
Articles

Product-by-Process Claims: Changes in the Japanese Practice further to the Supreme Court Decisions on the *Pravastatin Sodium Case*, and a Comparison with Other Jurisdictions

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Abstract

A product-by-process claim may be interpreted according to one of the two following theories: a “product identity theory” by which the claim is construed as being directed to the product irrespective of the recited manufacturing process; and the “process limitation theory” by which a claim is construed as being directed to the product and limited by the recited manufacturing process. In Japan, the Supreme Court clearly ruled in two decisions on June 5, 2015 that a product-by-process claim is to be construed according to the “product identity theory”, and introduced a new requirement for clarity of claims, which has caused some confusion in the current practice. Although, the confusion has somewhat settled through the guidance given by the

Japan Patent Office and the decisions of the Intellectual Property High Court rendered subsequent to the Supreme Court decisions, it remains that different approaches are adopted in Japan and other jurisdictions. The present article discusses the current practice in assessing product-by-process claims in various jurisdictions with a focus on changes in the Japanese practice further to the Supreme Court decisions.

1. Introduction

In some jurisdictions, the patent act and jurisprudence provide provisions for construing a claim based on its form. One of the widely known examples is means-plus-function claims under Section 112(f) of the U.S. Patent Act (35 U.S.C.), and

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All cited URLs are accessed in January 2017.

other examples include use claims, disclaimer, and Jepson claims, etc. Product-by-process claims constitute another example.

A product-by-process claim defines a product by reciting the process for manufacturing the product. There are essentially two approaches for construing product-by-process claims, namely, the “product identity theory” by which the claim is construed as being directed to the product irrespective of the recited manufacturing process, and the “process limitation theory” by which a claim is construed as being directed to the product limited by the recited manufacturing process. In some jurisdictions, the “product identity theory” is adopted for both examination of pending application and infringement actions, while in others, the “product identity theory” is adopted for the purpose of examination and the “process limitation theory” is adopted in infringement actions. Moreover, even in the jurisdictions where the “product identity theory” is adopted in both examination and infringement actions, there are cases where examination and litigation differ in terms of requirements for clarity, or where a claim is exceptionally construed as being limited to the scope of the manufacturing process. More particularly in Japan, the Supreme Court has established an approach differing from the conventional approach with respect to the clarity requirement of claims in its ruling on June 5, 2015 in the *Pravastatin Sodium Case*, which has caused some confusion among patent practitioners. During the period of about eighteen months following the Supreme Court decisions, confusion in the practice has been in the process of being settled through the guidance given by the Japan Patent

Office (JPO) and the decisions of the Intellectual Property High Court, etc.. However, it remains that the approach in Japan differs from the approach adopted in other countries with respect to product-by-process claims.

In light of this, the present article discusses the current state in the assessment of product-by-process claims in various jurisdictions with a focus on changes in the Japanese practice further to the Supreme Court decisions on the *Pravastatin Sodium Case*.

2. In Japan

2.1 Outline of the Supreme Court Decisions in the *Pravastatin Sodium Case*

The *Pravastatin Sodium Case* which concerned Japanese Patent No. 3737801 was the object of two Supreme Court decisions, ruled on June 5, 2015 (2012 (Ju) 1204¹ and 2012 (Ju) 2658²). Claim 1 of the patent reads as follows, as per the provisional English translation of the decisions.

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

As is evident from the term “pre-

pared by a process”, this claim is a typical product-by-process claim in that it defines an invention of a product in terms of its manufacturing process.

In both decisions, the Supreme Court made assertions as to the determination of the “technical scope of the invention” (2012 (Ju) 1204), for assessing infringement, and the identification of the “gist of the invention” (2012 (Ju) 2658), for assessing patentability during examination.

The following recites the Summary of the 2012 (Ju) 1204 Decision (as per the provisional English translation):

Determination of the technical scope

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 recited in the claim.

Clarity requirement for a product-by-process claim

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 claimed 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.

The following recites the Summary of the 2012 (Ju) 2658 Decision (as per the provisional English translation):

Identification of the gist of the invention

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 gist of the invention should be identified as referring to products that have the same structure, characteristics, etc. as those of the product manufactured by the manufacturing process recited in the claim.

The holding of the Supreme Court concerning the identification of the gist of the invention, which is used for the determination of patentability during examination, reflected the approach adopted by the JPO in the past.

On the other hand, the holding concerning the determination of the technical scope, which is used for the determination of infringement, overturned the 2012 decision³ of the Grand Panel of the Intellectual Property High Court, which distinguished “authentic product-by-process claims” from “inauthentic product-by-process claims” (also translated as “unauthentic product-by-process”). According to this approach, a product-by-process claim is considered as authentic “when the product is defined by the manufacturing process and there are circumstances where it was impossible or difficult to directly define the product by

means of its structure or characteristics at the time of the filing of the application” while a product-by-process claim is considered as unauthentic “where the manufacturing process of the product is additively recited, when it cannot be said that there are circumstances where it was impossible or difficult 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.” Further to this ruling as to the two types of product-by-process claims, the Grand Panel of the Intellectual Property High Court in the *Pravastatin Sodium Case* indicated the following distinction in determining the technical scope. That is, the Grand Panel of the Intellectual Property High Court adopted the “product identity theory” for authentic product-by-process claims by ruling that the technical scope of the invention is construed as including “products that are identical with the product manufactured by the manufacturing process recited in a claim without being limited by said manufacturing process”. On the other hand, the Grand Panel of the Intellectual Property High Court adopted the “process limitation theory” for inauthentic product-by-process claims by ruling that the technical scope of the invention is limited to the “products manufactured by the manufacturing process recited in a claim”.

However, the Supreme Court integrated the approach used for the determination as to infringement into the “product identity theory” (See 1. in Summary of 2012 (Ju) 1204). Moreover, these Supreme Court decisions had a great impact on examinations and trials at the JPO and on the determination of patentability by its determination concerning the clarity requirement for product-by-process

claims (Article 36, paragraph (6), item (ii)).

These Supreme Court decisions established a more stringent clarity requirement for product-by-process claims, as indicated in 2. in Summary of 2012 (Ju) 1204 (the same determination is also indicated in 2012 (Ju) 2658). That is, the Supreme Court ruled that a product-by-process claim meets the clarity requirement only when there are circumstances where it is 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 (“impossible or impractical circumstances”), which limited cases where a product-by-process claim could be permitted based on this new clarity requirement.

The *Pravastatin Sodium Case* was remanded to the Intellectual Property High Court after the Supreme Court judgments, but the defendant (appellee) Kyowa Hakko Kirin Co., Ltd. announced that the cases were terminated on December 16, 2015 when the patentee (plaintiff; appellant) Teva Pharmaceutical Industries Ltd., waived its claims⁴. The ending of the actions without the court's final determination resulted in doubt as to the clarity requirement for product-by-process claims. Indeed, the assessment of the clarity requirement remained unclear not only for the claims of the subject patent but, also for the specific examples of claims that are assumed as falling under the cases where there are impossible or impractical circumstances. Incidentally, the Supreme Court judgments have generated considerable commentary. Readers are invited to refer to the many reports⁵ that have been written about this case for additional information

on the background of the Supreme Court decisions and consideration immediately after the decisions.

Referring back to claim construction aside from the new clarity requirement, the approach now adopted in Japan regarding product-by-process claims as to the determination of novelty and inventive step (ground for invalidation of the patent), and as to the determination of patent infringement (finding of infringement), respectively, may be summarized as follows.

Determination of novelty and inventive step (ground for invalidation of the patent) i.e. “Identification of the gist of the invention”	Product identity theory
Determination of patent infringement (finding of infringement) i.e. “Technical scope of the invention”	Product identity theory

The assessment of product-by-process claims by the JPO and by the courts further to the Supreme Court decisions will now be outlined.

2.2 Handling by the Japan Patent Office

2.2.1 During Examinations

For product-by-process claims, novelty and involvement of an inventive step have been determined according to the “product identity theory” in examination at the JPO even before the Supreme Court decisions on the *Pravastatin Sodium Case*. Therefore, the Supreme Court decisions mainly affected the JPO’s examination practice as to the clarity requirement, changing the approach that had been indicated in the JPO’s Examination Guidelines in the past.

In the former version of the JPO’s Examination Guidelines, product-by-process claims had been considered not to meet the clarity requirement in such cases as follows.⁶

- 1) Cases where the invention is unclear because a manufacturing process (e.g., starting materials or manufacturing processes) cannot be understood from the claim, even when taking into consideration the description, drawings and the common general knowledge as of the filing date.
- 2) Cases where the invention is unclear because the characteristics of a product (e.g., the structure or property) cannot be understood from the claim, even by considering the statements of the description and drawings as well as the common general knowledge as of the filing.

However, the Supreme Court’s rulings as to the necessity of “impossible or impractical circumstances” in relation to the clarity requirement for product-by-process claims raised the possibility that even a claim that meets the requirements under the conventional Examination Guidelines would now fail to meet the clarity requirement also for examination purposes after the Supreme Court decisions. In addition, the Supreme Court decisions could impact a large spectrum of cases when taking into consideration all claims that define a product by some sort of manufacturing process even when worded in a way different from the claim of the subject patent in the Supreme Court decisions on the *Pravastatin*

Sodium Case. Therefore, it was considered that “patent applications in various technical fields filed prior to the decisions by the Supreme Court, and claiming a product by its manufacturing process, were subject to the approach set out by the Supreme Court during examination. Therefore, it became an important issue for the JPO to promptly and appropriately align with the Supreme Court's judgments”⁷.

The following documents (including those that are partially related) were published by the JPO made by the end of December 2016 further to the Supreme Court decisions on the *Pravastatin Sodium Case* on June 5, 2015.

Document 1 Interim Handling Procedures for Examinations and Appeals/Trials involving Product-by-process Claims⁸ (published on July 6, 2015)

Document 2 Revised Examination Guidelines for Patent and Utility Model in Japan⁹ and Revised Examination Handbook for Patent and Utility Model in Japan¹⁰ (published on September 16, 2015)

Document 3 Examples of Arguments and Verification presented by Applicants involving “Impossible or Impractical Circumstances”¹¹ (published on November 25, 2015)

Document 4 Addition of examples not considered to be Product-by-process claims¹² (published on January 27, 2016)

Document 5 Revision of the relevant parts in Examination Handbook on Clarity Requirement for Product-by-process claims (published on March 30, 2016)

Document 6 Background and Essential Point of Revision of the Relevant

Parts in Examination Handbook on Clarity Requirement for Product-by-process claims)¹³ (published on March 30, 2016)

Document 7 Addition of operative example and reference decision involving “Impossible or Impractical Circumstances” (published on September 28, 2016)

The changes in the assessment of the clarity requirement of product-by-process claims further to the Supreme Court judgments will now be outlined, with reference to Documents 1 to 7.

As of January 2017, an English version of the information relating to product-by-process claims in Japan has been consolidated, together with links to Documents 1 to 7 mentioned above, on the webpage entitled “Handling Procedures for Examinations involving Product-by-process Claims”¹⁴ on the JPO's website. The handling of product-by-process claims for examination based on the rulings of the Supreme Court is outlined as follows on this webpage:

When a claim concerning an invention of a product recites a manufacturing process of the product, the examiner will notify a reason for refusal in accordance with the Supreme Court decisions. However, this will not be the case when the examiner can find that the invention involves “impossible or impractical circumstances”.

The term “impossible or impractical circumstances” means any circumstances in which it is impossible or utterly impractical to define the product directly based on its structure or

characteristics at the time of the filing of the application.

The reasons for refusal will be notified to provide applicants with opportunities to argue and verify the existence of “impossible or impractical circumstances” and/or amend claim(s). These opportunities will be given in view of avoiding situations in which granted patents could include grounds for invalidation, or in which interests of third parties could be unfairly harmed.

In light of this, the following five options (i) to (v) are provided as possible measures for resolving a reason for refusal to the effect that a claim falls under a product-by-process claim and that the relevant invention of a product is therefore unclear.

- (i) deleting any claim concerned,
- (ii) amending any claim concerned into a claim concerning an invention of a process for producing a product,
- (iii) amending any claim concerned into a claim concerning an invention of a product which does not recite a manufacturing process,
- (iv) asserting and proving the existence of “impossible or impractical circumstances” based on a written argument, and/or
- (v) arguing to the effect that any claim concerned does not fall under a “case where a claim concerning an invention of a product includes a manufacturing method for a product”.

Moreover, arguments and verification concerning the existence of “impos-

sible or impractical circumstances” in examinations are handled as follows.

When the applicant argues and verifies the existence of “impossible or impractical circumstances”, the examiner will, normally, conclude that “impossible or impractical circumstances” do exist. However, this will not be the case when the examiner has doubts, based on a tangible reason, about the existence of “impossible or impractical circumstances”.

The changes in the examination of product-by-process claims further to the Supreme Court decisions will now be discussed.

On June 10, 2015, immediately after the Supreme Court decisions, the JPO announced on the webpage titled “Handling Procedures for Examinations and Appeals/Trials involving Product-by-process Claims”¹⁵, that it would consider the revision of the Examination Guidelines and would make no comment on the Supreme Court's judgments as to examination and trials until early July. In the following month, specifically on July 6, the JPO published the “Interim Handling Procedures for Examinations and Appeals/Trials involving Product-by-process Claims (Document 1),” and also published a series of documents thereafter, concerning handling during examination and trials.

In this “Interim Handling Procedures for Examinations and Appeals/Trials,” the subject applications were clearly specified as follows.

The interim handling procedures apply to examinations on patent applications which either has already been

filed or which will be filed at a future date. In the same manner, the interim handling procedures also apply not only to trials, oppositions to the grant of a patent, and advisory opinions (hereinafter referred to as “trials, etc.”) which will be requested in the future but also those that are currently pending. Therefore, trials, etc. against a patent that has already been granted are subject to the interim handling procedures.

Regarding item (iii) of the above-mentioned five options (i) to (v) cited as possible measures, the following explanation was given in response to concerns about restrictions on possible amendments at the time of filing a request for a trial against an examiner’s decision of refusal following the final notice of reasons for refusal or after receiving a notice referred to in Article 50-2 (notice to the effect that the reasons for refusal stated therein are the same as those stated in the previous notice.

An amendment that changes “recitation of a manufacturing process of the product” to recitation of the product as a product by means of its structure or characteristics or an amendment that changes the invention of a product to an invention of the manufacturing process of the product in the case where a claim for the invention of the product recites the manufacturing process of the product, which is made at the time of filing a request for a trial against an examiner’s decision of refusal following the final notice of reasons for refusal or after receiving a notice referred to in Article 50-2 of the

Patent Act is ordinarily recognized as an amendment that falls under the clarification of an ambiguous statement (Article 17-2, paragraph (5), item (iv) of the Patent Act).

Therefore, an amendment that changes the category of the claim (from a product-by-process to a manufacturing process) has become acceptable during examination, as a clarification of an ambiguous statement, even in response to the final notice of reasons for refusal, etc. provided that other requirements are met, for example not changing the special technical features of the invention nor adding any new subject matter. Thus, practical concerns in the case of choosing option (ii) or (iii) during examination were alleviated in the early stage.

On the other hand, since practical concerns related to options (iv) and (v) were not addressed, the JPO continued discussions and published Documents 2 to 7 over the following months.

The “Revised Examination Guidelines for Patent and Utility Model in Japan and the Revised Examination Handbook for Patent and Utility Model in Japan (Document 2),” published by the JPO on September 16, 2015 addresses product-by-process claims in the following items.

Examination Guidelines for Patent and Utility Model in Japan

Part II, Chapter 2, Section 3 Clarity Requirement

4.3 Expression specifying a product by a manufacturing process

Part III, Chapter 2, Section 4 Claims Including Specific Expressions

5. Expression Specifying a Product by a Manufacturing Process

Examination Handbook for Patent and Utility Model in Japan

Part II Description and Claims (→**2203 to 2204 correspond to “Interim Handling Procedures for Examinations and Appeals/Trials)**)

2203 Points to Note in Examination When a Claim for an Invention of a Product Recites the Manufacturing Process of the Product

2204 Determination on Whether or Not “When a Claim for an Invention of a Product Recites the Manufacturing Process of the Product” is Relevant

2205 Determination on “Impossible/Impractical Circumstances” in Examination When a Claim for an Invention of a Product Recites the Manufacturing Process of the Product

Part III Patentability

3222 When comparison with the cited invention is difficult, and exact comparison cannot be made, because it is extremely difficult to determine what the product itself is structurally (reason to doubt that novelty is prima facie denied)

3223 When comparison with the cited invention is difficult, and exact comparison cannot be made, because it is extremely difficult to determine what the product itself is structurally (reason to doubt that inventive step is prima facie denied)

Annex D Court precedents

1. Outline of Examination

(11)-9 “Studless tire having large braking force and manufacturing method thereof” (Appeal against an

Examiner’s Decision)

Decisions of the Intellectual Property High Court, December 18, 2014 (2014 (Gyo-Ke) 10102)

→ A court precedent concerning “How to proceed with examinations, and trials and appeals”

4. Novelty and Inventive Step

(59)-1 “A method of manufacturing diaphragms for speaker” (Trial for Invalidation)

Decisions of the Intellectual Property High Court, December 7, 2006 (2005 (Gyo-Ke) 10775)

→ A court precedent concerning “Finding of the invention and novelty and inventive step of the invention according to a claim that includes a description trying to identify the product with the manufacturing method in the claim”

The explanation based on the Supreme Court decisions on the *Pravastatin Sodium Case* is briefly stated in section “4.3 Expression specifying a product by a manufacturing process” under “Part II, Chapter 2, Section 3 Clarity Requirement” of the Examination Guidelines. In addition, the content corresponding to the “Interim Handling Procedures for Examinations and Appeals/Trials (Document 1)” was added to Sections 2203 to 2205 of the Examination Handbook for Patent and Utility Model in Japan. However, neither specific explanation nor case examples were given at this time. Incidentally, the Examination Handbook adheres fundamentally to the Examination Guidelines before the revision, for matters other than the clarity requirement. The court precedents before the Supreme Court decisions on the *Pravastatin Sodium Case* are introduced

in Appendix D, but they are not related to the clarity requirement.

Due to the lack of explanation or case examples in the Revised Examination Guidelines and the Revised Handbook, there have been a number of cases in which the examiner determined a claim to be a product-by-process claim by categorizing the claim as falling under the case “the manufacturing process of the product is recited” even if the claim was recited formally or idiomatically, and thus issued a notice of reasons for refusal involving a failure to meet the clarity requirement. In addition, due to lack of clear guidance, it was difficult for applicants to demonstrate “impossible or impractical circumstances” or to obtain recognition that the relevant claim does not fall under the cases “where the manufacturing process of the product is recited.” These circumstances created confusion in the practice for both examiners and applicants. In addition, as the handling of product-by-process claims was not limited to a specific technical field, confusion spread not only to the fields of pharmacy, chemistry, etc. but also the mechanical and electrical fields, etc.

Consequently, the JPO continued to conduct surveys¹⁶ and to assess considerations concerning product-by-process claims, and published a revision of the Examination Handbook for Patent and Utility Model in Japan (Documents 5 and 6) on March 30, 2016 and began applying the same to examination on April 1 2016. The outline of the revision of March 30, 2016 is as follows.

Determination concerning whether or not a claim falls under a product-by-process claim

The following was clearly specified in the part concerning the “basic idea” of determining whether or not there is a failure to meet the clarity requirement in Section 2204¹⁷ of the Revised Examination Handbook: “even if a claim corresponds formally to one of the following types or examples showing the cases “where a claim recites the manufacturing process of the product,” ... considering the description, claims and drawings as well as common general technical knowledge in the art to which the invention pertains at the time of the filing of the application.” In addition, examples were replaced and added.

Determination concerning “impossible or impractical circumstances”

In Section 2205¹⁸ of the Revised Examination Handbook, the reference examples of arguments and verification in the aforementioned Document 3 were incorporated, and operative examples were also added.

These revised points relate to the aforementioned options (iv) and (v) for resolving a reason for refusal. In particular, the revision of Section 2204 of the Examination Handbook, which relates to option (v), should be understood together with the “Background and Essential Point of Revision of the Relevant Parts in Examination Handbook” dated March 30, 2016, which dates to the same date as the revision.

This “Background and Essential Point of Revision” first states that the JPO was in a position where the “conclusion relating to the clarity requirement” in the Supreme Court decisions “should be apprehended in a strict manner” in the “Interim Handling Procedures for Exami-

nations,” and then gives explanation about the deletion of the following case of a bolt and nut which was included in the operative examples stated in the former version of section 2204 before the revision.

“a device having a fixed portion wherein a bolt having a convex portion is inserted into a hole having a concave portion so that the convex portion and the concave portion can be engaged, and a nut is screwed with the end of the bolt.”

The following is a citation from the explanation.

However, it is clear what structure of the “device” is represented by the manufacturing process of a “device” for this case, thus this case does not fall under the description “it is generally unclear...” stated in an explanation of the reason leading to the conclusion in the judgment of the Supreme Court. In view of this, and as a result of considering opinions of experts in the related areas and users, such case is treated as not applicable to a case “where claims concerning inventions of products recites manufacturing processes of the products.”

Such handling procedure is applicable when other typical and operative examples fall under cases where “a claim recites the manufacturing process of the product.”

At present, according to this explanation, if an applicant determines that a claim only formally falls under a product-by-process claim and makes a counter-

argument of the aforementioned option (v), he/she can resolve a reason for refusal without amending the claim in many cases by arguing, with appropriate explanation, that “the claim does not fall under the case ‘where a claim recites the manufacturing process of the product’ in consideration of the description, claims and drawings as well as common general technical knowledge in the art to which the invention pertains to at the time of the filing of the application.” in line with the approach indicated in Section 2204 of the Revised Examination Handbook and the “Background and Essential Point of Revision.”

The JPO published this “Background and Essential Point of Revision” and revised the “Examination Handbook for Patent and Utility Model in Japan.” After that, the JPO published a further revision (Document 7) of the “Examination Handbook for Patent and Utility Model in Japan” on September 28, 2016. In this revision, examples corresponding to the “impossible or impractical circumstances” and a reference decision (Trial against Examiner’s Decision of Refusal No. 2014-10863) were added to Section 2205 of the Examination Handbook. In the revision of September 28, 2016, the following are cited as types corresponding to “impossible or impractical circumstances” and types not corresponding thereto in Section 2205 of the Examination Handbook.

Types corresponding to “impossible or impractical circumstances”

Type (i): Case in which analyzing the structure or features of an item at the time of filing is technically impossible

Type (ii): Case in which, in view of the fact that, due to the nature of a patent application, rapidity, etc., are required, significantly excessive financial expenditure or time would be required to perform work to identify the structure or properties of the item

Types not corresponding to “impossible or impractical circumstances”

Type (iii): Case in which a relationship with the invention of the present application is completely undescribed

Thus, the above concerns changes in the assessment of the clarity requirement in product-by-process claims during examination further to the Supreme Court decisions on the *Pravastatin Sodium Case*. The outline of examination based on Documents 1 to 7 published by the JPO is summarized in the following flow chart of the next page. Although there was confusion in examination practice concerning the handling of product-by-process claims immediately after the Supreme Court decisions, the JPO altered its position of “apprehending the conclusion relating to the clarity requirement in a strict manner” into more relaxed one. Therefore, at present, when receiving a notice of reasons for refusal, it is important to first consider whether or not the claim falls under the case “where a claim recites a manufacturing process of a product” as indicated in the flow chart. Further to a reasonable determination by an examiner that the “claim recites the manufacturing method of the product”, it is appropriate to choose the most reasonable response among (a) arguing the existence of impossible or impractical circum-

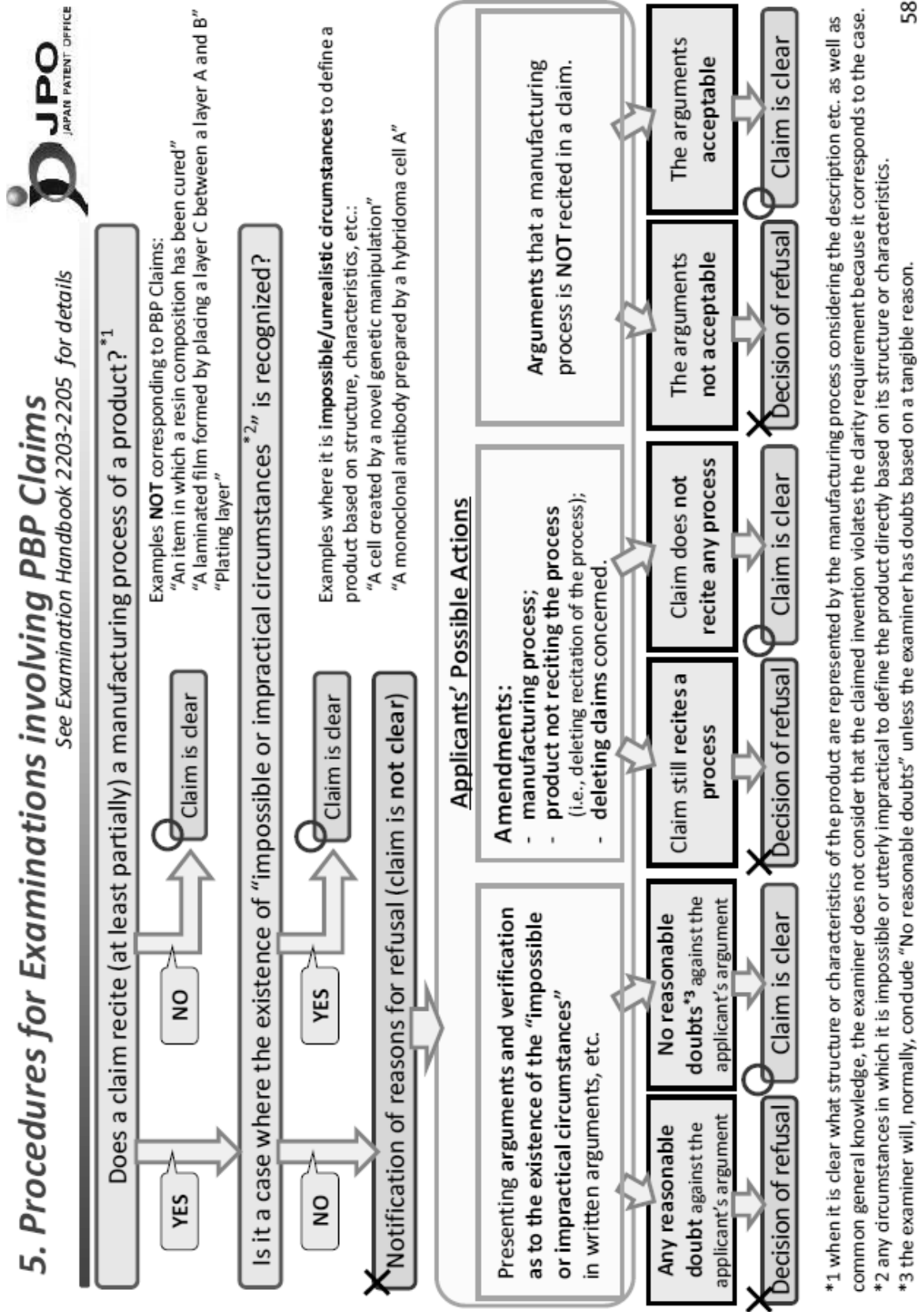
stances (it is also necessary to consider not only the propriety of such argument but also the possibility that such argument will cause some sort of estoppel) and (b) amending or deleting the claim.

2.2.2 Handling in trials and oppositions

As mentioned above, the approach established by the rulings of the Supreme Court decisions on the *Pravastatin Sodium Case* affected not only the prosecution of patent applications but also trials, oppositions, and advisory opinions handled by the Appeals Department of the JPO. Out of these procedures handled by the Appeals Department of the JPO, patentees were required to give sufficient consideration to meet the requirements provided for in the Patent Act in the case where “a product-by-process claim needs to be amended to a claim of a process of producing a product” or “a product-by-process claim needs to be amended to a claim of a product not including the manufacturing process” in a trial for correction and a request for correction during a trial for patent invalidation and an opposition, which are post-grant procedures.

For the overall handling in trials (including trials for correction, requests for correction during trials for patent invalidation and oppositions, and trials against an examiner’s decision of refusal) are to be carried out in line with the Supreme Court’s judgments in consideration of the “Interim Handling Procedures for Examinations and Appeals/Trials involving Product-by-process Claims,” and product-by-process claims are basically to be assessed in the same manner as during examination under the latest Examination Handbook.

<Extract from “Outline of the Examination Guidelines for Patent and Utility Model in Japan (2016.05)”¹⁹⁾>



(a) Trials against an Examiner's Decision of Refusal

On the above basis, regarding trials against an examiner's decision of refusal, the JPO added the following underlined part concerning the flow of trial proceedings, in the "Interim Handling of Appeals and Trials" in the revision of the webpage entitled "Interim Handling Procedures for Examinations and Appeals/Trials involving Product-by-process Claims (Document 1)" on January 27, 2016.

In a trial against an examiner's decision of refusal, if a claim for an invention of a product recites a manufacturing process of the product, the examiner gives a notice of reasons for refusal unless the panel can determine the existence of "impossible or impractical circumstances" without the need of asking the demandant of the trial. However, even if a claim for an invention of a product recites a manufacturing process of the product, if a reason for an examiner's decision of refusal or a reason for refusal notified after filing of a request for a trial can be maintained, the examiner may conclude the proceedings and render a decision without giving a notice of reasons for refusal again (added on January 27, 2016).

(b) Trials for Correction and Requests for Correction during Trials for Patent Invalidation and Oppositions

In addition, for a trial for correction and a request for correction, the following explanations were added with regard to determination concerning whether or not an amendment falls under the "clarification of an ambiguous statement" under

the provisions on a trial for correction (item (iii) of the proviso to Article 126, paragraph (1) of the Patent Act) and the provisions on a request for correction during an opposition to the grant of a patent (item (iii) of the proviso to Article 120-5, paragraph (2) of the Patent Act) in "4. Trial for Correction/Request for Correction: Q15"²⁰ and "Q4-21" in "Q&A about Proceedings of Request for Trial."²¹

For the "clarification of an ambiguous statement," there is no requirement as to "limited to the matters stated in the reasons for refusal in the notice of reasons for refusal", which is taken into consideration in the application of Article 17-2, paragraph (5) of the Patent Act in relation to an amendment.

Therefore, when a claim for an invention of a product recites a manufacturing process of the product, a correction to define the product by means of its structure or characteristics and a correction that makes the invention of the product into an invention of the manufacturing process of the product are recognized as a correction made for the purpose of the clarification of an ambiguous statement.

(only the common part between the aforementioned two Q&A sections was extracted)

Furthermore, in the Appeal or Trial Examination Manual (16th edition)²² which was put into effect by the JPO on November 1, 2015, the sections concerning "correction in general" were set as Sections 38-00 to 38-06 by transferring the content stated in the past. "Examples of correction that substantially enlarges or alters a claim" in relation to patents

granted for applications filed on and after July 1, 1995, which are described in “8. Correction should neither substantially enlarge nor alter a claim” in “54-01.1 Correctable Scope” (the requirements for correction are explained) in the 15th edition of the Appeal and Trial Examination Manual, were changed as follows in the corresponding part in “38-03 Requirements for Correction” in the 16th edition thereof.

“Examples of correction that substantially enlarges or alters a claim”

(Former 15th edition) F. Change of the category or subject matter of the claimed invention

(New 16th edition) F. Correction that changes the category of an invention from an “invention of a process” or an “invention of a process of producing a product” to an “invention of a product”

*The similar change was also added to example G which is applicable to patents granted for applications filed before June 30, 1995.

This change can also be understood as explicitly suggesting that correcting a product-by-process claim (an invention of a product) to a process claim (an invention of a process or an invention of a process of producing a product) sometimes does not fall under the prohibited “correction that substantially enlarges or alters a claim”. However, initially, there was no special explanation, announcement, etc. regarding this point on the JPO’s website.

Subsequently, on March 28, 2016, the JPO announced that the JPO rendered a decision accepting a category change from an invention of a “product” to an invention of a “process of producing a product” in Trial for Correction No.

2016-390005, on its webpage entitled “Regarding the JPO decision on a trial for correction of a product-by-process claim involving a category change from an invention of a ‘product’ to an invention of a ‘process of producing a product’”²³. It is particularly notable that the identity of the “problem to be solved of the invention and the means for solving the problem” before and after the correction of the claim and the absence of “unexpected disadvantage to a third party by correction” were used as standards for determining fulfillment of one of the requirements for correction, that is, “prohibition of substantial enlargement or alteration of a claim,” in this JPO decision. Incidentally, the claims of Patent No. 5759172 before and after the correction are as follows.

Claim before the correction

A fixing member used for a heat fixing device for an electrophotographic device, comprising:

a substrate,
an elastic layer comprising foam silicone rubber, and
a surface layer in this order,

wherein the foam silicone rubber is formed by foaming and hardening liquid silicone rubber mixture containing silica gel as a foaming agent.

Claim after the correction

A process of manufacturing a fixing member used for a heat fixing device for an electrophotographic device, comprising a substrate, an elastic layer comprising foam silicone rubber and a surface layer in this order,

wherein the foam silicone rubber is formed by foaming and hardening liquid silicone rubber mixture containing silica

gel as a foaming agent.

Even further to this correction, there were a series of opposition and trial cases in which the JPO permitted a category change in the same manner (Opposition No. 2015-700105, Opposition No. 2016-700161, and Trial for Correction No. 2016-390085).

Therefore, appropriate argument and proof of the identity of the “problem to be solved of the invention and the means for solving the problem” and the absence of “unexpected disadvantage to a third party by correction” is expected to serve as the substantial requirement for a correction involving a category change for the time being. However, the JPO clearly states on its webpage that “Even a correction of a product-by-process claim involving a category change from an invention of a ‘product’ to an invention of a ‘process of producing a product’ is not uniformly permitted, and the JPO makes a determination on a case-by-case basis.” In addition, careful handling is continuously required on a case-by-case basis as there was a court precedent in which the court did not permit an amendment to change the category of an invention (2006 (Gyo-Ke) 10494).

2.3 Handling by the Courts

As previously mentioned, the JPO changed its initial “position of apprehending the conclusion relating to the clarity requirement in a strict manner” based on the results of consideration of the scope covered by the Supreme Court decisions. However, there had been no decision in which the court indicated its determination concerning a product-by-process claim even one year after the Supreme Court decisions. However, in

the article written by the (then) Chief Judge of the Intellectual Property High Court²⁴, the scope covered by the Supreme Court decisions was dealt with and the JPO’s publications were examined. The point that should be especially noted in this article is the following statement to the effect that a claim which should be construed as an “apparent product-by-process claim” does not need to be construed as a product-by-process claim to which the Supreme Court’s judgments are applicable.

(According to the results of considering the scope covered by the Supreme Court’s judgments concerning product-by-process claims) Even if a claim recites a chronological element concerning a manufacturing process and is formally recognized as including a recitation as a manufacturing process, the claim does not need to be construed as a product-by-process claim to which the Supreme Court’s judgments concerning product-by-process claims are applicable if the structure and characteristics of the product meant by the recitation as a manufacturing process are clear in light of the description, claims, and drawings as well as common general technical knowledge (apparent product-by-process claim).

Moreover, the article deals with “impossible or impractical circumstances”, “correction to an invention of a process of producing a product”, and “determination of the technical scope of a product-by-process claim (product identity theory)” as future problems, and it concludes with the following.

... There is the possibility that cases that differ from those appeared in existing court precedents, claims which the applicant him/herself does not recognize as product-by-process claims, and claims which the parties to an infringement action or an action to seek rescission of a JPO decision to the effect that the patent is to be invalidated, etc. have not recognized as product-by-process claims are determined as product-by-process claims. Therefore, it is considered as an important choice for Japanese patent practice to reconstruct the definition of product-by-process claim in line with the revision of March 30²⁵ according to the substantial reason of the Supreme Court's judgments concerning product-by-process claims and to limit the applicable scope of the Supreme Court's judgments concerning product-by-process claims to the appropriate scope.

In this manner, the (then) Chief Judge of the Intellectual Property High Court expressed his opinion affirming the JPO's position after its change from its initial position. Concurrently with this article, determinations including the following statements were made with regard to product-by-process claims in three Intellectual Property High Court judgments (incidentally, in one of these judgments, the determination was made as an additional remark).

2015 (Gyo-Ke) 10242 (decision rendered on September 20, 2016)

A product-by-process claim is questioned in relation to the clarity of an invention because if the technical

scope of a patented invention is determined by considering that wherever a manufacturing process of a product is recited in a claim for the patent for the invention of the product, the patent right is effective against products which are identical with the product manufactured by the manufacturing process in structure, characteristics, etc., interest of a third party may be unjustly harmed as it is unclear what structure or characteristics of the product is expressed by the manufacturing process. Even if a recitation of a claim can be considered as reciting a manufacturing process of a product as it formally appears to be chronological, it can be said that the aforementioned problem does not arise if the structure or characteristics, etc. of the product manufactured by said manufacturing process is unambiguously clear in consideration of the recitation of the description as well as common general technical knowledge.

2015 (Gyo-Ke) 10184 (decision rendered on September 29, 2016)

According to the summary of the Supreme Court's judgments on PBP (product-by-process) claims, the Supreme Court required the arguments and verification of the aforementioned circumstances in said judgments in this manner because when a manufacturing process of a product is recited in a claim for the patent for the invention of the product, it is unclear what structure or characteristics of the product is expressed by the recitation of the manufacturing process and a person who reads the recitation of the claim, etc. is unable to clearly understand the content of said invention. In that case,

even if the manufacturing process of the product is recited in a claim, the content of the invention can be clearly understood in the nature of things if the recitation of said manufacturing process clearly expresses the structure or characteristics of the product. Therefore, it is reasonable to understand that the arguments and verification of the existence of impossible or impractical circumstances is not required if there are such special circumstances.

2015 (Gyo-Ke) 10025 (decision rendered on November 8, 2016)

In the Supreme Court decisions, the Supreme Court ruled that a claim fails to meet the clarity requirement unless there are the aforementioned circumstances, for the following purpose: The technical scope of a product-by-process claim is determined as products which are identical with the product manufactured by the relevant manufacturing process in structure, characteristics, etc., but what structure or characteristics of the product is expressed by said manufacturing process is generally unclear in such recitation of a claim, which results in removing the predictability of the scope of rights; therefore, such recitation of a claim is not permitted without constraints but is permitted only where there are the aforementioned circumstances. In that case, even if a manufacturing process of a product is recited in a claim, it is not necessary to consider the claim as falling under a product-by-process claim that should be questioned in relation to Article 36, paragraph (6), item (ii) of the Patent Act if what structure or characteristics of the product is expressed by said

manufacturing process is clear in consideration of the recitation of the claim, description, and drawings as well as common general technical knowledge.

These holdings are considered to be similar to the idea indicated in the article written by the (then) Chief Judge of the Intellectual Property High Court, and confirm the possibility that the court may indicate the determination that when a recitation of a manufacturing process clearly expresses the structure or characteristics of a product, the arguments and verification of the existence of impossible or impractical circumstances are not required because the content of the invention can be clearly understood in the nature of things. In addition, in the aforementioned three decisions, the Intellectual Property High Court dealt with whether or not there is the possibility that interest of a third party is unjustly harmed as the predictability of the scope of rights is removed by a product-by-process claim for the subject patent, in addition to whether or not the content of the invention recited by the claim can be clearly understood. This is notable in that the fulfilment of the clarity requirement is determined not only based on the form of recitation of a claim but also in consideration of the essential function of the claim in the patent, that is, the claimed scope of the invention.

3. Current State of Handling of Product-by-Process Claims in Other Countries

The current state of assessing product-by-process claims in some jurisdictions outside of Japan is explained below.

3.1 In the United States

Determination of novelty and inventive step (ground for invalidation of the patent)	Product identity theory
Determination of patent infringement (finding of infringement)	Process limitation theory

In the United States, product-by-process claims are construed in accordance with the Manual of Patent Examining Procedure (MPEP) in the examination stage and in accordance with court precedents after establishment of rights.

In the examination stage, a product-by-process claim is considered as being in a proper format (MPEP 2173.05(p))²⁶, and where the process has actually been used to produce the product, the written description requirement under Section 112(a) of the U.S. Patent Act (35 U.S.C.) is satisfied (MPEP 2163)²⁷.

Moreover, as determination of patentability, specifically, novelty (Section 102 of the U.S. Patent Act) and non-obviousness (Section 103 of the U.S. Patent Act; that is, inventive step), is based on the “product identity theory”, if the examiner finds the existence of a product appearing to be substantially identical with the claimed invention, the applicant is required to prove the existence of a non-obvious difference between the claimed invention and the product (MPEP 2113)²⁸.

On the other hand, although determination of patentability is also based on the “product identity theory” after establishment of rights in the same manner as in the examination stage, determination of the scope of rights is based on the “process limitation theory” on which the scope of rights is construed as being lim-

ited to the manufacturing process (Abbott Laboratories v. Sandoz, Inc. (Fed. Cir. en banc 2009))²⁹.

Therefore, if it is inevitable to obtain rights other than by means of a product-by-process claim, it is necessary to pay sufficient attention to the difference in the scope of rights.

3.2 In Europe

Determination of novelty and inventive step (ground for invalidation of the patent)	(EPO) Product identity theory
Determination of patent infringement (finding of infringement)	(Germany) Product identity theory (U.K.) There are court precedents that are based on the process limitation theory.

It is clearly indicated in F-IV 4.12 concerning product-by-process claims in the Guidelines for Examination in the European Patent Office (EPO)³⁰ that novelty and involvement of an inventive step are determined based on a product as such, which is the outcome, and that a product is not rendered novel merely by the fact that the claim defining the product is limited by a new process.

Moreover, the Guidelines for Examination make clear the burden of proof by indicating that, regarding a product-by-process claim feature (difference from the contrast product), the applicant has to provide evidence that a product different from the claimed product was obtained while the examiner needs to furnish reasoned argumentation with regard to lack of novelty.

A product-by-process claim is allowable only if the product as such fulfils the requirements for patentability, such as

novelty, and it is impossible to sufficiently define the product by means of its composition, structure, or any other testable parameters, etc. based on a recitation in the description. In other words, the examiner may determine the suitability of using the product-by-process claim format based on the scope recited in the description. That is, the EPO's Guidelines for Examination do not mention resorting to additional considerations such as "impossible or impractical circumstances," as indicated in the Supreme Court decisions in Japan, when a manufacturing process is recited in a claim for a product.

Incidentally, in F-IV 4.12, the Guidelines for Examination mention "Broccoli II (G 2/12)" and "Tomatoes II (G 2/13)," for which the Enlarged Board of Appeal rendered decisions in March 2015. In these two decisions, the Enlarged Board of Appeal held that even if the feature of a process recited in a product-by-process claim is an "essentially biological process" which is excluded from the subject matter of patent under Article 53(b) of the Convention on the Grant of European Patents (EPC), this had no effect on the determination of patentability³¹. This holding can be considered as being in line with the "product identity theory", in the same manner as the EPO's conventional practice.

In Germany, a patent infringement is determined not based on the way of recitation (terms used for the claim: for example, "obtainable by" and "obtained by") but based on whether or not the allegedly infringing product is identical to the product defined by the claim. On the other hand, there has been a case in which the court ruled that a manufacturing process is taken into consideration in the determination of a patent

infringement in the United Kingdom. Recently, the case was appealed to the Court of Appeal, but the Court of Appeal did not show any specific determination³².

3.3 In China

Determination of novelty and inventive step (ground for invalidation of the patent)	Product identity theory
Determination of patent infringement (finding of infringement)	Process limitation theory

The handling of special claims, such as product-by-process claims, in the examination of an application for an invention patent under the Patent Act of the People's Republic of China is explained in detail in the Guidelines for Patent Examination. The current Guidelines for Patent Examination³³ were put into force on February 1, 2010, and explanations about product-by-process claims are given in the following three parts.

- Part II, Chapter 2, 3.1.1 Kinds of Claims
- Part II, Chapter 3, 3.2.5(3) Product claims including feature of manufacturing process
- Part II, Chapter 10, 4.3 Claim of Chemical Product Which Cannot Be Clearly Characterized Merely by Features of Structure and/or Composition

According to these explanations, novelty and an inventive step is in principle determined during examination based on the "product identity theory," in which a determination is made based on the resulting product. Therefore, if the result of

an invention recited in a product-by-process claim has a specific structure and/or composition which differs from that of the products described in prior art documents, the invention is recognized as being novel.

Moreover, the Guidelines for Patent Examination permit the use of a manufacturing process to characterize a claim of a chemical product in relation to a “chemical product which cannot be sufficiently characterized by the features other than the manufacturing process in Part II, Chapter 10, 4.3, which is related to Article 26(4) of the Patent Act³⁴ including the clarity requirement. Incidentally, there is no requirements for applicants to make any argument or verification of circumstances corresponding to “impossible or impractical circumstances” as indicated in the Supreme Court decisions in Japan.

On the other hand, regarding determination of a patent infringement, it is provided, in Article 10 of the “Judicial Interpretation II of the Supreme Court on Several Issues Concerning the Application of Law in the Trial of Patent Dispute Cases³⁵,” which is a judicial interpretation on patent right infringement that was put into force on April 1, 2016, that interpretation based on the “process limitation theory” is used in the determination of infringement of a patented invention recited in a product-by-process claim.

3.4 In Korea

Determination of novelty and inventive step (ground for invalidation of the patent)	Product identity theory
Determination of patent infringement (finding of infringement)	Product identity theory

The Supreme Court of Korea rendered a series of decisions concerning product-by-process claims in January and February 2015, and indicated its decision to change the conventional claim construction approach³⁶. The key points are as follows.

Determination of requirements for patentability (2011 Hu 927; decision rendered on January 22, 2015)

Regarding a product-by-process claim, novelty and inventive step are determined by understanding the product-by-process claim as a “product” having the structure and characteristics, etc. defined by the recited manufacturing process, irrespective of whether there are circumstances such that there was no other way but to define the product by means of the manufacturing process.

However, this decision does not include any ruling to the effect that the “circumstances where it was impossible or utterly impractical to directly define the product by means of its structure or characteristics at the time of the filing of the application,” etc. are taken into consideration in the determination of the clarity requirement, thus differing from the Supreme Court decisions that were rendered on the Pravastatin Sodium Case in June 2015 in Japan.

Determination concerning the scope of rights (2013 Hu 1726; decision rendered on February 12, 2015)

The Supreme Court made clear that the principles used in determining patentability are also applicable to product-by-process claims in the assessment of infringement, and added a proviso to the effect that if there are “unreasonable circumstances, such as where the scope of

rights is excessively broad in light of the reality of the invention that is understood based on the overall recitation of the description,” the scope of rights can be limited to the manufacturing process recited in the claim.

3.5 In Germany, the United Kingdom, Taiwan and India

The determination of patentability is made essentially based on the product identity theory during examination also in the United Kingdom³⁷, Germany³⁸, Taiwan³⁹, India^{40,41}, etc., though the details are omitted in this article. Moreover, regarding the description requirements, there are provisions stipulating that a product-by-process claim is permitted only where it is impossible to define the product by means of its structure or composition, etc., but there are no strict regulations that correspond to the “impossible or impractical circumstances” requirement as indicated in the Supreme Court decisions in Japan. Therefore, although attention should be paid to the point that a product is not determined as being novel just because of the recitation that the product was manufactured by a new manufacturing process, it can be said that there is room to consider reciting an invention by a product-by-process claim as one of the options if there is no choice but to recite the invention by a product-by-process claim and it is possible to argue not only novelty but also involvement of an inventive step.

However, in terms of determination of patent infringement, there are court precedents that are based on the process limitation theory at least in the United Kingdom, as mentioned above. In addition, in Taiwan, the “Directions for Determining Patent Infringement⁴²,” pub-

lished by the Taiwan Intellectual Property Office on February 5, 2016, adopt the “product identity theory” in cases where a claim falls under “authentic product-by-process claims” and the “process limitation theory” in cases where a claim falls under “inauthentic product-by-process claims,” in finding the scope of rights, by using the similar distinction as the distinction between “authentic” and “inauthentic” product-by-process claims indicated by the Grand Panel of the Intellectual Property High Court in Japan in 2012. Although these “Directions” were published by the Taiwan Intellectual Property Office, they are positioned as those used by the court for reference. Furthermore, in other countries and regions, such as India, the scope of rights covered by a product-by-process claim is not sufficiently predictable not only for third parties but also for patentees due to lack of well-established court precedents.

4. Conclusion

In many countries and regions, it is generally difficult to indicate differences from prior art when using a product-by-process claim because the claim is construed as being directed to the product irrespective of the recited manufacturing process. Moreover, in some cases, the clarity of a product-by-process claim is also questioned, though there is a difference in the strictness of the required clarity. Furthermore, it also seems necessary to consider whether or not a claim is determined as a product-by-process claim based on an expression that can be formally or idiomatically recognized as expressing a manufacturing process, in consideration of the art to which the invention pertains and the level of persons

ordinarily skilled in the art, etc. as in the recent discussions and handling by the JPO and the courts in Japan.

Furthermore, even if an applicant can obtain a patent based on the recitation of a product-by-process claim, the scope of rights may be limited for some countries and regions due to the use of the process limitation theory in the determination of patent infringement. Even in Japan, there may be difficult cases in the future where the scope of rights is uncertain depending on the determination of the aforementioned “apparent product-by-process claim” where it may mean that the manufacturing process recited in the claim may be substantially ignored or the determination that the claim is a product-by-process claim which may lead to invalidation due to lack of clarity. That is, from the perspective of patentees, there may be situations where the scope of rights differs depending on countries and regions even if the recitation of the claim is the same.

For these reasons, it can be said that a product-by-process claims is generally risky and is a form of claim that should be avoided whenever possible, and an applicant should use it based on sufficient intention if he/she chooses to do so.

(Notes)

- ¹ 2012 (Ju) 1204, Supreme Court of Japan, June 5, 2015, “Provisional English translation of the decision” URL <http://www.courts.go.jp/app/hanrei_en/detail?id=1365>
- ² 2012 (Ju) 2658, Supreme Court of Japan, June 5, 2015, “Provisional English translation of the decision” URL <http://www.courts.go.jp/app/hanrei_en/detail?id=1364>
- ³ 2010(Ne)10043, IP High Court, January 27, 2012, “English Summary and full text of the decision”: URL: http://www.ip.courts.go.jp/eng/hanrei/g_panel/index.html
- ⁴ Kyowa Hako Kirin Co., Ltd. “Regarding the closing of the actions concerning pravastatin,”

- December 16, 2015 (*Only in Japanese) URL <http://www.kyowa-kirin.co.jp/news_releases/2015/pdf/20151216_01.pdf>
- ⁵ For example, Masaru Nakajima and Kenji Yamaguchi “Outline of the Supreme Court Judgments on Product-by-Process Claims” AIPPI Journal, November 2015.
 - ⁶ Japan Patent Office “Examination Guidelines for Patent and Utility Model in Japan: Part II Chapter 2 Section 3 Clarity Requirement 4.3 Expression specifying a product by a manufacturing process” URL <http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/files_guidelines_e/02_0203_e.pdf> Although the citations in the text are from the current Examination Guidelines which have been applied to examinations on and after October 2016 (in other words, after the Supreme Court decisions), there were similar statements in the old Examination Guidelines which were applied to examinations until September 30, 2015.
 - ⁷ Tomonori Yagi “Handling Procedures for Patent Examinations involving Product-by-process Claims” Tokugikon No. 282 (September, 2016) (*Only in Japanese) URL <<https://tokugikon.smartcore.jp/uploads/ckfinder/files/gikonshi-latest/282tokusyul-3.pdf>>
 - ⁸ URL <http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/product_process_C150706_e.htm>
 - ⁹ URL <http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/1312-002_e.htm>
 - ¹⁰ URL <http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/handbook_sinsa_e.htm>
 - ¹¹ URL <http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/pdf/product_process_C151125_e/pbpc_sankourei_e.pdf>
 - ¹² URL <http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/pdf/product_process_C160127_e/pbpc_higaitou_e.pdf>
 - ¹³ URL <http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/pdf/product_process_C151125/eigo_20151001_0000.pdf>
 - ¹⁴ Japan Patent Office “Handling Procedures for Examinations involving Product-by-process Claims” URL <https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/product_process_C151125_e.htm>
 - ¹⁵ (*Only in Japanese) URL <http://www.jpo.go.jp/torikumi/t_torikumi/product_process_C.htm>
 - ¹⁶ The results of surveys are summarized in FY2015 JPO-commissioned research study report on the issues related to the industrial property rights system titled “Handling of

- Product-by-Process Claims in Examination Procedures.” Incidentally, in this report, surveys were conducted on documents and court precedents concerning product-by-process claims in Japan and other countries, and a questionnaire survey was also conducted with local law firms outside Japan. (*Only in Japanese)
- URL <http://www.jpo.go.jp/shiryoutoushin/chousa/pdf/zaisanken/2015_13.pdf>
- ¹⁷ URL <http://www.jpo.go.jp/tetuzuki_e/tokkyo_e/files_handbook_sinsa_e/02_e.pdf#page=36>
- ¹⁸ URL <http://www.jpo.go.jp/tetuzuki_e/tokkyo_e/files_handbook_sinsa_e/02_e.pdf#page=40>
- ¹⁹ URL <https://www.jpo.go.jp/tetuzuki_e/tokkyo_e/pdf/outline_guideline_patents/outline.pdf>
- * The cited figure is indicated on slide 58.
- ²⁰ (*Only in Japanese) URL <https://www.jpo.go.jp/toiawase/faq/sinpan_q.htm>
- ²¹ (*Only in Japanese) URL <https://www.jpo.go.jp/toiawase/faq/pdf/sinpan_q/tokkyo_igi_moushitate.pdf>
- ²² (*Only in Japanese) URL <http://www.jpo.go.jp/shiryou/kijun/kijun2/sinpan-binran_16kouhyou.htm>
- ²³ (*Only in Japanese) URL <https://www.jpo.go.jp/tetuzuki/sinpan/sinpan2/pbp_teisei_sinpan.htm>
- ²⁴ Ryuichi Shitara, “PBP saikōsaihanketsu to jitsumujō no shomondai” (Supreme Court decisions concerning PBP claims and practical problems), *Law and Technology*, no. 73 (October 2016).
- ²⁵ Meaning Documents 5 and 6 out of the aforementioned documents published by the JPO.
- ²⁶ URL <<https://www.uspto.gov/web/offices/pac/mpep/s2173.html#d0e218855>>
- ²⁷ URL <<https://www.uspto.gov/web/offices/pac/mpep/s2163.html>>
- ²⁸ URL <<https://www.uspto.gov/web/offices/pac/mpep/s2113.html>>
- ²⁹ URL <<http://www.cafc.uscourts.gov/sites/default/files/opinions-orders/07-1400.pdf>>
- ³⁰ URL <http://www.epo.org/law-practice/legal-texts/html/guidelines/e_f_iv_4_12.htm>
- ³¹ However, due to the issue relating to the invention of a plant or animal obtained by an essentially biological process, the European Patent Office decided to stay all proceedings in examination and opposition cases on December 12, 2016.
- EPO website “EPO stays proceedings in certain biotechnology cases” URL <<https://www.epo.org/news-issues/news/2016/20161212.html>>
- ³² Ibid. 16, p. 71-77 (Germany and U.K.) Darren Smyth “Hospira v Genentech - revocation of patents confirmed on appeal” (U.K.) The IPKat (July 29, 2016) URL <<http://ipkitten.blogspot.jp/2016/07/hospira-v-genentech-revocation-of.html>>
- ³³ URL <<http://www.wipo.int/wipolex/en/details.jsp?id=6511>>
- ³⁴ URL <<http://www.wipo.int/wipolex/en/details.jsp?id=5484>>
- ³⁵ A provisional English translation prepared by CCPIT PATENT AND TRADEMARK LAW OFFICE is available at the below URL. URL <<http://www.ccpit-patent.com.cn/node/3219/3218>>
- ³⁶ KIM & CHANG “IP Newsletter | Spring 2015” URL <http://www.kimchang.com/newsletter/20150210/ip/fra/newsletter_ip_fra_spring2015_article01.html>
- ³⁷ U.K. Intellectual Property Office “Manual of Patent Practice: 14.120.1 Product by Process claims” (December 2016) URL <<https://www.gov.uk/guidance/manual-of-patent-practice-mopp/section-14-the-application#product-by-process-claims>>
- ³⁸ American Intellectual Property Law Association “Chemical Practice Chronicles Quarterly Newsletter of the AIPLA Chemical Practice Committee Spring 2014 Volume 2, Issue 2” URL <http://www.aipla.org/committees/committees_pages/Chemical-Practice/Committee%20Documents/Newsletters%20-%20Chemical%20Practice%20Chronicles/2014/Newsletter%20Spring%202014.pdf>
- ³⁹ Information on Foreign Industrial Property Systems (Link to Provisional Japanese Translation of Examination Guidelines) URL <http://www.jpo.go.jp/shiryou/s_sonota/fips/mokuji.htm#taiwan>
- ⁴⁰ Indian Patent Office “Guidelines for examination of patent applications in the field of Pharmaceuticals: 7.9 Product-by-process claims” (October 2014) URL <http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_37_1_3-guidelines-for-examination-of-patent-applications-pharmaceutical.pdf>
- ⁴¹ Indian Patent Office “Guidelines for Examination of Biotechnology Applications for Patent: 7.1. PRODUCT-BY-PROCESS CLAIMS” (March 2013) URL <http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf>

⁴² Taiwan Intellectual Property Office “TIPO completes revision to Directions for Determining Patent Infringement” (Overview Only)
URL < <https://www.tipo.gov.tw/ct.asp?xItem=585780&ctNode=6687&mp=2> >