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Change in JPO's Examination Practice for Use-Limited Food/Drink Inventions

Masaru Nakajima (partner: patent attorney)

ABSTRACT

The Japan Patent Office (JPO) has announced that it will allow patenting of food/drink inventions characterized by their novel use applications (use-limited food/drink invention) based on its newly-revised Examination Guidelines and Examination Handbook, which came into effect on April 1st, 2016. Under previous JPO examination practice, the patentability of a use-limited food/drink invention, characterized solely by its novel use limitation, was denied due to lack of novelty, since such a use-limited food/drink invention was not deemed to fall under the category of a "use invention", and the use limitation was therefore not deemed to be a matter to define the invention. However, the market for foods falling under the category of "foods with health claims" (FHC) has been growing in recent years. In addition to the original two sub-categories of FHC, i.e., "foods for specified health uses" (FOSHU) and "foods with nutrient function claims" (FNFcC), a new sub-category of FHC, i.e., "foods with function claims" (FFC), was introduced in April 2015. Therefore, there is growing demand for effective protection of use-limited food/drink inventions with patent rights. As a result, the current revisions to the Examination Guidelines and Handbook are expected to change the JPO's examination practice greatly, and open the possibility of patent protection of use-limited food/drink inventions. This article summarizes expected changes in examination practice at the JPO for use-limited food/drink inventions, following the current revisions to the Examination Guidelines and Handbook.

1. "Use Invention"

The JPO Examination Guidelines specifically define the term "use invention" as an invention based on both (i) a discovery of an unknown property of a product and (ii) a finding that the product is suitable for a novel use application due to the discovered property (see the Examination Guidelines for Patent and Utility Model in Japan, Part III, Chapter 2, Section 4, "3.1.2 Cases where an invention of a product with limitation of use application should be interpreted as a use invention").

According to the Examination Guidelines, if the invention according to a claim including a use limitation corresponds to a "use invention", the JPO Examiner recognizes the use limitation as a matter to define the claimed invention, and identifies the claimed invention in consideration of the use limitation. This concept of "use invention" is generally applied to technical fields where it is difficult to understand the use applications

of a product based on the structure or name of the product, such as chemical or pharmaceutical compositions containing chemical substances.

On the other hand, even in the case where an invention according to a claim including a use limitation is based on a discovery of an unknown property of a product, if, taking into consideration technical common knowledge in the art, the claimed invention is not deemed to provide a novel use application for the product, then the claimed invention does not correspond to a "use invention". In this case, the JPO Examiner ignores a use limitation recited in a claim as not having any role in specifying the claimed invention, and identifies the claimed invention without considering the limitation. Accordingly, if the use limitation is the only novel feature of the claimed invention over the prior art, then the claimed invention is rejected as lacking novelty over the prior art. A typical technical field to which the concept of a "use invention" is not applied is the field of food and beverage products.

2. Previous Examination Practice for Use-Limited Food Inventions

According to the previous examination guidelines, if a claim drawn to a food or a beverage includes a use limitation, the claimed invention does not correspond to a "use invention", and the use limitation is deemed as not having any role in specifying the claimed invention (see the previous Examination Guidelines, Part III, Chapter 2, Section 4, "3.1.2 Cases where an invention of a product with limitation of use application should be interpreted as a use invention"). The previous examination guidelines cite an example of "a yogurt for strengthening bones, comprising ingredient A" (see Example 2 in the above guidelines), and prescribe that since the claimed invention is directed to a food, i.e., "yogurt", the use limitation "strengthening bones" is ignored as not having any role in specifying the claimed invention.

The reason the concept of a "use invention" is not applied to food/drink inventions under the previous Examination Guidelines is not clear. However, this is presumably because, while pharmaceuticals are placed on the market with indications of their specific medical efficacy/utility, the laws prohibit marketing of foods by explicitly indicating such efficacy/utility, or even indicating functions or effects implying such efficacy/utility.

However, this situation changed in 2001, when the registration system for "foods with health claims" (FHC) was established. This system allows for registration of FHCs. Specifically, FHCs include: "foods for specified health uses" (FOSHU: foods which are officially accepted as having specific efficacy/utility in relation to the human body based on experimental data, and allowed to be sold with indication of such efficacy/utility); and "foods with nutrient function claims" (FNFC: foods labeled with functions of specific nutritional ingredients contained in the foods, such as vitamins and minerals). Since the establishment of this FHC registration system, there has been a growing demand to protect food/drink inventions characterized by use applications thereof based on their efficacy/utility and functions.

Under such circumstances, patent applicants have attempted to obtain patent protection for use-limited food/drink inventions with a variety of different types of claims as follows (in the following claims, “ingredient A” means an active ingredient and “use X” means its use application based on the efficacy/utility or functions thereof).

(i) Claims including indication of uses, such as “food/drink comprising ingredient A with a label indicating that the food/drink is for use X. Although there were several examples in the past where claims of this type were successfully granted and patented (e.g., JP3519419A, JP3581157B, and JP3615397A), this type of claim is currently not allowed.

(ii) Agent claims, such as “an agent for use X comprising ingredient A”. This type of claim expression is generally used for defining use inventions of pharmaceuticals, but is also deemed likewise applicable to use inventions directed to foods and beverages. However, claims of this type have been less effective in recent years as a means to protect use-limited food/drink inventions, since if the specification includes a general description regarding embodiments of foods/drinks, the JPO Examiner often requests the applicant to incorporate a disclaimer into the claims to explicitly recite that foods/drinks are excluded from the claimed invention.

(iii) Method claims, such as “a method for use Z comprising administrating ingredient A to a subject”. Claims of this type are normally deemed as including a so-called “medical activity”, such as a therapeutic method of treating the human body, and rejected under Article 29, paragraph 1 of the Patent Law as lacking industrial applicability. There are several cases in which this reason for rejection was overcome by amending the claims so as to explicitly recite that a “medical activity” is excluded from the claimed invention. However, considering that the term “medical activity” is defined in the Examination Guidelines very broadly, we believe that the scope of protection provided by a method claim explicitly excluding such “medical activity” would be too narrow to effectively protect use-limited food/drink inventions.

(iv) Claims drawn to foods/beverages comprising additives, such as “a food/drink to which purified/isolated ingredient A has been added”. Such claims may be deemed novel if a food/drink comprising purified/isolated ingredient A as an additive was not known to the art at the filing date, even if the claims do not explicitly recite use X. However, we do not believe that such claims are effective in protecting use-limited food/drink inventions, since it is generally difficult to prove that ingredient X is not derived from a component of the food/drink, but has been purified/isolated and then added to the food/drink.

Thus, it was very difficult to protect use-limited food/drink inventions under the previous examination practice.

3. Current Revisions to the Examination Guidelines and Handbook relating to Use-Limited Food/Drink Inventions

Under such circumstances, the Ministry of Health, Labour and Welfare (MHLW) revised the registration system for foods with health claims (FHC) in April 2015, to introduce a new category of FHC, i.e., foods with function claims (FFC), which can be registered under less strict requirements than foods for specified health uses (FOSHU). This revision to the FHC system has added momentum to the demand for effective protection of use-limited food/drink inventions by means of patents.

In response to the changing circumstances, the JPO announced in January 2016, that it has decided to revise the Examination Guidelines to accept the patentability of use-limited food/drink inventions, while suspending examination of use-limited food/drink inventions until the revised guidelines come into effect. The JPO then disclosed the text of the revised Guidelines and Handbook in March 2016, and resumed examination of use-limited food/drink inventions based on the revised guidelines and handbook on April 1, 2016.

4. Summary of Revised Examination Guidelines and Handbook relating to Use-Limited Food/Drink Inventions

Under the revised Examination Guidelines, an example relating to foods (Example 2) described in the previous Guidelines, Part III, Chapter 2, Section 4, 3.1.2 "(2) Cases where claimed invention is not considered to be use invention though there is a limitation of use application in a claim" has been removed. Instead, the revised Guidelines, Part III, Chapter 2, Section 4, 3.1.2 "(1) Cases where claimed invention is considered to be a use invention" recites a new example relating to use-limited food/drink inventions as follows.

"*[Claim 1]*
A food composition for use in preventing a hangover containing an ingredient A as an active ingredient.
[Claim 2]
A food composition for use in preventing a hangover according to claim 1, wherein the food composition is a fermented milk product.
[Claim 3]
A food composition for use in preventing a hangover according to claim 2, wherein the fermented milk product is yogurt."

According to the explanation of this example in the revised guidelines, when there exists a prior art invention relating to "a food composition comprising ingredient A" and if the only difference between the claimed invention and the prior art invention is that the claimed invention includes a use limitation, i.e., "for use in preventing a hangover", the JPO Examiner will judge that the claimed invention is novel over the prior art invention, provided that (i) the claimed use application of "*preventing a hungover*" is based on a new discovery that ingredient A promotes decomposition of alcohol, and (ii) the claimed use

application of "*preventing a hungover*" is novel and clearly distinguishable from the conventional uses of the prior art "*food composition comprising ingredient A*".

On the other hand, the revised Examination Guidelines, Part III, Chapter 2, Section 4, 3.1.3 "Cases where ideas described in 3.1.1 or 3.1.2 are not applied or generally not applied" mention, as new examples of inventions to which the concept of a "use invention" does not apply, inventions directed to animals or plants, in addition to previous examples of inventions directed to chemical compounds and microorganisms.

In accordance with these revisions to the guidelines, "Annex A: Case Examples" of the Examination Handbook for Patent and Utility Model has also been revised to include new case examples relating to use-limited food/drink inventions in Section "1. Description Requirements (Article 36)" (Case No. 45), Section "4. Novelty (Article 29(1))" (Cases Nos. 30 to 34), and Section "5. Inventive Step (Article 29(2))" (Cases Nos. 21 to 25).

5. Conclusion

According to the revised Guidelines and Handbook, a use-limited food/drink invention is deemed to correspond to a "use invention" and thus to have novelty over prior art, provided that (i) the claimed use application is based on a newly discovered property of the active ingredient and (ii) the claimed use application is novel clearly distinguishable from the conventional use applications of the active ingredient (see, e.g., the revised Examination Handbook, Annex A; Case Examples "4. Novelty (Article 29(1))", Cases Nos. 31, 32, and 34). As a result of this revision, we expect that it will become possible to effectively protect use-limited food/drink inventions by using more straightforward claim expressions such as "a food composition for use X, comprising ingredient A".

However, it should be noted that even in the case where a use-limited food/drink invention satisfies requirements (i) and (ii) above, if the claimed food/drink is a microorganism, animal, or plant (such as a vegetable or fruit), the invention will be considered as not corresponding to a "use invention" and therefore as being unpatentable (see, e.g., the revised Examination Handbook, Annex A; Case Examples "4. Novelty (Article 29(1))", Cases Nos. 30 and 32).

Lastly, the revised Guidelines and Handbook do not clearly define what "use applications" can be considered in examination of use-limited food/drink inventions, i.e., whether they are limited to specific use applications associated with efficacy/utility or functions on which registration of foods with health claims (FHC) is based, or if they also include more general use applications such as "foods for infants and young children". Therefore, it will be necessary to monitor the JPO's new examination practice in accordance with the revised Guidelines and Handbook starting from April 1, 2016.

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