handling of applications containing a product claim and a PBP claim, it was answered for all jurisdiction that there were no specific case examples, but if such both types of claims exist at the same time in a single application, no "Circumstances" would exist, and thus PBP claim would not be allowed, however, if the PBP claim can be better distinguished from prior art, the PBP claim may be allowed.

With respect to (6) handling of a product claim dependent on an independent process claim, it was answered that it is rather extremely general situation and thus it is allowed.

With respect to (7) prior art search for PBP claims, it was answered that at least at the EPO and in Germany, a search shall be conducted based on not only the characteristics of the product/structure but also characteristics of process, and if the process step do not clearly bring an additional characteristic to the product, namely, if the Examiner believes that the process may be replaced by a different process without affecting the product itself, lack of novelty objection shall be raised, and the burden to show the novelty by a new process shall be shifted to the applicant.

With respect to (8) the situation where the PBP claim does not fulfill the description requirements as well as the responses to be made in such situation, at the EPO and in Germany, there were no description requirements. Moreover, in Germany, there are no conditions corresponding to the clarity requirements under Article 84 of the European Patent Convention (EPC), and thus objection may not be raised based on violation of the requirements of clarity. Instead, the application may be objected for insufficient description under Article 34 of the German Patent Act. At the EPO, if the process defined in the claim is not to produce the product with the characteristics of the product indicated in the claim, objection may be raised for insufficiency. If the description of the process is (overly) equivocal but the process seems to be prima facie decisive to define the claimed subject matter and to distinguish from prior art, either clarity requirement objection or prima facie novelty objection would be raised. Meanwhile, it was answered that in the U.K., PBP claims would be handled in the same manner as other claims.

With respect to (9) the situation where the PBP

claim does not fulfill the requirements for novelty or inventive steps as well as the responses to be made in such situation, it was answered that in all jurisdiction, if the product itself does not fulfill the requirements, objection may be raised.

With respect to (10) the response to resolve objections for PBP claims, it was answered for all jurisdiction that the following responses are available:

- \* To submit comparative experimental data or other technical arguments that show that the subject matter of the PBP claim is actually novel, namely, different from a prior art product manufactured by a different process;
- \* To delete the PBP claim (if other types of claims are remaining);
- \* To rewrite the PBP claim into a process claim;
- \* To maintain the product claim while rewriting the wordings specified as a process into wordings representing the structure (in most cases, this is difficult at the EPO due to its strict standard for added subject-matters);
- \* To describe the process in the claim in more details but based on the application as filed in order to resolve lack of clarity or prima facie novelty.

## **2 Allegation and Proof for the Description as PBP Claims to be Found as Clear**

With respect to (1) cases where the PBP claim would be found to be in violation of the requirements of patentability due to reasons such that "impossible or impractical circumstances" do not exist or other and (2) the specific requirements of clarity for PBP claims, at the EPO and in the U.K., it is an established case law that PBP claims would be allowed only if the product cannot be defined in other way (such as the composition, structure or other structural or physical parameter) together with the information available in the application text. However, in Germany, there is no such clarity requirement as mentioned above.

With respect to (3) allegation and proof that the "impossible or impractical circumstances" exist, at the EPO and in the U.K., PBP claims are generally formally allowed if it is evaluated based on the disclosure of the application as initially filed that the product cannot be defined by a structural/physical parameter and further data is not available to define the product itself based on the descriptions. Moreover, in the U.K., it was suggested as appropriate to indicate that there is no analysis technique available to accurately decide the structure of the product or that the product is a complicated mixture of compounds that are difficult to clarify. However, it was answered that in Germany, there seems to be no case laws where the details of "impossible circumstances" were specifically explained.

## V Consideration by the Committee

### 1 Determination on the "Cases where the Manufacturing Process of the Product is Recited in the Claims for the Invention of a Product"

At the committee formed for this study, consideration was made by using a draft of the material "Addition of examples not considered to be product-by-process claims" later published by the JPO on January 27, 2016. Various opinions were presented by the committee members among which the major ones were: the judgments of the Supreme Court should be thoroughly understood and the coverage of the rulings in the judgments should not be expanded too much; the judgments of the Supreme Court were based on the premise that when the manufacturing process is recited, it would be generally unclear how the structure is, and thus claims in which the structure is clear would not fall under PBP claims; determinations must be made not only by the expressions in the claims but also by taking into consideration the intention of the applicant that can be read from the claims in whole, the description of the specification as well as the common technical knowledge, etc.; and guidelines for increasing the examples that does not fall under the "Case," and enrichment of specific examples.

### 2 Allegation and Proof of "Impossible or Impractical Circumstances"

Considerations were made at the committee by using a draft of the material "Reference examples of arguments and verification presented by applicants involving 'impossible or impractical circumstances' concerning product-by-process claims" later published by the JPO on November 25, 2015. Various opinions were presented by the committee members among which the major ones were: the extent that "there is no reasonable doubt" as stated in Section 2205 of the Examination Handbook should be clarified; and since polymers may fall under the "Case," it is questionable whether or not polymers should be published as one of the examples of PBP claims where the "Circumstances" exist.

## VI Conclusion

As pointed out at the committee for this study as well as the literature obtained by the surveys of public information, it would be necessary to determine the coverage of the ruling in the judgments of the Supreme Court by taking into consideration the reasoning such that "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 manufacturing process

[...]." For example, the following opinions presented by the committee members should be sufficiently taken into consideration in examining whether or not the claim that recites the manufacturing process is clear and further deciding to what claims the rulings in the judgments of the Supreme Court are applicable: claims with expression like a process at the first glance but clearly indicating the state of the product should not be regarded as PBP claims in the first place; determinations must be made by taking into consideration not only the expression in part of the claim but also the intention of the applicant that can be read from the claim in whole, the description of the specification and the common technical knowledge; and the judgments of the Supreme Court are based on the premise that if the manufacturing process is recited, the structure would generally be unclear, and thus claims in which the structure is clear would not fall under PBP claims.

Meanwhile, reviewing the situations of the EPO, the U.K. and Germany that were surveyed by this study, with respect to claim construction they are agreed in the product identity theory which was also applied in the judgments of the Supreme Court of Japan (though there is a case in the U.K. case laws where the manufacturing process imitation theory was applied in deciding infringement). However, with respect to "Circumstances," it was not usual there to determine on the clarity requirements for PBP claims in such a manner as ruled by the Supreme Court of Japan, but, in many cases, the court first determined the novelty and inventive steps whereby it was examined whether or not there are circumstances under which the claim cannot be expressed by the composition, structure, or other testable parameter, but only by the manufacturing process in distinguishing from prior art. That is, "Circumstances" had a different meaning.

It is expected that further consideration will be made for the planned revision of the Examination Handbook in light of the results of this survey.

Moreover, since there are no court decisions at present that were rendered based on the rulings presented in the judgments of the Supreme Court, attention should continuously be paid to how such rulings would be applied to future litigations.

Finally, a better direction should be sought to enable the PBP claims to meet the purpose of the Patent Act and to be used in a manner preferable for applicants and third parties while looking closely to the future reactions of the applicants and operations of the JPO.

(Chief Researcher: Takeyuki IWAI)

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<sup>1</sup> Judgment of the Second Petty of the Supreme Court of June 5, 2015; Case No. H24(2012) (Ju) 1204 and 2658 [http://www.courts.go.jp/app/hanrei\\_en/detail?id=1365](http://www.courts.go.jp/app/hanrei_en/detail?id=1365)

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- [http://www.courts.go.jp/app/hanrei\\_en/detail?id=1364](http://www.courts.go.jp/app/hanrei_en/detail?id=1364)
- 2 JPO, "Interim Handling Procedures for Examinations and Appeals/Trials Involving Product-by-Process Claims"
  - 3 Material 1 "Review and Revision of the Examination Guidelines Concerning Product-by-Process Claims" at the 6th meeting of the Working Group on the Patent Examination Standards, the Patent System Subcommittee, the Intellectual Property Committee of the Industrial Council
  - 4 Summary of the minutes of the first meeting of the Working Group on the Patent Examination Standards, the Patent System Subcommittee, the Intellectual Property Committee of the Industrial Council (August 25, 2014);  
URL: [http://www.jpo.go.jp/shiryoutoushi/shingikai/new\\_shinsakijyun01\\_gijyoushi.htm](http://www.jpo.go.jp/shiryoutoushi/shingikai/new_shinsakijyun01_gijyoushi.htm) (only in Japanese)
  - 5 JPO, "Interim Handling Procedures for Examinations and Appeals/Trials Involving Product-by-process claims," July 6, 2015;  
URL:[http://www.jpo.go.jp/tetuzuki\\_e/t\\_tokkyo\\_e/product\\_process\\_C150706\\_e.htm](http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/product_process_C150706_e.htm)
  - 6 JPO, "Examination Guidelines for Patent and Utility Model"  
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