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## LIFE SCIENCES

**WHAT'S INSIDE?**

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## JAPAN

# Some interesting aspects of food patents in Japan

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Regarding the examination of an invention of a food product with a limitation of use, there was a significant change in the Examination Guidelines for Patent and Utility Model (hereinafter, "JPO Guidelines") and the Examination Handbook for Patent and Utility Model (hereinafter, "Examination HB") in Japan in 2016. The revision, published on March 23 and took effect on April 1, 2016, has opened a path to recognize patentability of a claim directed to the invention of novel use of a known food ("food use invention"; hereinafter, "FUI").

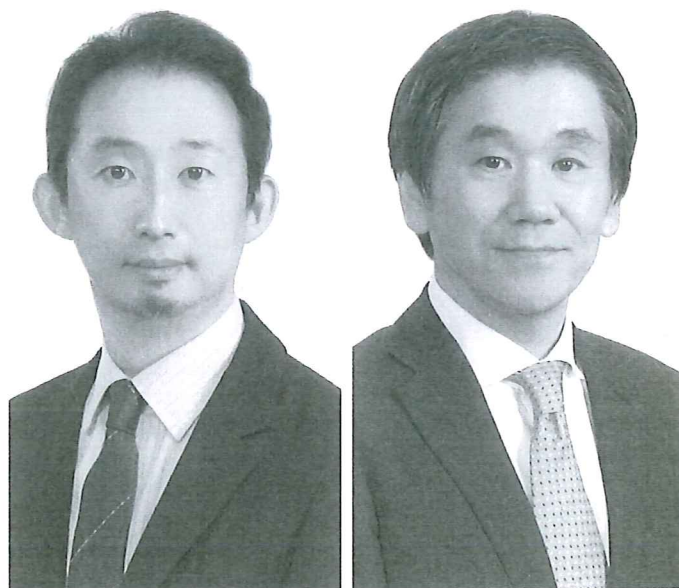
The established practice in the Japan Patent Office (JPO) prior to the revision was to deny patentability of an invention of a food product with a limitation of use due to lack of novelty or inventive step. For example, when "a yogurt comprising A as a component" was known, novelty or inventive step of "a yogurt for use in strengthening bones comprising A as a component" was not recognized, because "a yogurt for use in strengthening bones" was still used as a yogurt and did not provide any new use of the known yogurt.

On the other hand, the Japanese regulatory systems permit the food industries to use certain expressions to claim functional aspects of food products. For example, the Food Sanitation Act permits labeling of food products with "nutrient function claims" when the food conforms to the criteria set forth by the national regulatory authority or with "specified health use" when a special permit is issued by the national regulatory authority. Besides, the regulatory control on the labeling of food products has also been changed by the amended Food Labeling Act which took effect on April 1, 2015, to introduce the new system known as "food with function claims", which generally allows the food industries to label functions on their own responsibilities. Encouraged by these developments in the Japanese regulatory systems, the voices of the food industries became stronger, demanding more appropriate protection of FUIs by patent rights.

The 2016 revision of the JPO Guidelines and Examination HB on FUIs was a dramatic shift from the conventional practice to more practical ones, increasing chances to obtain protection of the food products as used, i.e., as labeled on the market, by claiming FUIs. The JPO Guidelines have inserted the following example as patentable claims for FUIs:

Example 2:

[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.

Since 2016, the JPO recognizes the limitations of use as exemplified above as allowable elements of invention as a basic rule, when reviewing novelty and inventive step of the claimed food product (composition).

Having said that, the JPO Guidelines and Examination HB also provide exceptions to the basic rule. When the claimed subject matter is directed to a compound, microorganism, animal or plant, even if it is specified with a limitation of use (e.g., "Compound Z for use in ..."

or "a banana for use in ..."), the limitation of use is not considered in the determination of novelty or inventive step of the subject matter. In addition, in the case where the claimed subject matter is expressed as "a food for use in X ...", when the claimed food is considered to encompass a plant or animal itself based on the descriptions in the specification, novelty or inventive step of the food may be denied in view of the existing food without the limitation of the use.

The revision of JPO Guidelines and Examination HB has enabled us to obtain protection of FUIs, i.e., food products as labeled on the market, but sales of food products generally

SOME FOOD PRODUCTS  
MAY BE OFFERED ON  
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EXPLICIT INDICATION  
OF THEIR USE

## JAPAN

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Mr Kamada has a life sciences and pharmaceuticals practice for clients based in Japan, the United States, the UK, the rest of Europe, Australia, Israel, China, Taiwan and Korea. He has directed prosecution of patent families covering over 50 countries, but his main work relates to prosecution, opposition and appeal procedures before the Japan Patent Office (JPO), as well as litigations before the IP High Court. He has handled more than 60 opposition and appeal proceedings before the JPO and their High Court appeals over the course of his carrier to date. Recent technologies he has been involved with include advanced life sciences such as regenerative medicine (e.g., stem cell technologies), cancer immunotherapy (e.g., TCR and CAR-T technologies, immune checkpoint inhibitors), gene therapy (e.g., genome editing, viral cancer therapy, DNA vaccine), nucleic acid medicine (e.g., antisense oligonucleotide, siRNA, miRNA, aptamer), antibodies (e.g., antibody medicine, diagnosis, human antibody production system), gene diagnosis (e.g., epigenetic diagnosis, metagenome analysis), biomarkers and the like, pharmaceuticals (e.g., new chemical compounds, second medical use, pharmaceutical compositions, new dosage form), biomaterials (e.g., culture medium, culture device, DDS carrier), bioinformatics, AI-technologies for medicine and drug discovery, foods and cosmetics.

With extensive experience in formulating patent strategies and managing patent portfolios, Mr Kamada counsels and renders opinions on patent validity, patent infringement and patent or knowhow licensing. He also counsels clients on freedom-to-operate issues.

Mr Kamada provides a number of lectures for IP members and researchers in pharmaceutical companies, universities, research institutes and other organizations related to IP in Japan on how to patent biotechnology inventions. He has also published articles in IP journals in Japan.

Mr Kamada graduated from Kyoto University with B.S. degrees in biology and chemistry, and then pursued graduate studies on molecular biology and genetic engineering at Hiroshima University. He joined TAKASHIMA International Patent Office in 1995, became Head of the Biotechnology Department in 2000 and has served as President of the firm since 2019.



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Natalia Gulyaeva is recognized as a leading Russian Life Sciences specialist and is named in international legal directories including *Chambers & Partners* as a highly recommended Russian practitioner who is “really on top of things”.

Natalia heads Moscow Life Sciences Practice since 2004. Natalia advises clients on all aspects of contentious and non-contentious work including strategic counseling, portfolio management/ auditing, dispute resolution (litigation and arbitration), anti-piracy actions and transactional work. According to *Chambers & Partners*, Natalia is praised by the peers and clients for “her business sense and clear management style” and is defined as a “creative, flexible and able to guide clients through the specifics of the Russian market” lawyer and “tough and focused attorney”. The clients do particularly compliment Natalia’s talent to see the legal matters from the in-house counsel perspective. The latter is no doubt due to the fact that Natalia joined Hogan Lovells after having spent several years in the role of counsel of an international corporation where she gained extensive experience within and outside of her Life Sciences expertise.

Natalia is admitted to represent clients before the Russian Patent and Trademark Office and enjoys rights of audience in the Chamber for Patent and Trademark Disputes and Russian courts. In addition to her qualification as a Russian lawyer, Natalia is admitted as English solicitor. Natalia is well-known for a chain of victories in IP disputes before the Russian courts. She is equally creative and successful in handling complex disputes between international and domestic corporations in Russia and other CIS countries and coordinating multi-jurisdictional litigations. Natalia also acts as arbitrator.

Natalia is widely published and is a regular speaker at high profile conferences, including ABA, ICC, MIP and INTA events. Natalia’s team has received over the years several WORLDLeaders International Awards for the work in representing international and domestic companies in IP litigious and transactional matters in Russia and other CIS countries. Natalia is the winner of 2015, 2016 and 2018 “Client Choice Award”.

Professional Memberships: Fellow of CI Arb, INTA.

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