Patent Protection for a Food Product in Consideration of the Scope of a Patent Right for a Use Invention (*)

Under the current patent and utility model examination guidelines, a newly discovered property of a publicly known food product would not constitute any new use that could distinguish the product from other publicly known food products. As far as food products are concerned, novelty as a use invention cannot be recognized. However, some people highlighted that it is important to recognize novelty of a food product as a use invention and to give an incentive to early developers trying to find a new property in a food product in order to promote their research and development activities. Due to the commencement of a new labeling system for functional food products, the early developer would be unable to distinguish its product from other companies' products if they file an application (they can cite a paper written by the early developer) and start affixing functional food labels on their products. Under these circumstances, it has been noted that patent protection for a use of a food product has become especially important.

The purpose of this research is to conduct research on patent protection for food products in consideration of the scope of a patent right for a use invention and to provide basic data for further examination as to whether or not the Examination Guidelines should be amended in order to recognize novelty in a food product as a use invention.

I Introduction

1 Background and Purpose of This Research

Under the current Examination Guidelines for Patent and Utility Model in Japan, it is generally considered that, if the invention described in a claim can be interpreted to be an invention made based on the discovery of an unknown property of a product and the discovery of a new use of the product due to the property, even if the product itself is already known, the invention described in the claim can be regarded to have novelty as a use invention.[1] However, in the case where a product is a food product, in consideration of the common general technical knowledge in the food industry, it is considered that the discovery of a new property of a publicly known food product would not constitute any new use that can distinguish the product from other food products. In sum, in the case of a food product, novelty as a use invention cannot be recognized.[2]

However, some people highlighted that it is important to recognize novelty of a food product as a use invention and to give an incentive to early developers trying to find a new property in a food product in order to promote their research and development activities. Traditionally, an early developer that has discovered a new property in a food product can distinguish its product from other companies' products by using the results of its research and development activities and filing an application under the food for specified health use (FOSHU) system. On the other hand, due to the commencement of a new labeling system for functional food products,[3] the early developer would be unable to distinguish its product from other companies' products if they file an application under this system (they can cite a paper written by the early developer) and start affixing functional food labels on their products. Under these circumstances, it has been noted that patent protection for a use of a food product has become especially important.

Before determining whether it is appropriate to recognize novelty in a food product as a use invention, it is necessary to examine the international trend as well as the possible effects of such recognition of novelty, more specifically, the types of inventions that would become patentable and the scope of the patent right (whether the effect of the patent right extends to any publicly known food product whose use has not been clearly defined). To conduct such examination, it is also necessary to study the relevant systems in other countries and the implementation practices thereof and also examine judicial precedents, academic theories, etc. and gather information against what types of acts of a third party a patent right for a use invention is exercisable. It is also important to listen to the opinions of Japanese companies and experts.

The purpose of this research is to conduct research on patent protection for food products in consideration of the scope of a patent right for a use invention and to provide basic data for further examination as to whether or not the Examination Guidelines should be amended in order to recognize novelty in a food product as a use invention.

2 Method of this research

(1) Research on Publicly Available Information

We used books, academic papers, judicial precedents, research reports, committee reports, databases, online

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

information, etc. to collect information about the systems in Japan and other countries and the implementation practices thereof, and examined and analyzed the collected information.

We also examined and analyzed the judgments handed down in infringement lawsuits over the effect of a patent right for a use invention and compiled the results of our analysis on the judgments with the support of attorneys.

(2) Domestic Questionnaire Survey

We conducted a domestic questionnaire survey on 135 Japanese food-related companies in order to understand their actual business practices and needs in connection with use inventions of functional food products.

(3) Domestic Interview Survey

In order to deepen the knowledge obtained in our research on publicly available information, we conducted an interview survey on eight experts and ten persons selected from the respondents of the questionnaire survey and analyzed the survey results.

(4) Overseas Questionnaire Survey

We prepared questions mostly about matters about which we were unable to collect information in our research on publicly available information, and sent questionnaires to law firms in the U.S., the U.K., Germany, China, South Korea, and Taiwan.

(5) Discussions at the Committee

We established a five-person research committee consisting of one specialist, one corporate IP expert, two attorneys, and one patent attorney in order to obtain advice based on their examination and analysis from an expert perspective. The committee held a discussion three times about the methods of conducting research on publicly available information, a domestic questionnaire survey, domestic interview survey, and overseas questionnaire survey and, based on the survey results, examined, among other things, the scope of the effect of a patent right for a use invention of a food product and the styles of claim based on which novelty can be recognized.

II Use Inventions in Japan

A use invention is defined as an invention made based on (i) discovering an unknown property of a product and (ii) finding out that the product is suitable for a novel use because of the property (Part III, Chapter 2, Section 4, 3.1.2 of the Examination Guidelines for Patent and Utility Model in Japan).

If a claim contains a certain phrase such as "for use in ..." (the limitation of use) in order to specify a product by referring to a use of the product, the examiner should take into consideration the description and drawings as well as the common general knowledge available at the time of application filing and interpret what the limitation of use means as a claimed element presented in the claim. Based on that interpretation, the claimed invention will be identified.

In the case of any invention embodied in a food product, even if a new property is discovered in a publicly known food product, it usually cannot be considered to constitute a new use that can distinguish the product from other publicly known food products (Part III, Chapter 2, Section 4, 3.1.2 (2) Example 2 of the Examination Guidelines for Patent and Utility Model in Japan).

Chapter 3 (Medicinal Inventions) of Annex B of the current Examination Handbook for Patent and Utility Model in Japan was newly established as Chapter 3 of Part VII "Examination Guidelines for the Specified Technical Fields" of the Examination Guidelines for Patent and Utility Model in Japan. In November 2004, a report titled "Patent Protection in Field of Advanced Medical Technologies" was submitted to the Advanced Medical Patent Exploratory Committee of the Intellectual Property Strategy Headquarters. The report examined the technologies related to the "method of generating new medicinal potency or effects applicable to the manufacturing and sale of a medicine" and sought the possibility of expanding the scope of product patent protection as far as possible in consideration of the issues related to the effect of a patent right with reference to the cases where a medicine is patented and cases in other fields and proposed amendments to the Examination Guidelines, etc.

III Functional Food Labeling System

1 Functional Food

There have been two types of labeled food products in Japan, namely, food for specified health use (FOSHU), which shows the compatibility of the food with the national standards, and food with nutrient function claims (FNFC), which shows governmental permission for the specific food. Since the amendment to the Food Labeling Act on April 1, 2015, a new system was introduced, which allows food manufacturers to label their food products on their own responsibility, in addition to the FOSHU system and the FNFC system.

2 Necessity of Patent Protection for Functional Food Products

Under the new system of functional food labeling, it is possible for late-comer companies, etc. to easily and inexpensively label their functional food products by

citing a paper, etc. written by the early developer that made substantial research and development investments. There is a risk that the new system will discourage early developers from conducting research and development activities and making development investments. It has been noted that Japan should emulate Western countries and amend the current Examination Guidelines for Patent and Utility Model in Japan in such way that a new function discovered in a food product can be recognized as "new use," which is subject to patentability evaluation.[4]

According to the results of the research on documents such as unexamined patent application publications and examined patent application publications issued from January 2009 to December 2013, food claims (claims related to food products) are lower than effective agent claims (claims related to effective agents) and medicine claims (claims related to medicines) in terms of the rate of patent grant.[5]

IV Scope of the Effect of a Patent Right for a Use Invention

It is necessary to examine whether the effect of a patent right granted for a use invention would extend to a publicly known product whose use has not been clearly defined. This is the reason why this research was conducted.

The following is a summary of the results of our research on judicial precedents, our questionnaire survey and interview survey, from the perspective of the effect of a patent right for a use invention.

- The effect of a patent right for a use invention would not extend to a publicly known product whose use has not been clearly defined. Whether the effect would extend to such product or not should be determined after examining whether the product has the use in question.
- If a suspected infringer fails to sufficiently allege and prove that the publicly known products that the suspected infringer handles do not have such use in question, the effect of the patent right could extend to those products. However, this is the issue of the sufficiency of the provided allegation and proof that needs to be examined on a case-by-case basis.
- If novelty is found in a food product as a use invention, the effect of a patent right should be examined in the same manner as we examined any other types of use inventions and no particular precautions are necessary just because it is related to a food product.
- According to the survey results, 73% of the responding companies said that, if novelty is found in a food product as a use invention, the effect of a patent right would extend to any act of manufacturing and selling a food product carrying a functionality label. 21% of the responding companies said that the effect of a patent right would extend to an act of manufacturing and selling a product that does not carry a functionality label, if the functional component in question is added to or increased in the product without any advertisement, etc. It is predicted that even fewer people would consider that, if novelty in a food product is recognized as a use invention, the effect of the patent right in question would extend to an act of manufacturing and selling a publicly known food product that does not carry any label about the use of the product.
- Although a use of a product does not directly affect infringement judgment, the judgment handed down in a lawsuit to seek rescission of a JPO decision to the effect that a use should be taken into consideration when determining whether or not a product invention is identical to another product invention has revealed that a court clearly recognizes a use separately from other factors.[6]

V Styles of Claim Based on Which Novelty Should Be Recognized

The questionnaire survey and interview survey on the issue of whether novelty should be recognized in a functional food product as a use invention has shown that there are users' needs for patent protection for a functional food product as a use invention. The respondents to the questionnaire survey and interview survey presented examples of the appropriate styles of patent claims including the claims that end with certain words such as "XXX agent," "composition," "food composition," and "food" as well as the claims containing certain phrases such as "containing an active ingredient" and "labeled as." In the interview survey, the respondents made various comments.

Based on the results of the aforementioned research, the research committee made a discussion regarding the following styles of claim.

Style 1: Banana for XXX
Style 2: Yogurt for XXX containing Ingredient P as an active ingredient
Style 3: Food composition for XXX containing Ingredient P as an active ingredient
Style 4: Composition for XXX containing Ingredient P as an active ingredient
Style 5: XXX agent containing Ingredient P as an active ingredient

The opinions of the committee members are listed below.

(1) Definition of the Appropriate Style of Claim Based on Which Novelty Should be Recognized

- Since it is difficult to differentiate "composition" from "active agent," a political decision must be made as to which one should be appropriate.

-Before discussing the appropriate styles of claim, a political decision must be made to determine what should be protected.

- Novelty should not be recognized in natural foods due to negative consequences. Since a non-natural food product such as yogurt could be regarded to fall under a concept lower than "composition," it would be impossible to distinguish between Style 2 and Style 3 to make a distinction between a style of claim based on which novelty can be recognized and a style of claim based on which novelty cannot be recognized. Such distinction should be made between Style 1 and Style 2.
- In principle, satisfaction or dissatisfaction of the novelty requirement should be determined based on the interpretation of the invention as a technical thought. Therefore, the style of claim should not be used as a single factor to officially determine whether the claim is appropriate or not.

(2) Style 1

- This style should not be permitted in principle because it is essential to indicate the active ingredient.

(3) Style 2

- This style can be considered to be appropriate as a food-related claim.

(4) Styles 3 and 4

- In the case of a food product whose configuration cannot be specified (e.g., health drink, tea), it may be reasonable to recognize novelty in the form of a food composition and determine the satisfaction or dissatisfaction of the description requirement in accordance with the guidelines that are similar to those for medical products.

- This style seems to be the most appropriate in terms of the scope of a food-related claim.

(5) Style 5

- It is not necessary for the JPO to specify that the JPO would accept a claim if it contains a phrase "XXX agent." It would be more reasonable to check the general meaning of such phrase (in a comprehensive dictionary such as Kojien) and examine the content of the description, and then determine whether novelty or an inventive step can be recognized or not.
- If the phrase "XXX agent" is used in a food-related claim, it would cause difficulty in distinguishing it from medical use invention and could cause confusion.

VI Others (Determination of the Satisfaction or Dissatisfaction of the Inventive Step Requirement and the Description Requirement)

Under the current Examination Guidelines for Patent and Utility Model in Japan, a use invention having novelty will be considered to involve no inventive step if any person ordinarily skilled in the art could easily conceive of the use based on the already known product property, structure, etc.[7] In the case of a medical invention, the applicant is usually required to present more than one major working example unless any person ordinarily skilled in the art could manufacture or obtain a chemical compound, etc. based on the common general technical knowledge as of the time of the application filing and could use the chemical compound, etc. for a medical use. In order to prove the medical use, the applicant is usually required to present the results of a pharmacological test as a working example.[8]

In the questionnaire survey and the interview survey, many respondents said that the JPO should make appropriate determinations on the satisfaction or dissatisfaction of the inventive step requirement and the description requirement. It is important to make appropriate determinations from the perspective of not only novelty but also the inventive step requirement and the description requirement.

The opinions given by committee members are as follows.

- If it is simply a matter of evaluating a good thing as a good thing as is the case with a medical invention, it might be a good idea to recognize novelty and make an appropriate determination from the perspective of an inventive step.
- If a new function is accidentally discovered in a common food product, the grounds for denying the existence of an inventive step would be important.
- In the case of a claim that yogurt is effective against cancer, it would be possible to make an appropriate determination from the perspective of the description requirement.

VII Use Invention in Various Countries and Regions

1 U.S.

In the U.S., in the case of an invention of a new use of a publicly known product or composition, novelty would not be recognized if the invention is described in a product claim (MPEP2112 I). A use claim would not be acceptable either. (MPEP2173.05 (q)). The invention would be found patentable only if it is described in a

"process of use" claim (Section 100 (b) of 35 U.S. Code, MPEP2112.02, MPEP2103 IIIA). The holder of a process patent for a use invention of a food product could allege that a third party's act of manufacturing and selling a food product constitutes induced infringement (Section 271 (b) of 35 U.S. Code) or contributory infringement (Section 271 (c) of 35 U.S. Code). On the other hand, it has been noted that recent judgments handed down by the Supreme Court have exhibited stricter application of the criteria for proving the occurrence of induced infringement.

2 EPO

If a new use of a publicly known food product that is claimed as an invention is regarded as a medical use (the first or second medical use), the EPO would carry out the examination practices for a medical use invention and recognize novelty as an invention described in a product claim with limited uses (Article 53 (c) and Article 54 (4) and (5) of the EPC). The description requirements applicable to the medical field would be applied to this case. If the food product has a non-medical use, a process claim or a use claim will be permitted to describe the invention (Part G, Chapter VI, 7.2 of the Guidelines for Examination).

3 U.K.

In the U.K., if a new use of a food product claimed as an invention can be regarded as a medical use, the UK IPO would carry out the same examination practices as those of the EPO and patent it as an invention described in a product claim with a specified use (Section 4A (2) and (3) of the Patent Act). Since a medical use invention of a food product will be protected as a product, the patentee can allege that a third party's act of manufacturing or selling a patented functional food product constitutes direct infringement. On the other hand, in connection with the restrictions imposed by the EU food labeling law, it has been noted that there is an issue with regard to protection for a food product that does not carry a medical function label.

4 Germany

In Germany, a use invention of a food product can be patented as an invention described in a product claim with limited uses in the same manner as the EPO would treat such invention (Section 2a (1) 2, Section 3 (3) and (4)). In the case of an invention for a medical use and a second non-medical use, an invention would be patentable if it is described in a use claim.

When a patent is granted for a use invention of a food product, in the case of a medical use invention, patent protection would be provided for a product with limited uses. In this case, the patentee can allege that a third party's act of manufacturing and selling the patented functional food product constitutes direct infringement. In the case of a second non-medical use invention, patent protection would be provided by considering the invention as a process invention. Therefore, the patentee can allege that such third party's act constitutes indirect infringement.

5 China

In China, novelty cannot be recognized for a use invention of a publicly known food product if an invention is described in a product claim. Even if the invention is described in a process claim, a patent right would not be granted as long as the invention is related to medical diagnosis or treatment. In the case of a medical use invention of a substance, the invention could be patented if it is described in a Swiss-type claim (e.g., "manufacture of a medicament for treating a disease") (Article 25, 1 (3) of the Patent Law, Part II, Chapter 10, 4.5.2 of the Guidelines For Patent Examination). The patentee can allege that a third party's act of manufacturing a food product by use of the invention described in the manufacturing process claim constitutes direct infringement. In the case of an invention for a non-medical use, it is permissible to describe the invention in a widely used process claim. However, due to the lack of the provision concerning indirect infringement, the patentee needs to allege that a third party's act constitutes joint infringement under Article 130 of the General Principles of the Civil Law of the People's Republic of China.

6 South Korea

In South Korea, if a use invention of a food product is described in a claim concerning a health-related functional food product or food composition, the limitation imposed on uses can be considered to constitute a constituent feature (Part IX, Chapter 3, 2.2.(1) of the Patent Examination Guidelines). If the use in question is novel, novelty can be recognized as a food product. An invention described in a process claim cannot be considered to be an industrially applicable invention and cannot be considered to be patentable, if the claimed process can be regarded as a medical act.

The effect of a patent right for a use invention of a food product extends to any product with limited uses.

7 Taiwan

In Taiwan, in the case of a use invention of a publicly known food product, novelty cannot be recognized if the invention is described in a product claim. Even if it is described in a process claim, a patent right would not be granted as long as the invention is related to diagnosis of a human or animal disease or a process of medical treatment or surgical operation. In the case of a medical use invention of a substance, the invention could

be patented only if the invention is described in a Swiss-type claim (e.g., "Use of Chemical Compound P in the manufacturing process of Medicament X for treating Disease X") (Article 24(2) of the Patent Act, Part II, Chapter 1, 2.5.5 of the Patent Examination Guidelines). The patentee can allege that a third party's act of manufacturing a product by use of the invention described in the manufacturing process claim constitutes direct infringement. However, due to the lack of a provision concerning indirect infringement, it is difficult to provide patent protection for an invention described in an ordinary process claim or use claim.

8 Results of Overseas Surveys

In all of the countries in which we conducted a survey, the effect of a patent right for a use invention of a food product extends to any product or process with limited uses, although the claim style permitted in each country is different. The EPO, the U.K., Germany, and South Korea provide patent protection for food products with limited uses. China and Taiwan provide patent protection for the manufacturing processes of food products with limited uses. The U.S. provides patent protection for the methods of improving health through specific food intake.

IX Conclusion

This research has revealed that patent system users strongly wish that patent offices could recognize novelty of a use invention of a food product based on the use.

The effect of a patent right for a use invention should not unconditionally extend to publicly known products without any use limitation. It will be necessary to examine whether the product in question is designed for the use in question and determine whether the effect of the patent right would extend to it or not. If a suspected infringer fails to sufficiently allege and prove that the product is not designed for such use, the effect of the patent right would extend to the publicly known product handled by the suspected infringer. However, this is the issue of the sufficiency of the provided allegation and proof that needs to be examined on a case-by-case basis.

The examples of appropriate styles of claim for a use invention of a food product would include the claims that end with certain words such as "XXX agent," "composition," "food composition," and "food" as well as the claims containing certain phrases such as "containing an active ingredient" and "labeled as." In the interview survey, we received various comments from the respondents. Many companies made a comparison between Japan and other countries in terms of patent examination practices and commented that it would be necessary to provide appropriate patent protection for a use invention described in a certain style of claim.

It would be necessary for each patent office to take the results of this research into consideration and make appropriate determinations as to whether or not a use invention of a food product satisfies the inventive step requirement and the description requirement as well as the novelty requirement.

Further examination needs to be made based on the results of this research in consideration of the system users' needs.

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[1] Part III, Chapter 2, Section 4, 3.1.2 of the Examination Guidelines for Patent and Utility Model in Japan

[2] Part III, Chapter 2, Section 4, 3.1.2 (2) Example 2 of the Examination Guidelines for Patent and Utility Model in Japan

[3] Consumer Affairs Agency, Government of Japan, "Kinousei hyouji ni kansuru jouhou" (Information on Functional Food Labeling) (http://www.caa.go.jp/foods/index23.html) [Last date of access: October 6, 2015]

[4] "Kinousei shokuhin no youto hatsumeito shiteno shinkisei handanni tsuite" (Novelty judgment for a use invention of a functional food products), Examination Standards Office, Coordination Division, JPO [http://www.kantei.go.jp/jp/singi/tiiki/kokusentoc_wg/hearing_s/150327shiryou08-02.pdf] [Last date of access: October 13, 2015]

[5] First meeting of the Bio-Life Science Committee in FY2013 (Naomi Yoshida, Izumi Uchiyama, Noriko Tsujimoto, Yu Morita, Shota Yamanaka), "Baio kanren iyaku hatsumei no shinsa unyo tou ni tsuiteno chousa kenkyu" (Research on the examination system and the implementation thereof, etc. for bio-related and medical inventions), Patent, vol. 67, no. 13, at 4 to 24 (November 2014)

[6] Judgment of Intellectual Property High Court dated November 29, 2006, 2006 (Gyo-Ke) 10227 [http://www.courts.go.jp/app/files/hanrei_jp/865/033865_hanrei.pdf] [Last date of access: November 6, 2015]

[7] Part III, Chapter 2, Section 4, 3.2.3 (Note) of the Examination Guidelines for Patent and Utility Model in Japan

[8] Annex B, Chapter 3, 1.1.1 of the Examination Handbook for Patent and Utility Model in Japan