



HISAO SHIOZAWA
MASAZUMI IMAMURA
JUNJI KAMATA
MAKOTO AIHARA

SHIOZAWA, IMAMURA & KAMATA
Patent Attorneys

YUMIKO YAMADA
SHUNICHI SUGAWARA
HISAKO NOZAKI

SHIHO WATANABE
MARIKO MATSUKAWA
YOSHINOBU MUROFUSHI

8TH FLOOR KYOBASHI-NISSHOKU BUILDING
8-7, KYOBASHI 1-CHOME, CHUO-KU
TOKYO 104-0031 JAPAN

MARIKO NOZU
HIDEYO NISHIDA
KAORI INOUE

TEL: 81-3-3538-5680 / FAX: 81-3-3538-5686

E-MAIL: mail@siks.jp

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Product-by-process (PBP) claims in Japan Handling Procedures for Examinations involving PBP Claims

Dear valuable clients and colleagues:

The Japan Patent Office (JPO) published “Handling Procedures for Examinations involving **Product-by-process (PBP) Claims**” on November 25, 2015 which includes Examples of arguments and verification presented by applicants involving “**impossible or impractical circumstances**” concerning PBP claims.

1. Overview

On June 5, 2015, the Supreme Court entered judgments on two cases (2012 (Ju) 1204 and 2012 (Ju) 2658) involving PBP claims, i.e., claims for inventions of products reciting manufacturing processes of the products.

2. Examinations of pending applications

2.1. Interim Handling Procedures for Examinations of pending applications

The JPO has published handling procedures in accordance with the Supreme Court decisions in “interim Handling Procedures for Examinations involving PBP Claims (July 6, 2015).”

- 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) (see below). 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.

- The applicant can also respond to a notice of reasons for refusal by filing an amendment including:

- (i) deleting any claim concerned,
- (ii) amending any claim concerned into a claim concerning an invention of a process for producing a product; and/or
- (iii) amending any claim concerned into a claim concerning an invention of a product which does not recite a manufacturing process, apart from arguing and verifying the existence of "impossible or impractical circumstances" based on a written opinion.

- 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".

2.2. Examples of arguments and verification presented by applicants involving "impossible or impractical circumstances"

- Examples of arguments and verification presented by applicants involving "impossible or impractical circumstances" concerning PBP claims was published on November 25, 2015. See the attachment.

3. Interim Handling of Appeals and Trials

- Appeals/trials, etc. involving product-by-process claims will be examined based on the opinion of the judgments by the Supreme Court, in the same manner as "**2. Interim Handling of Examinations of pending applications**".

- Regarding appeals against any examiner's decision of refusal, when a claim concerning an invention of a product recites a manufacturing process of the product, the appeal examiners will notify the reasons for refusal whenever the invention of a product is not clear. However, this will not be the case when the appeals panel can clearly find, even without inquiring to the subject demandant of an appeal, that "impossible or impractical circumstances" do exist.

- Correction of claims in Invalidation Appeal and Post-Grant Opposition (IA and PGO)

The JPO announced that in IA and PGO, correction of PBP claims in which definition is made with the structure of characteristics of the product or changing to a manufacturing process of the product is allowable under the reason of correction of indefinite (unclear) description under the Art. 120-5, paragraph 2, provisional section 3, of the Patent Law.

However, the correction is not allowed if the correction is "substantial change or enlarge of the scope of the claims" under Art. 126 para. 6 being referred to in 120-5, paragraph 9.

As to assessment of the "substantial change or enlarge of the scope of the claims" we need to wait for appeal decisions from the JPO and decisions from the IP Court.

Please feel free to contact us if you have any questions on this matter.

SIKs & Co.
Tokyo, Japan

**Reference examples of arguments and verification
presented by applicants involving
“impossible or impractical circumstances”
concerning product-by-process claims**

1. Background

The Japan Patent Office (JPO) published interim handling procedures of product-by-process claims¹ (i.e. claims for products reciting manufacturing processes of the products; hereinafter referred to as “PBP claims”) on July 6, 2015 in accordance with the Supreme Court decisions of June 5, 2015², and showed types of examples considered to be PBP claims and those not considered to be PBP claims, as well as types of examples where “impossible or impractical circumstances”^{3,4} are considered to exist and those where the circumstances are not considered to exist. The details of those examples have been reflected in the revised “Examination Handbook for Patent and Utility Model” (hereinafter referred to as “Examination Handbook”. See 2203-2205) published on September 16, 2015. The Examination Handbook did not yet contain any example of arguments and verification which could be considered to show the existence of “impossible or impractical circumstances”.

The JPO has now prepared and hereby publishes reference examples of arguments and verification which can be considered, in patent examination, to show the existence of “impossible or impractical circumstances”, in light of the cases in which arguments and verification for such circumstances were presented.

The JPO will continue to review handling procedures of PBP claims in view of, *inter alia*, adding examples which can be considered to show the existence of “impossible or impractical circumstances” and also examples of claims not

¹ “Interim Handling Procedures for Examinations involving Product-by-process Claims”

² 2012 (Ju) 1204 and 2012 (Ju) 2658

³ Circumstances in which it is impossible or utterly impractical to specify the product directly based on its structure or property at the time of the filing of an application.

⁴ As described in the interim handling procedures of product-by-process claims, if a claim is determined to fall under the PBP claims, a notice of reasons for refusal (violation of the clarity requirement) will be issued except a case where the existence of “impossible or impractical circumstances” is recognized. An applicant can amend a claim to a non-PBP claim, or can submit a written opinion in which the applicant can argue and verify the existence of the circumstances, thereby the reasons for refusal (violation of the clarity requirement) can be resolved.

considered to be PBP claims. Based on the results of the review, the JPO will update the Examination Handbook around the beginning of April 2016.

2. Reference examples of arguments and verification involving “impossible or impractical circumstances”

The followings are reference examples of arguments and verification involving “impossible or impractical circumstances”⁵.

The JPO hereby provides applicants with those examples, for a reference purpose, where the existence of “impossible or impractical circumstances” can be recognized in patent examination, but does not show types of examples in an exhaustive manner. Thus, even if a case does not fall under any of those, it does not necessarily mean that the existence of “impossible or impractical circumstances” for that case cannot be recognized. Conversely, even if the formality of any of the examples below is followed, such circumstances are not always recognized, since, in practice, the existence of “impossible or impractical circumstances” is considered on a case by case basis, taking into account the specific content of arguments and verification. In addition, it is noted that, in procedures in which a third party is involved after a patent is granted, a conclusion on whether the circumstances exist or not may change depending on the contents of arguments and verification presented by the parties.

Regarding PBP claims, when a person skilled in the art cannot understand features of a product (structure, property, etc.) even considering the content of the description and drawings as well as the common general knowledge at the time of the filing of an application, to the extent that patentability requirements such as novelty and inventive step cannot be determined, the invention is deemed to be unclear regardless of the existence of “impossible or impractical circumstances”, since the invention cannot be understood from one claim in such a case⁶. The following examples are shown on the premise that an invention does not involve such unclearness⁷.

⁵ In light of the purpose of the claim system, one invention should be identified based on the matters stated in one claim (“Examination Guidelines for Patent and Utility Model”, Part II, Chapter 2, Section 3, Clarity Requirement, 2.1(1)). This is also applicable to a case where the existence of “impossible or impractical circumstances”.is recognized.

⁶ Examination Guidelines for Patent and Utility Model, Part II, Chapter 2, Section 3, Clarity Requirement, 4.3.1(2).

⁷ Furthermore, the following examples do not prejudice whether an invention satisfies the patentability requirements such as novelty and inventive step.

Example 1

(1) Claim

[Claim 1] An aromatic device comprising:
a holder having at least one air vent opening; and
an aroma generation source and a heating element disposed in said holder,
wherein said aroma generation source includes an activated carbon molding and is heated with said heating element at the temperature in the range from X to Y degrees Celsius,
wherein said aroma generation source is produced by heating said activated carbon molding impregnated with a solution of an aromatic ingredient A at the temperature of less than or equal to the heating temperature of said heating element for Z hours or longer.

(2) Arguments and verification regarding “impossible or impractical circumstances” presented by the applicant in a written opinion

The present invention relates to an aromatic device having an aroma generation source where an aromatic ingredient A existing near the surface of an activated carbon molding is volatilized and the aromatic ingredient existing deeply inside of the activated carbon molding remains. In order to specify the feature of the present invention which cannot be seen in the prior art, claim 1 includes a part stating that said activated carbon molding impregnated with a solution of an aromatic ingredient A is heated at the temperature of less than or equal to the heating temperature of said heating element for Z hours or longer. With that claim element as described, the present invention can obtain an aromatic device which is capable of preventing volatilization of the aromatic ingredient in storage, thereby it can solve the problem of the prior art that the emission efficiency of the aromatic ingredient varies depending on the state of preservation (see paragraphs X-X in the description of the present application).

However, it is not possible to directly define the feature of the present invention described above by the structure or property of the product.

First, it is impossible to specify the feature of the invention (i.e. the aromatic ingredient exists not near the surface but deeply inside of the activated carbon molding) simply by the wording such as “said aromatic ingredient exists only in the region deeper than XX μm from the surface”, in light of the fact that each activated carbon molding has a different structure and different properties associated therewith. In addition, there is no other wording clearly specifying the feature described above by structure or property.

Secondly, it is also impossible to specify the structure or property of the aroma generation source having the feature described above by analyzing the results of measurement, even considering the analytical technique at the time of the filing of the application. Specifically, methods of measuring the state of existence of materials in detail include, for example, a scanning electron microscope (SEM), ..., but any of those measuring methods can only measure the state of the surface of samples and thus is not appropriate for analyzing porous material having complicated inside structures such as activated carbon. Even if an analytical technique such as X-ray diffraction (XRD) is used, accurate data cannot be obtained due to volatilization of the aromatic ingredient. As described, there was actually no appropriate means for measurement and analysis.

Assuming that the state of the aromatic ingredient existing inside of the activated carbon molding can be measured by cutting off a sample of the molding to expose the inside thereof, this only reveals a microscopic state of the specific sample. It is utterly impractical to find an index specifying the feature described above through numerous trial-and-error processes by performing difficult operations and measurements repeatedly many times and then utilizing statistical processing methods.

In Example 1 described above, the written opinion explains in a concrete manner that the wording cannot be found specifying the structure or property concerning the difference between the present invention and the prior art, and that it is impossible or impractical to analyze and specify such structure and property based on the measurement. Therefore, Example 1 is deemed to be the case where the existence of “impossible or

impractical circumstances” can be recognized.

Example 2

(1) Claim

[Claim 1] A thin film semiconductor device comprising:
a structure of ...; and
an oxide semiconductor film consisting of XXX oxide as an active layer,
wherein the oxide semiconductor film is formed on a substrate by sputtering, using a target of metal oxide, at the temperature of the surface of the substrate from X to Y degrees Celsius.

(2) Arguments and verification regarding “impossible or impractical circumstances” presented by the applicant in a written opinion

An oxide semiconductor film consisting of XXX oxide is formed on a substrate by sputtering under controlling the temperature of the surface of the substrate from X to Y degrees Celsius, so that the resulting oxide semiconductor film has high crystallinity. The present invention provides a thin film semiconductor device having the resulting oxide semiconductor as an active layer, thereby a high performance of switching can be achieved (see the description of the present application, paragraphs X-X).

A conventional thin film semiconductor device using an oxide semiconductor film can be only obtained with a relatively low performance due to low crystallinity of an oxide semiconductor film (see JP YYYY-XXXXXX A). This means when the thin film semiconductor is used for a cellular phone of which battery capacity is limited, available time on one charge is not long, and thereby usability as the cellular phone is impaired (see the description of the present application, paragraphs Y-Y).

Though the difference between the present invention and the prior art is attributed to the difference in crystallinity of an oxide semiconductor film, in light of the non-uniformity of the thin film crystal, it is not possible categorically to specify the structure or property of the difference.

Meanwhile, the difference in crystallinity between them could be measured by X-ray diffraction (XRD) in principle, however, in practice, it is required to produce or purchase the statistically-significant number of thin film semiconductor devices of the present invention and those of the prior art respectively, and to measure a numerical feature of XRD spectrum for statistically processing the feature, and then to find a significant index and its actual value to distinguish between the present invention and the prior art through those processes. Those processes need enormous time and costs. Furthermore, since the prior art has huge variations, the number to be statistically significant cannot be clearly determined.

Therefore, it is not practical that the feature of the present invention is specified by the structure or property of the product of the invention after the index and its value are found in the way as described above.

In Example 2 described above, similar to Example 1, the written opinion also explains in a concrete manner that the wording cannot be found specifying the structure or property concerning the difference between the present invention and the prior art, and that it is impossible or impractical to analyze and specify such structure and property based on the measurement.

Therefore, Example 2 is deemed to be the case where the existence of “impossible or impractical circumstances” can be recognized.

Example 3

(1) Claim

[Claim 1] An oil-in-water type creamy emulsion composition for foods comprising water, an oil component, emulsifiers, a component A and a component B, and having viscosity of X-Y mPa · s ,

wherein said emulsion composition includes an emulsifier X and an emulsifier Y with 10-20/30-40 weight ratio,

and wherein an oil phase containing said emulsifiers, the component A and the component B are prepared in advance by mixing and stirring them and then the resulting product is added to a

water phase to obtain said emulsion composition.

(2) Arguments and verification regarding “impossible or impractical circumstances” presented by the applicant in a written opinion

The present invention prepares in advance an oil solution in which the prescribed emulsifiers, component A and component B are dispersed in the solution, and then the oil solution is added to a water phase for emulsion. The present invention provides an oil-in-water type creamy emulsion composition for foods having a good foam stability compared to one obtained by a conventional method in which a water phase dissolving an emulsion, a component A and a component B is added to an oil phase for emulsion (see the description of the present application, paragraphs X-X).

As described, compared to the prior art, the good foam stability achieved by the present invention is caused by the microscopic difference in a dispersed state of the components provided by the different manufacturing process. The microscopic difference in the dispersed state cannot be identified by the general index such as a composition or viscosity.

Even if it is attempted to express the property of foam stability itself in a numerical range, a microscopic dispersed state in an oil-in-water type creamy emulsion composition for foods varies depending on a composition of a raw material, a temperature, a stirring speed and other manufacturing conditions. Then, if a microscopic dispersed state is different, a numerical value of foam stability naturally changes. Thus, manufacturing the product with raw materials constituting various compositions under various manufacturing conditions such as the temperature and the stirring speed and measuring the foam stability of each resulting product requires impractical numbers of experiments and drastically huge economic expenses. Furthermore, the result cannot be expressed in a claim comprehensively.

Therefore, it is utterly impractical to “specify a product directly by structure or property at the time of the filing of an application” with regard to the present invention.

Example 3 as described falls under the case where the concrete aspects of the structure or property of the product vary depending on various concrete modes of the manufacturing method recited in the claim, and those concrete aspects cannot be expressed comprehensively, thus it is impossible or impractical to specify the product directly by its structure or property. The written opinion explains the situation concretely. Therefore, Example 3 is deemed to be the case where the existence of “impossible or impractical circumstances” can be recognized.

Example 4

(1) Claim

[Claim 1] A flavor improving agent prepared by the successive steps of: obtaining a concentrated solution by heating and concentrating sugar cane juice at the temperature of 120-130 degrees Celsius until an indicator of a sugar refractometer becomes 70-80 degrees with a Brix scale; and collecting distillation by collecting and cooling vapor which can be obtained by distilling said concentrated solution at the temperature of 120-130 degrees Celsius.

(2) Arguments and verification regarding “impossible or impractical circumstances” presented by the applicant in a written opinion

The present invention relates to a flavor improving agent obtained by collecting the distillation of sugar cane juice through each manufacturing process described in claim 1 of the present invention. The flavor improving agent of the present invention is manufactured by heating and concentrating the sugar cane juice at the temperature of 120-130 degrees Celsius until an indicator of a sugar refractometer becomes 70-80 degrees with a Brix scale before distillation, thereby the flavor improving agent of the present invention can have an effect of adding an agreeable natural flavor of brown sugar on foods compared to the conventional flavor improving agent produced by simply distilling and purifying concentrated sugar cane juice without heating and concentrating the juice which can bring such high sugar content. This comparison is clearly shown in Examples X-X and Comparative examples Y-Y in the present description.

First, the description “an agreeable and natural flavor” cannot be expressed quantitatively such as in the numerical range because it is an index relying on a subjective preference of people.

It is the common general knowledge at the time of the filing of the present application that a flavor improving agent derived from a natural product such as sugar cane juice is a composition containing various different chemical substances, and the flavor becomes different from an interaction of the each chemical substance. The flavor improving agent of the present invention and the conventional flavor improving agent as described above have 99.99 wt% of the same composition, as described in Table X in the present description. From this fact, it is apparent that very small amount of a component (a trace component) contributes to giving a good effect of the flavor improving agent of the present invention as described above. However, there are a very large number of such components which constitute the flavor improving agent of the present invention, and some of those components are less than the detection limit of analytical instruments.

Therefore, it is impossible to analyze and specify which chemical substance in trace components contributes to giving an effect of adding a good flavor among a very large number of trace components constituting the flavor improving agent of the present invention. This is because there are a large number of types of chemical substances contained in the analysis objects and the components less than the detection limit cannot be analyzed.

Assuming that an analyzer which has a quite low detection limit of concentration is used and thereby the trace components constituting the flavor improving agent can be all specified, a chemical substance which generates “an agreeable and natural flavor” of the present invention cannot be specified just by identifying a flavor of each trace component because a flavor in the flavor improving agent is generated by blending flavors of a plurality of chemical substances. Therefore, in order to specify the chemical substance, it is required to try all the combination of all chemical substances constituting the flavor improving agent of the present invention including a large number of trace

components and to identify the flavor generated by each combination one by one, which needs an enormous number of trials. In addition, for these trials, a large number of all trace components should be purified until they reach to a high purity respectively since an influence of a chemical substance other than a chemical substance used for a trial should be completely eliminated.

In conclusion, it would have to be said for “a flavor improving agent” of claim 1 of the present invention that it is utterly impractical to specify “a flavor improving agent” directly by its structure or property, by means of clearly specifying component(s) contributing to the effect of the present invention.

In Example 4 as described above, the written opinion concretely explains that it is impossible or impractical to specify the product directly by its structure or property since the product is derived from a natural product. Therefore, the present example is deemed to be the case where “impossible or impractical circumstances” exist.

Example 5

(1) Claim

[Claim 1] A polymerized composition prepared by the steps of:
reacting preliminarily a compound having three or more mercapto groups in one molecule and a compound having two or more isocyanate groups in one molecule for 5 to 10 minutes at the temperature of 40-50 degrees Celsius; and then
reacting a reaction solution containing the oligomer obtained by the reaction described above, a compound having two mercapto groups in one molecule and

(2) Arguments and verification regarding “impossible or impractical circumstances” presented by the applicant in a written opinion

... A polymerized composition defined in claim 1 comprises a compound having three or more mercapto groups in one molecule as a raw material, and further comprises an oligomer obtained under the reaction condition that the compound is preliminary reacted at the temperature of 40-50 degrees Celsius for

5-10 minutes. Therefore, a structure of the resulting polymerized composition becomes absolutely too complicated to express by a general formula (a structural formula), which is the common general knowledge for a person skilled in the art. It is also impossible to express the polymerized composition by the property because a property of a substance cannot be easily understood until a structure thereof is specified, as the property can be determined accordingly, and also because a property of a resulting polymerized composition obtained by a reaction of multiple different kinds of monomers varies depending on a compounding ratio of monomers or a reaction condition. Namely, a polymerized composition defined in claim 1 of the present invention cannot be specified directly by the structure or property of the product, but can be specified only by a process (manufacturing process) for preparation of the product.

Therefore, the invention of the polymerized composition defined in claim 1 is deemed to be the case where impossible or utterly impractical circumstances to “specify the product directly by its structure or property at the time of the filing of an application” exist.

In Example 5 as described above, the written opinion concretely explains that it is impossible or impractical to specify the product directly by its structure or property since the product is a polymer having complicated and a wide variety of structures. Therefore, the present example is deemed to be the case where the existence of “impossible or impractical circumstances” can be recognized.