

Tap into Japan's demand for functional foods

The market for foods for specific health uses in Japan is large and growing. **Hiroshi Sorimachi** of **Kyowa Patent and Law Office** explains how to obtain patent protection for functional foods

Recently, research and development into health foods in Japan has risen dramatically, reflecting national health trends. In particular, health food, which is generally referred to as a functional food, has been developed by focusing on the physiological regulatory function of a food such as biological defence, prevention of disease, recovery from illness and age control. Further, when a functional food is allowed or accepted under the Japanese Health Promotion Law, the functional food can be labelled as “a food for specified health use” with a display of its likely effects of reducing the risk of disease. If a person labels a food as a food for specified health use without permission from the relevant authorities, they will be punished under the Japanese Health Promotion Law or Food Hygiene Law.

Since 1991, when a food for specified health use system started, the number of foods for specified health use has increased and now exceeds 800. Various types of foods for specified health use are available in Japan. For example, recent popular products include tea (healthya ryokucha, KAO corporation) labelled as “being suitable for people who are anxious about body fat since the tea contains tea catechin in abundance”. Although it has its ups and downs, the size of the market in Japan for foods for specified health use is increasing. According to a report by the Japan Health Food & Nutrition Food Association, the size of the Japanese market for foods for specified health use was more than ¥500 billion (\$5.9 billion) in 2009.

Despite the fact that there is an attractive market, under Japanese patent practice, obtaining protection for a functional food characterised in its physiological regulatory function such as biological defence, prevention of disease, recovery from illness and age control is extremely difficult.

JPO examination guidelines

Under Japanese Patent Law, inventions fall into three categories: an invention of a product, an invention of a process and an invention of a method for manufacturing a product.

Although a use invention is not specifically defined in Japanese Patent Law, according to the JPO Examination Guidelines (Part II, Chapter 2, 1.5.2 (2)), a use invention is defined as follows: “Generally, a use invention is construed as an invention based on discovering an unknown attribute of a product and finding that the product is suitable for a new use due to the presence of such attribute.” Further, under Japanese patent practice, a use invention is generally protected by a claim directed to a product with the limitation of an intended use or a process for using a product. For example, in the case where pest control use of a compound A is novel over the prior art, the pest control use can be protected by a claim such as “A composition for use in pest control, comprising a compound A” or “A method for controlling pests, comprising applying a compound A to a subject.” Accordingly, under Japanese patent practice, a use invention is basically protected by a product claim as well as a process claim.

On the other hand, in cases where a subject to which a compound is applied is a human body, a process claim is not allowable since such a process claim is regarded as a process of treatment of a human body which is unpatentable subject matter in Japan. Thus, in a technical field such as medicine or cosmetics where the subject is a human body, a use invention is protected only by a product claim with the limitation of an intended use.

Medicine

According to the JPO Examination Guidelines (Part VII, Chapter 3, Medicinal invention, 3.1, Example 1), there is an example of a patentable claim regarding a use invention in the field of medicine as follows.

Claim

A pharmaceutical composition for treatment of Alzheimer's disease comprising a compound A as active ingredient.

Prior art

Although it is already known that a compound A is an active ingredient for an antimicrobial agent, the prior art documents do not describe a pharmaceutical composition for treatment of Alzheimer's disease comprising a compound A as an active ingredient. Moreover, the documents do not describe or suggest the existence of the structural similarity between a compound A and compounds having an acetylcholine-esterase activity and the relationship between the mechanism of a compound A for acting as an antimicrobial agent and the treatment of Alzheimer's disease.

Summary of the invention

It is found that a compound A, which is known as an active ingredient for an anti-microbial agent, can inhibit the function of acetylcholine-esterase and suppress degradation of acetylcholine. It is shown in an example with the result of a pharmacological test that a compound A has an excellent inhibitory activity of acetylcholine-esterase and decreases the symptom of Alzheimer's disease.

Cosmetics

In the field of cosmetics, there is a recent precedent which provides a criterion for judging success and failure of a use invention. In this case, a patent claim, the prior art and a summary of the judgment are exemplified as follows.

Claim

A wrinkles formation suppressant, comprising a compound A as active ingredient.

Prior art

Although it is already known that a compound A is an active ingredient for a skin whitening agent, the prior

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art documents do not describe that the compound A can be used for suppressing the formation of wrinkles.

Summary of the judgment

According to the judgment, the use invention of this case is successful for the following reasons: (1) wrinkles (which are the target of the present invention) and deposits of a pigment (which are the target of the whitening of the prior art) are different not only as a phenomenon but also in functional mechanism. (2) At the filing

date of the present application, a cosmetic product for whitening the skin and a cosmetic product for preventing signs of aging such as the formation of wrinkles were recognised as different products in the market.

The criterion provided in the precedent may affect judgments regarding a use invention in the future not only in the field of cosmetics but also in other technical fields.

Food

Foods have a common feature with medicine and cosmetics in that these are all applied to a human body. However, under Japanese patent practice, a use invention of a food is not generally protected by a product claim, nor by a process claim.

A claim directed to a process comprising of applying a food to a human is not allowable since the process claim is regarded as involving a process of treatment of a human body under Japanese patent practice. Further, a food product claim is also not allowable since an intended use of a food is not considered under Japanese patent practice. According to the JPO Examination Guidelines, a discovery of a new attribute of a publicly known food usually does not provide a new use that can distinguish the invention from the known food in view of the common general technical knowledge in the food field, with regard to any products used for food. That is, the JPO believes that the intended use of a food is neither more nor less than for eating and other use is not considered.

The JPO Examination Guidelines (Part II, Chapter 2, 1.5.2), records an unsuccessful case regarding a use invention of a food as follows.

Claim

Yogurt containing Ingredient A, for use in strengthening bones.

Summary of the judgment

Even though "yogurt containing Ingredient A, for use in strengthening bones" is an invention based on an unknown attribute that it promotes calcium absorption in bones, both "yogurt containing Ingredient A" and

"yogurt containing Ingredient A, for use in strengthening bones" are used as foods. Therefore, "yogurt containing Ingredient A, for use in strengthening bones" cannot be regarded as providing a new use as a food; and "yogurt containing Ingredient A, for use in strengthening bones" is regarded as lacking novelty in light of "yogurt containing Ingredient A".

Under such practice, it would be difficult to obtain patent protection for a functional food characterised in a new physiological regulatory effect.

Growing interest

However, in spite of such strict patent practice, the number of patent applications relating to a functional food is increasing.

- i) The most popular claim for obtaining patent protection for a functional food would be a claim directed to an agent for a specific use as follows.

Claim

An agent containing Ingredient A for use in strengthening bones.

The agent claim is used widely for protection of a use invention in a variety of technical fields and would be first choice for protecting a functional food in Japan though there is no case law which provides a criterion for judging whether a functional food is directly covered by the agent claim.

In addition, it should be noted that the JPO examiner sometimes requests to limit the term “an agent” to “a pharmaceutical agent”. In this case, a functional food would be excluded from the scope of the agent claim.

- ii) A claim directed to a food having the limitation of its specific composition is also a major example for protecting a functional food in the case where the composition of the functional food is novel over the prior art. An example of this case is as follows.

Claim

A food product for use in strengthening bones containing more than 15 w/w% by weight of the food product of an ingredient A.

Prior art

Although a food product comprising less than 15 w/w% of an ingredient A is already known, the prior art documents do not describe a food product containing 15 w/w% or more of the food product of the ingredient A by weight.

- iii) Further, if prior art documents do not describe the isolated form of the active ingredient, a claim style below may be acceptable.

Claim

A food product for use in strengthening bones wherein an isolated ingredient A is added to the food product.

This claim style is sometimes allowed by the JPO examiner on the basis that the food to which the isolated ingredient A is added is novel since the isolated form of the ingredient A is novel.

Obtaining protection

Since the system for foods for specified health use started in Japan, the market size of functional foods characterised in their new physiological regulatory functions is expanding and Japanese food companies are investing large amounts of money in developing functional foods. On the other hand, under Japanese patent practice, it is generally difficult to protect a functional food characterised in its physiological regulatory function since a use

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invention in the field of foods is not generally allowable under Japanese patent practice. However, you may protect a functional food characterised in its physiological regulatory function by using the following claim styles:

- A claim directed to an agent comprising an active ingredient for use in regulating specific physiological activity. This would be first choice for the protection of a functional food.
- A claim directed to a food for use in regulating specific physiological activity having the limitation of its specific composition. This is also an option in the case where the composition of the functional food is novel.
- A claim directed to a food for use in regulating specific physiological activity wherein an isolated active ingredient is added to the food. This style may be used in the case where the isolated form of the active ingredient is novel.

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