



Influences of the Supreme Court Decisions in June 2015 on the Practice of Product-by-Process (PBP) Claims

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ABSTRACT

Almost two years have passed since the Supreme Court of Japan (SCJ) rendered controversial decisions concerning the claim construction and clarity requirement of product-by-process (PBP) claims (2012 (ju) No.1204 and No.2658, both handed down on June 5, 2016; so-called “Pravastatin” cases), which have radically altered the environments surrounding PBP claims in Japan. This article summarizes changes in the JPO’s examination practice after the SCJ decisions, and explains important points for the patent applicants/holders to remember in terms of patent prosecution and litigation practice relating to PBP claims.

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1. Rulings by the SCJ Decisions:

The main rulings by the Supreme Court of Japan (SCJ) in its decisions concerning the claim construction and clarity requirement of product-by-process (PBP) claims (2012 (ju) No.1204 and No.2658, both handed down on June 5, 2016) are as follows:

*Re: Gist of the invention defined by a PBP claim at prosecution:

“(w)hen a claim defining a product recites a process of production of the product, the gist of the invention shall be determined as covering any product which is identical to the product produced by the claimed process in terms of structure, characteristics, etc.” (SCJ decision 2012 (ju) No.2658, held on June 5, 2016)

*Re: Technical scope of the patent invention defined by a PBP claim at litigation:

“(w)hen a patent claim defining a product recites a process of production of the product, the technical scope of the patented invention shall be determined as covering any product which is identical to the product produced by the claimed process in terms of structure, characteristics, etc.”(SCJ decision 2012 (ju) No.1204, held on June 5, 2016)

*Re: Clarity of the invention defined by a PBP claim:

“(w)hen a claim defining a product recites a process of production of the product, the requirement that “the invention shall be clear” as prescribed in Article 36, paragraph 6, item 2 of the Patent Law can be satisfied only when there were such circumstances where it was impossible or utterly impractical to directly define the product based on its structure or characteristics at the time of filing of the application.” (SCJ decisions 2012 (ju) No.1204 and No.2658, both held on June 5, 2016)

These rulings by these SCJ decisions can be summarized as follows:

- (i) With regard to the claim construction issue, the SCJ ruled that a PBP claim shall cover any product which is identical to the claimed product, regardless of whether it was actually produced by the claimed process. This means that a PBP claim encompasses a product which was produced by a different process from the process recited in a PBP claim but is indistinguishable from the claimed product as a product, both at prosecution and at litigation.
- (ii) With regard to the clarity issue, the SCJ set a new standard: a PBP claim is deemed clear only when there were such circumstances where it is impossible or utterly impractical to directly define the product based on its structure or characteristics at the time of filing of the application (hereinafter “impossible/impractical circumstances”). The SCJ’s such ruling caused considerable confusion in the JPO’s examination practice for a while, as will be explained below.



(iii) In relation to the rulings (i) and (ii) above, the SCJ used the expression “*when a patent claim drawn to an invention relating to a product includes a statement relating to a process of a production of the product*”. This means that the SCJ interpreted the term “PBP” claims very broadly, i.e., that the SCJ’s above rulings apply not only to product claims reciting a full process of production of the claimed product (i.e., “PBP” claims in a limited sense), but also to product claims reciting only a part of a process for producing such a product (i.e., “PBP” claims in a very broad sense).

2. Influences of the SCJ’s rulings on the Prosecution Practice of PBP Claims

(1) JPO’s Changes to its Examination Practice in response to the SCJ Decisions:

In response to the SCJ decisions, the JPO made several changes to its examination practice of PBP claims as follows:

- (i) June 10, 2015: The JPO announced that it would halt examination of PBP claims for a while.
- (ii) July 5, 2015: The JPO announced the “*Interim Examination Guidelines about PBP Claims*”, and resumed examination of PBP claims based thereon. As a result, the JPO started issuing a considerable number of Office Actions including clarity objections to PBP claims.
- (iii) September 16, 2015: The JPO revised the “*Examination Guidelines for Patent and Utility Model in Japan*” (hereinafter the Examination Guidelines) and the “*Examination Handbook for Patent and Utility Model in Japan*” (hereinafter the Examination Handbook), by incorporating the contents of the “*Interim Examination Guidelines*” in item (ii) above into the “*Examination Handbook*” as sections 2203 to 2205 (effective from October 1, 2015).
- (iv) November 25, 2015: The JPO announced the “*Examples of Allegations and Proof that There Were ‘Impossible/Impractical Circumstances’*”.
- (v) January 27, 2016: The JPO announced a number of new examples of claims not corresponding to PBP claims.
- (vi) March 28, 2016: The JPO announced a trial decision in a trial case for correction (post-grant amendment) which allowed a correction of a patented PBP claim by changing the category of the claimed invention from a product to a process for producing a product for the first time.
- (vii) March 30, 2016: The JPO revised the Examination Handbook again, by incorporating the examples in items (iv) and (v) above into sections 2204 and 2205 of the Examination Handbook along with a significant number of



examples, and also adding a statement that “*even when a product claim literally corresponds to one of the types and examples of PBP claims mentioned in section 2204, the Examiner shall not consider that the claimed invention fails to comply with the clarity requirement at least for that reason, provided that it is clearly understandable as to what structure or characteristics of the product are represented by the claimed process, taking into consideration the description, claims and drawings as well as technical common knowledge at the time of the filing of the application in the art to which the invention belongs*” (effective from April 1, 2016). As a result, the number of Office Actions issued by the JPO including clarity objections to PBP claims significantly decreased.

(2) Basic Idea of Examination according to the Revised Examination Guidelines:

The JPO’s revised Examination Guidelines summarize the basic idea of how to examine the clarity requirement for PBP claims in PART II, Chapter 2, Section 3 “*Clarity Requirement*”, subsection 4.3 “*Cases where claims include an expression specifying a product by a manufacturing process*” as follows:

Item 4.3.1 of this subsection (“*Types of unclear inventions*”) states that PBP claims are considered as being unclear when **(1) the feature of the claimed process cannot be understood from the claim statement**, or **(2) the feature of the claimed product cannot be understood from the claim statement**, even taking the specification, etc., and technical common knowledge. These two types were also mentioned in the previous Examination Guidelines before the SCJ decisions. This means that the basic framework of clarity examination for PBP claims was not changed before and after the SCJ decisions.

Item 4.3.2 of this subsection (“*Cases where a claim drawn to an invention of a product includes a manufacturing process of a product*”) states that **PBP claims shall be deemed clear only when there were such circumstances where it was impossible or utterly impractical to directly define the product based on its structure or characteristics at the time of filing of the application**. This reflects the SCJ’s ruling (ii) mentioned above. The detailed procedure for judging this requirement is not explained in the Examination Guidelines but in the Examination Handbook as will be summarized below.

Item 4.3.3 of this subsection (“*Points to note*”) states that in the examination of novelty and inventive step, **the gist of the invention according to a PBP claim shall be determined as covering any product which is identical to the product produced by the claimed process in terms of the structure and characteristics**. This reflects the SCJ’s ruling (i) mentioned above.



(3) Examination Procedure according to the Revised Examination Handbook:

The detailed procedure for judging the clarity requirement for PBP claims is prescribed in the revised Examination Handbook, PART II, Chapter 2, sections 2203 to 2205, which are summarized as follows:

***Basic flow of examination of the clarity requirement for a PBP claim**

(Examination Handbook, section 2203: see Annex 1 for details)

Section 2203 of the Examination Handbook (“*Points to Note in Examination When a Claim for an Invention of a Product Recites the Manufacturing Process of the Product*”) outlines the basic flow of examination of the clarity requirement in relation to PBP claims. According to this flow, for each claim drawn to a product, the Examiner first judges **whether or not the product claim corresponds to a PBP claim (Step 1)**, in accordance with section 2204 of the Examination Handbook. If it is determined that the claim corresponds to a PBP claim, then the Examiner judges **whether there were “impossible/impractical circumstances” for the PBP claim (Step 2)**, in accordance with section 2205 of the Examination Handbook. If it is determined that there were no “*impossible/impractical circumstances*” for the PBP claim, then the Examiner issues an objection to the PBP claim as being unclear (Step 3).

***Step 1: Whether a product claim corresponding to a PBP claim**

(Examination Handbook, section 2204: see Annexes 2 and 3 for details)

Section 2204 of the Examination Handbook (“*Determination on Whether or Not ‘When a Claim for an Invention of a Product Recites the Manufacturing Process of the Product’ is Relevant*”) defines the procedure for judging whether a claim drawn to a product corresponds to a PBP claim. This section mentions three types of claims corresponding to PBP claims (Types (1-1) to (1-3) below) and one type of claims not corresponding to PBP claims (Type (2) below), and enumerates various examples for each of the types (see Annexes 2 and 3 for details of the examples).

***Types of claims corresponding to PBP claims:**

Type (1-1): Product claims including a time-dependent element relating to a process

Type (1-2): Product claims including a statement about technical features and/or conditions relating to a process

Type (1-3): Product claims referring to an invention drawn to a process

***Type of claims not corresponding to PBP claims:**

Type (2): Product claims reciting a state of a product simply for defining a structure or characteristics of the product.



In the revisions to the Examination Handbook on March 30, 2016 (effective from April 1, 2016), the JPO added numerous examples for the type of claims not corresponding to PBP claims, and also added the statement that “*even when a product claim literally corresponds to one of the types and examples of PBP claims mentioned in section 2204, the Examiner shall not consider that the claimed invention fails to comply with the clarity requirement at least for that reason, provided that it is clearly understandable as to what structure or characteristics of the product are represented by the claimed process, taking into consideration the description, claims and drawings as well as technical common knowledge at the time of the filing of the application in the art to which the invention belongs*”. These revisions significantly reduced the possibility that product claims be considered as corresponding to PBP claims (especially in the technical fields of mechanics and electronics). As a result, the number of clarity objections to PBP claims significantly decreased from April 2016.

***Step 2: Whether there were “Impossible/Impractical Circumstances” for a PBP claim (Examination Handbook, section 2205: see Annexes 4 to 6 for details)**

Section 2205 of the Examination Handbook (“*Determination on ‘Impossible/ Impractical Circumstances’ in Examination When a Claim for an Invention of a Product Recites the Manufacturing Process of the Product*”) defines the procedure for judging whether there were any “*impossible/impractical circumstances*” for a PBP claim. This section mentions two types of cases where “*impossible/impractical circumstances*” are found (Types (i) and (ii) below) and one type of cases where “*impossible/impractical circumstances*” are not found (Type (iii) below), and enumerates a few examples for each type (see Annexes 4 and 5 for details of the examples).

Types of cases where “impossible/impractical circumstances” are found:

Type (i): Cases where analyzing the structure or characteristics of the claimed product was technically impossible at the filing date.

Type (ii): Cases where identifying the structure or characteristics of the claimed product required an undue amount of cost and/or time, especially in view of the fact that the patent application should have been filed as soon as possible.

Type of cases where “impossible/impractical circumstances” are not found:

Type (iii): Cases where such circumstances are not specifically explained in relation to the claimed invention.

In addition, after two additional revisions made on March 30 and September 28, 2016, section 2205 now recites three specific examples for “*Types of cases where ‘impossible/impractical circumstances’ are found*” as follows. If the invention according to a PBP claim belongs to the technical field of any of the examples (a) to (c) below, the JPO basically deems that there were “impossible/impractical circumstances” for the claim, even if the applicant makes no specific arguments as to such circumstances.



- (a) A cell produced by a new gene technique (cf. the SCJ decisions for Cases H24 (ju) Nos. 1204 and 2658).
- (b) A monoclonal antibody produced by hybridoma A (cf. the JPO's Trial Decision in Case No. 2014-17732).
- (c) An animal/plant obtained by a cross-breeding method (cf. the JPO's Trial Decision in Case No. 2014-10863).

Section 2205 also includes five specific examples of recommendable arguments about “impossible/impractical circumstances”, and categorized these examples into the following four typical arguments (see Annex 6 for details).

(4) Applicant's Measures to Overcome Clarity Objections according to the Revised Examination Handbook (see Annex 7 for details):

Section 2203 of the Examination Handbook states that the applicant who receives a clarity objection to a PBP claim can choose one of the following five measures for overcoming the objection.

- (a) Cancellation of the claim.
- (b) Amendment to change the claim into a claim drawn to a process for producing a product.
- (c) Amendment to change the claim into a claim drawn to a product without any process limitation.
- (d) Allegation and proof that there were any “impossible/impractical circumstances” via, e.g., filing a written argument.
- (e) Allegation that the claim does not correspond to a PBP claim.

Section 2203 of the Examination Handbook also states that when the purposes of possible amendments are limited under Article 17-2, paragraph 5 of the Patent Law, such as when responding to a final Notice of Reasons for Rejection or when demanding an appeal against a Decision of Final Rejection, an amendment made under item (b) or (c) above is normally considered as corresponding to clarification of an unclear statement as prescribed in Article 17-2, paragraph 5, item 4 of the Patent Law, and thereby satisfying the requirement prescribed in Article 17-2, paragraph 5 of the Patent Law.

(5) Problems Involved in Trial Examination Practice:

With regard to trial cases involving correction (post-grant amendment) of PBP claims, such as trials for correction or requests for correction in the proceeding of invalidation trials, the JPO announced



that it would carry out trial examination of such cases basically in accordance with the revised examination practice.

However, section 2205 of the Examination Handbook also states that in the trial examination of post-grant procedures, the results of judgment as to whether there were “impossible/impractical circumstances” may vary depending on the contents of the allegation and proof by both parties. Accordingly, it will be more difficult to predict as to whether arguments as to “impossible/impractical circumstances” can be allowed in post-grant procedures than in examination procedure.

In addition, post-grant amendments (such as trials for correction or requests for correction in invalidation trials) must satisfy, in addition to the requirements for amendments in the examination, the additional requirement prescribed in Article 126, paragraph 6 of the Patent Law, which recites that the correction shall not substantially expand or alter the claimed invention. This raises a question as to whether a post-grant amendment (correction) to change a PBP claim into a process claim or into a product claim without any process limitation (i.e., option (b) or (c) recited in section 2203 of the Examination Handbook) can satisfy the requirement under Article 126, paragraph 6 of the Patent Law.

Although no specific guidelines have been issued for such post-grant amendments, the JPO announced on March 28, 2016, that it accepted a post-grant amendment (correction) changing a PBP claim to a claim drawn to a process for producing a product (i.e., a change in claim category) accepted in a specific trial decision (Correction Trial Case No. 2016-390005). According to this trial decision, the JPO appears to deem that a post-grant amendment involving a change in claim category satisfies the requirement under Article 126, paragraph 6 of the Patent Law, provided that (i) the amendment does not substantially alter the problem to be solved by the invention and/or the means to solve the problem, and that (ii) the amendment does not render the resultant claim newly cover an act which was not covered by the original claim, and thereby cause any unexpected disadvantage on a third party.

3. Q's &A's about Prosecution and Litigation relating to PBP claims

(1) Questions about Prosecution involving PBP Claims:

Q1: How should a product claim be drafted so as not to be deemed a PBP claim?

A1: As explained above, section 2204 of the Examination Handbook mentions three types of claims corresponding to PBP claims and one type of claims not corresponding to PBP claims, and enumerates various examples for each of the types (see Annexes 2 and 3 for details). Therefore, we recommend drafting product claims in view of the types and examples mentioned in this section,



i.e., avoiding the types and examples of claims corresponding to PBP claims and following the type and examples of claims not corresponding to PBP claims. Specifically, it would be advisable to avoid using a time-dependent statement relating to a process (Type (1-1)), a statement about technical features and/or conditions relating to a process (Type (1-2)), or a reference to an invention drawn to a process (Type (1-3)). If it is difficult to avoid reciting a feature relating to a process, then it would be advisable to recite such a process feature using a statement reciting a state of a product simply for defining a structure or characteristics of the product (Type (2)).

Q2: How should “impossible/impractical circumstances” be argued for a PBP claim?

A2: Section 2205 of the Examination Handbook mentions that the applicant can “impossible/impractical circumstances” by submitting a written argument in the examination process. Accordingly, it is not necessary to describe “impossible/impractical circumstances” in the original specification. We rather recommend deferring arguing such circumstances until after receiving a clarity objection, since describing such circumstances in the specification may unexpectedly be detrimental to the patentability of foreign counterpart applications in the prosecution stage and/or to the enforcement of foreign counterpart patents in the litigation stage.

As explained above, section 2205 of the Examination Handbook states two types of cases where “*impossible/impractical circumstances*” are found and one type of cases where “*impossible/impractical circumstances*” are not found (see Annexes 4 and 5 for details). This section also mentions five specific examples of recommendable arguments about “*impossible/impractical circumstances*”, and categorized these examples into the following four typical arguments (see Annex 6 for details). It would therefore be advisable to make arguments of “*impossible/impractical circumstances*” in view of these types and examples. However, we also recommend making such arguments as simple as possible, since explaining the existence of such circumstances in too much detail may unexpectedly be detrimental to the enforcement of the resultant patent in the litigation stage.

Q3: In view of the SCJ’s rulings, which claim format is most advantageous: product claims without any process limitation, process claims, and PBP claims?

A3. In principle, the claim format should be determined based on the essential feature of the invention. Specifically, if the product according to the invention can directly be defined based on its structure or characteristics, then product claims are most recommendable, while if such a definition is “impossible/impractical”, then PBP claims will be the first option. On the other hand, if the essential feature of the invention resides in the process of producing the product rather than the product itself, then the invention will be best drafted in the form of process claims.



Nevertheless, since the future changes in the JPO's examination practice and the court's litigation practice are unpredictable, we recommend drafting the claims using different claim formats, in order to protect the same invention from multiple aspects.

Q4: Is it at all possible to obtain a patent for a product invention using both product claims without process limitation and PBP claims? Specifically, if the product according to the invention can directly be defined based on its structure or characteristics, then PBP claims will not be allowed. On the other hand, if the product according to the invention cannot directly be defined based on its structure or characteristics, then it will not be able to use product claims without process limitation. Thus, it appears that a product claim without process limitation and a PBP claim cannot co-exist for covering the same product invention.

A4. It will normally be difficult to cover the same product invention using both a product claim without process limitation and a PBP claim. Nevertheless, there may be some cases where the same product invention can be defined from multiple different aspects. In such cases, the same product invention can be covered by a product claim without process limitation and a PBP claim overlapping with each other (the JPO admits in its explanation materials about PBP claims that such cases may exist). For example, If the invention relates to newly-found stem cells produced by introduction of a specific set of genes, it will normally be "impossible/impractical" to directly define the stem cells based on its structure or characteristics. Accordingly, the first choice of claim format for defining the stem cells will be a PBP claim. However, if it is also found that the novel stem cells express a novel cell marker which may also be expressed by some different cells, then it will also be possible to define the stem cells based on this novel cell marker. Thus, there will be a possibility that the same product invention can be defined both using a product claim without process limitation and a PBP claim, provided that the product claim and the PBP claim are not identical to each other but overlap with each other.

(2) Questions about Litigation involving PBP Claims:

Q1: If the applicant obtains a patent for a PBP claim by arguing/proving "impossible/impractical circumstances", it will be extremely difficult to prove that an allegedly infringing product is identical to the claimed product, since the argument/proof of "impossible/impractical circumstances" will act as a so-called file wrapper estoppel. Thus, it will practically be impossible to enforce the resultant PBP claim on an allegedly infringing product unless it was actually produced by the process recited in the claim. Accordingly, the scope of a PBP claim is substantially the same as the scope of a process claim, which can also be enforced on the product produced by the claimed process. Based on these premises, is there any advantage to obtain a patent for a PBP claim?



A1: We believe that it will be difficult to prove that an allegedly infringing product is identical to the claimed product. Nevertheless, in a rapidly-progressing technical field, there may be cases where it is “impossible/impractical” to directly define the product based on its structure or characteristics at the time of filing of the application, but it subsequently becomes possible to directly define the product based on its structure or characteristics at the time when the application is granted a patent. There may also be cases where the analysis data of the claimed product is insufficient to directly define the product based on its structure or characteristics, but sufficient to prove that the claimed product is identical to an allegedly infringing product. In these cases, PBP claims will be more advantageous than the corresponding claim claims. In addition, even when enforcing a PBP claim on a product produced by the claimed process, it will not be necessary to prove that the alleged infringer carries out all of the claimed steps, which is often be a problem when enforcing a process claim. Taking all these points into consideration, we believe that it is still of strategic significance to obtain a patent for PBP claims depending on circumstances.

Q2: How should patents already granted with PBP claims be treated?

A2: Since the JPO’s trial examination practice are still not completely clear, it is not always necessary to take any actions to all the patents involving PBP claims at the moment. Still, we recommend reviewing at least important patents to filter ones whose claims are likely to be considered as PBP claims, and remedying (or preparing remedy for) such PBP patents by post-grant amendments (corrections) or by allegation/proof of “*impossible/impractical circumstances*”.

END



Annex 1: Examination chart as to whether a PBP claim satisfies the clarity requirement (Examination Handbook, section 2203)

Step 1: Examine whether a product claim corresponds to a PBP claim in accordance with Examination Handbook, section 2204.

If affirmative... ↓

Step 2: Examine whether there are any impossible/impractical circumstances for the PBP claim in accordance with Examination Handbook, section 2205.

If negative... ↓

Step 3: Issue a reason for rejection due to non-compliance with the clarity requirement under Article 36, paragraph 6, item 2 of the Patent Law.

Annex 2: Types and examples of claims corresponding to PBP claims (Examination Handbook, section 2204)

*Type (1-1): Product claims including a time-dependent element relating to a process

Example:

“Sodium salt of Compound A prepared by a process comprising:

- a) forming an organic solution of Compound A;
- b) precipitating Compound A as ammonium salt;
- c) purifying the ammonium salt by recrystallization;
- d) transposing the ammonium salt into sodium salt; and
- e) isolating the sodium salt of Compound A.”

*Type (1-2): Product claims including a statement about technical features and/or conditions relating to a process

Examples:

“Polymer C obtained by reacting monomer A with monomer B at 50°C”

“A fluorescent body formed by sintering under 1 to 1.5 atmospheric pressures”

“A rubber product with an exterior surface onto which roughening treatment has been applied by causing particulate substances to collide with the exterior surface”

*Type (1-3): Product claims referring to an invention drawn to a process

Examples:



“A rubber composition manufactured by the process as defined in any one of claims 1 to 8”

“A polymer produced by the method according to any one of claims 1 to 4”

Note: Even when a product claim includes a statement relating to a process and formally corresponds to any of these types of claims corresponding to PBP claims, it shall not be objected to as being unclear if the structure or characteristics of the product defined by the process statement can clearly be understood (revised on March 30, 2016).

Annex 3: Types and examples of claims not corresponding to PBP claims (Examination Handbook, section 2204)

*Type (2): Product claims reciting a state of a product simply for defining a structure or characteristics of the product.

Examples:

“A cured product of a resin composition”

“An article comprising an affixed chip bonded to a sensor chip”

“A tire produced using a rubber composition”

“A laminated film formed by interposing layer C between layer A and layer B”

“An isolated cell”, “An extracted product”, “A plated layer”, “Removably configured”

“Member X welded to a member Y”, “A chamfered member”,

“A lid caulked to a body”, “Spun twisted yarn using roving X and roving Y”,

“A pigment coated with polymer X”, “A polymer polymerized monomer X and monomer Y”

“A PEGylated protein”, “A modified protein after translation”, “A humanized antibody”

“A protein having an amino acid sequence represented by SEQ ID NO:1 in which at least one amino acid is deleted, substituted or added”

Terms whose concept is established as those specifying the structure or characteristics of products (e.g., terms whose definitions, etc., can be found in a dictionary, a textbook, or a technical standards document, and are considered as effectively identifying a structure or characteristics of a product based on the definitions)

“A cast metal”, “A cast product”, “A forged product”, “A welded part”, “A brazed part”,

“A soldered part”, “A fusion-spliced part”, “A machined part”, “A cut off part”,

“A ground surface”, “A press-fit surface”, “A press-fit structure”, “A sintered object”,

“A compacted pellet”, “An oriented film”, “A blown film”, “Printed parts”,

“A printed coil”, “A printed capacitor”, “A coating film”, “A vapor-deposited film”,

“A coating layer”, “A diffusion layer”, “An epitaxial layer”, “An epitaxial growth layer”,

“Float glass”, “A hot-dip zinc-coated steel sheet”, “Vulcanized rubber”,

“An embossed product”, “A welded assembly”, “An integrally molded article”

Annex 4: Types and examples of cases where “impossible/impractical circumstances” are found (Examination Handbook, section 2205)



*Type (i): Cases where analyzing the structure or characteristics of the claimed product was technically impossible at the filing date.

*Type (ii): Cases where identifying the structure or characteristics of the claimed product required an undue amount of cost and/or time, especially in view of the fact that the patent application should have been filed as soon as possible.

Examples:

(a) A cell produced by a new gene technique

(cf. the SCJ decisions for Cases H24 (ju) Nos. 1204 and 2658)

(b) A monoclonal antibody produced by hybridoma A

(cf. the JPO's Trial Decision in Case No. 2014-17732)

(c) An animal/plant obtained by a cross-breeding method

(cf. the JPO's Trial Decision in Case No. 2014-10863)

Annex 5: Types and examples of cases where “impossible/impractical circumstances” are not found (Examination Handbook, section 2205)

*Type (iii): Cases where such circumstances are not specifically explained in relation to the claimed invention.

Examples:

* Case where the applicant merely argues that drafting the claims based on a structure or characteristics of the product required undue amount of time.

* Case where the applicant merely argues that the claimed product is more easily understood when defined by a process rather than when defined by a structure or characteristics.

Annex 6: Examples of Arguments that there were “impossible/impractical circumstances” (Examination Handbook, section 2205)

Example	Subject matter	Gist of Argument
Example 1	“An aromatic device”	Typical Argument A: Cases where the applicant specifically explains in the written argument that it was impossible to find a claim statement that defines a structure or characteristics reflecting the difference between the claimed product and the prior art, and it was also impossible or impractical to analyze and define the structure or characteristics of the claimed product based on any measurement.
Example 2	“A thin-film semiconductor device”	
Example 3	“An oil-in-water type creamy emulsion composition”	Typical Argument B: Cases where the applicant specifically explains in the written argument that it was impossible or impractical to directly define the claimed



		product based on its structure or characteristics, since specific embodiments of the structure or characteristics of the claimed product largely vary depending on specific embodiments of the process of production recited in the claim, and it was also difficult to find a generic statement that can collectively cover such specific embodiments of the structure or characteristics of the claimed product.
Example 4	“A flavor improving agent”	Typical Argument C: Cases where the applicant specifically explains in the written argument that it was impossible or impractical to directly define the claimed product based on its structure or characteristics, since the product is derived from a naturally-occurring product.
Example 5	“A polymerized composition”	Typical Argument D: Cases where the applicant specifically explains in the written argument that it was impossible or impractical to directly define the product based on its structure or characteristics, since the product is derived from a polymer that may have a variety of complex structures.

Annex 7: Possible measures the applicant can make in response to a clarity objection to a PBP claim (Examination Handbook, section 2203)

- (a) Cancellation of the claim.
- (b) Amendment to change the claim into a claim drawn to a process for producing a product.*
- (c) Amendment to change the claim into a claim drawn to a product without any process limitation.*
- (d) Allegation and proof that there were any “impossible/impractical circumstances” via, e.g., filing a written argument.
- (e) Allegation that the claim does not correspond to a PBP claim.

*: When the purposes of possible amendments are limited under Article 17-2, paragraph 5 of the Patent Law, such as when responding to a final Notice of Reasons for Rejection or when demanding an appeal against a Decision of Final Rejection, an amendment made under item (b) or (c) above is normally considered as corresponding to clarification of an unclear statement as prescribed in Article 17-2, paragraph 5, item 4 of the Patent Law, and thereby satisfying the requirement prescribed in Article 17-2, paragraph 5 of the Patent Law.

END