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The Japanese food industry

There have been significant impacts on the Japanese food industry recently, caused by changes in health claim law and use-limited food invention. Osamu Yamamoto, Yuasa & Hara, explains the changes and the subsequent impacts.

From last year, there have been two major changes affecting the food industry in Japan. One of them is a new health claim law enacted on April 1, 2015, and the other is a change in patentability requirements for use inventions in foods, effective as of April 1, 2016. These two changes are set to become driving forces behind market growth of the functional food industry in Japan.

UNESCO registered *washoku* (traditional Japanese cuisine) on December 2013 as a quintessential part of Japanese cultural heritage. *Washoku* is well known as a “well-balanced and healthy diet”. The Japanese are in general health-conscious, particularly with regard to their food intake. Life expectancy is longer in Japan than anywhere else in the world, and it can be said that this is because of the way people eat. Many companies are marketing healthy food products and growth of the industry shows no sign of abating. The current market size of functional foods in Japan is about 2 trillion yen (19.5 billion US dollars).

New health claim law – The third category

In April 2015, Japan’s Consumer Affairs Agency (CAA), a governmental organization, introduced a third category of health claim labeling for food. The new category is named as Food with Functional Claims (FFC), and allows companies voluntarily to display a product’s specific

health benefit and an associated area of the human body on retail food packaging.

Before the introduction, there had been two categories of health claims in Japan: Food for Specialized Health Uses (FOSHU) and Food with Nutrient Functional Claims (FNFC). FOSHU was introduced in 1991, and there were about 1,250 FOSHU products registered as of April 28, 2016. The current market size of FOSHU is about 600 billion yen (5.85 billion US dollars). However, utilization of FOSHU has remained limited due to rigorous requirements for registration. Clinical trials of a product are required to qualify for FOSHU, which has proven too great a burden, particularly for small or medium-sized companies, considering the necessary cost and time. In some cases, companies have paid more than 100 million yen and have waited about three years for approval. The FNFC system was introduced in 2001, and registration is not required to participate. Products containing vitamins and minerals that meet the standards determined by CAA are eligible to be labeled without application.

The third new FFC registration process is more affordable and faster than the registration process for FOSHU. This process was introduced in line with Prime Minister Abe’s regulatory reform plan. This shift has been fueled by Japan’s rapidly ageing population; about 25% of the population is aged 65 or older, making Japan one of the oldest nations on Earth. Amid such demographic shifts, the government is aware that it cannot afford to treat an increasing number of medical problems in the elderly and is therefore keener than ever to back improved nutrition to prevent disease.

In accordance with the FFC guidelines, food manufacturers must provide CAA with scientific information on the safety and functionality of their products. Food manufacturers are also required to provide the FFC health claims labeling contents, information about the manufacturer, production and quality management, and a system to gather information on possible adverse health outcomes from the use of the product.

The FFC category should present a variety of new opportunities not only for Japanese companies but also for foreign companies. Further, the FFC category provides

Résumé

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Osamu is a patent attorney, and a managing partner of YUASA and HARA, and is the acting Chief of the Chemical Section. He has extensive experience in pharmaceutical and biotechnology research and development at a chemical company for 10 years before specializing in intellectual property. He has represented a variety of companies in the fields of pharmaceuticals, biotechnology, diagnostics and food and beverages. In addition to patent prosecution he is experienced in handling invalidation trials and providing expert opinions. He was chosen by Lawyer Monthly Legal Awards 2014 and 2015 as “Biotechnology Lawyer of the Year” etc.

merits for small or medium-sized companies, since it eliminates the need for costly and lengthy approval procedures before a specific functional claim can be added to a product label.

Use-limited food invention – now patentable!

Until very recently, the Japan Patent Office (JPO) had continued to reject use-limited food inventions for the reason of lack of novelty, stating that it is not possible to imagine a new use in the area of foods. Now, however, a new medical use invention, including a second medical use invention, of a known compound is considered as novel, and therefore may be patentable. The differences in JPO practice in these two areas were difficult to understand and accept for applicants. Finally, the JPO changed its stance on novelty of use-limited food inventions on April 1, 2016. This major change was triggered by the introduction of FFC as described above.

The Examination Guideline, effective on and after April 1, 2016, states that if there is a limitation of use in a claimed invention of foods, the examiner recognizes that the limitation of use defines the claimed invention. This means that the JPO no longer ignores use limitations in inventions of foods.

“ The JPO changed its stance on novelty of use-limited food inventions on April 1, 2016. ”

The guideline includes an example of novel invention with the following explanations:

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

The use in “preventing a hangover” is derived from discovery of a previously unknown attribute that promotes alcohol metabolism by an ingredient A. The use application that is derived from the attribute is different from any known uses and is novel. The same way of specifying the claimed invention also applies to a fermented milk product and yogurt, which are more specific concepts of a food composition.

There are some seemingly strange criteria that will be interpreted as limitation of use. A claim describing “Banana for use in X” is not interpreted as a use-limited invention, and therefore it is regarded as banana itself. On the other hand, “Banana juice for use in X” is interpreted as a use-limited invention, and therefore if such use is new, it will be patentable on the condition that other patentability requirements, including inventive step, are met. This is because the examination guideline states that “...in cases where the invention is that of an animal or plant product, even if there is a limitation of use in a claimed invention, the examiner interprets such an animal or plant product as the animal or plant itself, without limitation of use, because such a limitation of use only indicates the utility of the animal or plant product”.

Banana juice is somewhat processed from banana and is no longer regarded as the plant itself, and therefore the limitation of use is contemplated. There are tendencies to claim food compositions with





numeric limitations, for example, complicated mathematical combinations of several variables expressed as formulae. One of the background reasons for the tendency is that a use-limited food invention could not be patented; this tendency may change at least slightly due to the recent change in the JPO's stance. Having said that, there are still uncertainties on how the scope of patents of use-limited food inventions will be judged by the courts, and it is necessary to wait and see what will happen. To obtain patents effectively and strategically in Japan, it is recommendable to draft claims that meet

the patentability requirements, the Japanese health claim law etc.

In Japan, through active use of the accelerated examination system, many applications have been granted a patent before being laid open: this means that many patents are firstly disclosed in a patent gazette. On the other hand, the opposition system was re-introduced on April 1, 2015. Due to such circumstances and the above-mentioned two big changes, the food industry has entered a new era, encountering harsh competition, which competition itself may be ironically said to be "well-balanced and healthy."

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