



Gut Check: Microbiome patent update

By Mark J. FitzGerald and David S. Resnick

In this issue:

A survey of subject matter patent eligibility for microbiome-related technology in key jurisdictions around the world.

A recurring theme on these pages has concerned the various ways to satisfy the requirements regarding patent-eligible subject matter under §101 of the U.S. patent statute for microbiome-related technology. Of course, the U.S. isn't the only jurisdiction with limits on what can be protected under its patent laws; consider for a moment that the U.S. is largely alone in permitting patent claims drawn directly to methods of treatment of the human body. This begs the question of how other jurisdictions look at claims relating to the microbiome, e.g., coverage of naturally-occurring microbes, their metabolites, compositions comprising them and methods of using them. To address this, we asked trusted patent counsel who practice before the Australian, Canadian, Chinese, European and Japanese patent offices to comment for this issue of Gut Check. Their replies are compiled below. A special thanks to all!

AUSTRALIA:

As reported by Dr. Tony Davis of FB Rice

The most recent High Court decision concerning patentable subject matter in life science patents in Australia was *D'Arcy v Myriad Genetics Inc* [2015]. This decision concerned the patentability of isolated BRCA1 nucleic acid molecules having a sequence of nucleotides identical to naturally occurring nucleic acid molecules. Whereas the U.S. Supreme Court had invalidated Myriad's BRCA patents on the basis that products of nature are not patentable, the Australian High Court held that the "substance of the invention" of Myriad's claims to isolated nucleic acids was the sequence of nucleotides, or "genetic information," in the nucleic acid molecule itself. In particular, the Court found the substance of the invention was genetic information in the form of the mutations and polymorphisms in the BRCA gene sequence. Thus, in contrast to the U.S. Supreme Court, the Australian law on patentable eligibility has not adopted a product of nature exclusion to patent eligibility.

As a consequence, **claims to isolated natural products** (except isolated nucleic acids in which the substance of the invention is genetic information) **are still patent eligible in Australia**. The Australian patent office (IP Australia) states explicitly:

A standard patent can be obtained for isolated bacteria, cell lines, hybridomas, some related biological materials and their use and genetically manipulated organisms. Examples of patentable inventions include:

- isolated bacteria and other prokaryotes, fungi (including yeast), algae, protozoa, plasmids, viruses, prions
- cell lines, cell organelles, hybridomas
- genetic vectors and expression systems
- apparatus or processes for enzymology or microbiology
- compositions of microorganisms or enzymes
- propagating, preserving or maintaining microorganisms
- mutagenesis or genetic engineering
- fermentation or enzyme using processes to synthesise a desired compound or composition
- measuring or testing processes involving enzymes or microorganisms
- processes using enzymes or microorganisms to liberate, separate, purify or clean
- the use of microorganisms to produce food or beverages

Recently issued Australian microbiome-related patents

The granted patents detailed below provide examples of the claim scope that can be obtained in Australia.

AU 2017201330

- Title: Microbiota restoration therapy (MRT), compositions and methods of manufacture
- Assignee: Rebiotix, Inc.
- Date of Issue: 6 September 2018

Claim of interest

- A microbiota restoration therapy composition, comprising: a fresh stool sample from a human donor; and a cryoprotectant, the cryoprotectant comprising polyethylene glycol in saline at a concentration of 30-90 g/L.

The claims in this granted patent are of interest because they are directed to a stool sample composition for microbiota restoration and demonstrate that relatively broad claims may be achievable in Australia.

No patentable subject matter objection was raised during examination. Support and inventive step objections were overcome by argument without having to amend the claims.

AU 2015255313

- Title: Antibacterial phage, phage peptides and methods of use thereof
- Assignee: Tecnofar-Industria Tecnica Farmaceutica, SA; Technophage Investigacao E Desenvolvimento Em Biotecnologia SA
- Date of Issue: 2 November 2017

Claim of interest

- A purified bacteriophage having a genome which comprises at least 99% sequence identity to the nucleotide sequence of SEQ ID NO:560 and having antibacterial activity against *Staphylococcus aureus*.

The claims in this patent are of interest because they relate to isolated bacteriophage for the treatment of bacterial infections. The only objection raised in the examination report was a unity of invention objection, because the claims originally filed with the application covered multiple phages with different nucleic acid sequences.

AU 2013288416

- Title: Colicins for treating bacterial infections
- Assignee: The University of Glasgow
- Date of issue: 21 June 2018

Claim of interest

- Use of a therapeutic agent in the preparation of a medicament for treatment of Crohn's disease in a subject, wherein the therapeutic agent is selected from the group consisting of: (i) a colicin; (ii) a polynucleotide that encodes a colicin; (iii) a bacterium which produces and releases a colicin; and (iv) a food product comprising a bacterium which produces and releases a colicin.

The claims in this patent are of interest because they relate to the treatment of Crohn's disease by targeting pathogenic adherent *E. coli* in the ileal mucosa with colicins. The claim covers the delivery of the colicins by administering bacteria, such as *Lactobacilli* that express the colicins, to patients.

During examination, a patentable subject matter objection was raised to claims directed to polynucleotides encoding colicins on the basis that they comprise naturally occurring nucleic acid sequences. Other objections raised in the first examination report include novelty, inventive step and unity objections. To address the patentable subject matter objection, the claims to polynucleotides were deleted.

CANADA:

As reported by Justin Thuss, Alexander Camenzind and Trevor Newton of Gowling WLG

In recent years, researchers have discovered new and unexpected roles of the body's bacterial flora. The makeup, health, and complexity of what were previously considered "everyday bacteria" has led to new insights into their role in maintaining digestive health, and their impact on certain diseases and cancers. As research into this area becomes more prominent, companies look to protect their investment through a robust patent portfolio.

In Canada, microorganisms are patentable as they are classified as a “lower life form,” typically viewed as a composition of matter. Patent portfolios for microorganisms can be classified into two main categories:

- Patents protecting novel, genetically modified microorganisms, or microorganisms that have been isolated for the first time.
- Patents protecting new uses for previously known microorganisms.

Novel microorganisms

Recent advances in bioengineering through the modification of the DNA of existing strains of microorganisms allows for the creation of novel strains, which have never before existed. Patent protection is available for these microorganisms in Canada via novel compositions of matter, uses, formulations or synthesis/process claims.

Unlike some jurisdictions, Canada permits claims to compositions of matter which are derived from nature, but which have been studied and found to have a particular function. This includes isolated microorganisms, which were previously only available in a mixed form. Typically, to overcome issues of obviousness, isolation of the microorganism is accompanied with accompanies an unexpected activity or improvement.

Novel uses for known microorganisms

For existing microorganisms, which lack novelty, patent protection remains available in Canada for newly discovered industrial or therapeutic uses. New-use patents can provide protection for the time and expense of researching novel therapeutic treatment options, and justify the high price of regulatory trials. Novel treatment methods in Canada are protected through use claims, typically with Swiss-type claims in the form of “X for use in treating Y,” since methods of medical treatment are not permitted under Canadian law. Swiss-type use claims are common in Canada, routinely used to protect specific indications of small molecule pharmaceuticals, and would work equally well to protect microorganisms.

Recently issued Canadian microbiome-related patents

These three patents exemplify the coverage strategies described above.

[CA2753103](#)

- Title: Equol-producing bacterium and use thereof
- Assignee: Yakult Honsha Co. Ltd.
- Granted: September 12, 2017
- **Category A**—discovery and isolation of a previously unknown microorganism.

Claims of interest:

1. A bacterium which is *Slackia* sp. YIT 11861 (FERM BP-11231).
2. A food or beverage or pharmaceutical composition, comprising the bacterium of claim 1 and a carrier or diluent.

CA2734327

- Title: Compositions comprising *Lactobacillus casei* for improving resistance to common infectious diseases
- Assignee: Gervais Danone Cie
- Granted: July 31, 2018
- **Category B**—new use of a previously known microorganism.

Claims of interest:

1. Use of a *Lactobacillus casei* strain deposited at the CNCM under the reference I-1518, for the preparation of a composition for the treatment or prevention of a respiratory common infectious disease chosen among upper respiratory tract infection, rhinopharyngitis and sore throat, in a tobacco smoker, said composition further containing *Lactobacillus bulgaricus* and *Streptococcus thermophilus* bacteria.

CA2785268

- Title: Composition containing bacterium capable of producing propionic acid bacterium, and use thereof
- Assignee: Meiji Co Ltd, MEIJI FEED Co Ltd
- Granted: February 27, 2018
- **Category B**—new use of a previously known microorganism.

Claims of interest:

1. A method for preventing or treating, or preventing and treating rumen acidosis in ruminants, the method comprising orally administering a viable propionic acid bacterium and a clear culture supernatant of a lactic acid bacterium to a ruminant in need thereof, wherein the propionic acid bacterium is the *Propionibacterium freudenreichii* ET-3 strain (FERM BP-8115), and the clear culture supernatant of the lactic acid bacteria is obtained by removing solids from a culture of the *Lactobacillus gasseri* OLL2716 strain (FERM BP-6999).

As can be seen, broad patent coverage is available in Canada for both novel microorganisms, newly discovered or isolated microorganisms, and newly discovered uses for existing microorganisms. While the above examples all involve bacterial strains, this approach would apply equally to yeast, fungi, algae, protozoa, or other single-celled organisms.

CHINA:

As reported by Dr. Xin Hong, Insight Intellectual Property Attorneys

In general, an isolated strain or species of a naturally occurring microorganism *per se*, or modified or derived from a naturally occurring microorganism with an artificial chemical/physical process, an ingredient thereof, a lyophilized or viable preparation thereof, a composition containing the same, and use thereof constitute eligible subject matter under the current patent practice in China. However, a claim to a method for screening a specific microorganism from a natural environment, or a method for preparing a new microorganism by a chemical/physical process of artificial mutagenesis is deemed not repeatable, and will be rejected as lacking practical applicability unless

the applicant can prove the repeatability of the method—namely, prove that the microorganism having the desired characteristics can be re-obtained or reproduced with the claimed method. The first example below provides more specific commentary on this issue.

Recently issued Chinese microbiome-related patents

The following four patent examples (the prosecution of each of which were handled by Insight IP) focus on the isolated strain or species of a naturally occurring or modified microorganism, methods for preparing the same and use thereof.

Chinese Patent No. 201210310374.4

- Title: Compositions Comprising Derivative Bacterial Strains of *Clostridium Ghonii* and Methods of Use
- Original Applicant: Griffith University

Assignee: Shangdong Xinchuang Biotech Co., Ltd.

1. A bacterial strain derived from an avirulent, non-pathogenic strain of *Clostridium ghonii*, wherein the derived bacterial strain is capable of arresting growth of a solid tumor, and the derived bacterial strain comprises those having oncolysis obtainable by injecting the clostridial spores of *Clostridium ghonii* into an animal that supports growth of a solid tumor, and repeatedly adapting, selecting and re-isolating strains.

2. A bacterial strain derived from an avirulent, non-pathogenic strain of *Clostridium ghonii*, wherein the derived bacterial strain is capable of regressing or destroying a solid tumor, and the derived bacterial strain comprises those having oncolysis obtainable by injecting the clostridial spores of *Clostridium ghonii* into an animal that supports growth of a solid tumor, and repeatedly adapting, selecting and re-isolating strains.

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13. The strain of claim 1 or 2, wherein the avirulent, non-pathogenic strain of *Clostridium ghonii* is selected from the group consisting of ATCC Accession No. 25757, BCRC Accession No. 14548, CCUG Accession No. 9282, DSM Accession No. 15049, NCIMB Accession No. 10636, PEV, Prevot PEV, VPI Accession No. 4897 and VTT Accession No. E-042451.

16. The strain of claim 1 or 2, wherein the strain is MW-DCG_LCv26 as represented by Accession Number V12/001486.

Comments: The subject matter of “[A] bacterial strain derived from an avirulent, non-pathogenic strain of *Clostridium ghonii*” actually is a specific strain of *Clostridium ghonii* which is screened or adapted from known or naturally occurring strains, such as those recited in Claim 13, with a method as recited in below Claim 50. Interestingly, independent claims 1 and 2 are broad as they do not limit the bacterial strain to a specific one, such as that as recited in claim 16. One of the reasons for allowance is that the method of producing the strain, such as claim 50, does not comprise any step of artificial chemical/physical mutagenesis, and the strain will be deemed as being reproducible with the method.

17. A Clostridial spore of the strain of any one of claims 1 to 16.

Comment: The spore form of a bacterium is also patent eligible subject matter.

19. Use of a therapeutically effective amount of one or more clostridial spores according to claim 17 in the manufacture of a medicament for arresting the growth of, regressing, or destroying one or more solid tumors in a subject.

Comment: The medical use of a microorganism should be drafted in the Swiss type, which is patent eligible under the current patent practice.

30. A pharmaceutical composition comprising one or more clostridial spores of claim 17 and a physiologically acceptable carrier and/or excipient.

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Comment: A composition comprising an isolated strain or species of naturally occurring microorganism is patent eligible subject matter.

...

50. A process of deriving a bacterial strain from an avirulent, non-pathogenic strain of *Clostridium ghonii*, wherein the derived bacterial strain produced by the process is capable of arresting the growth of, regressing or destroying one or more solid tumors by oncolysis of cells within the microenvironment of the one or more tumors, wherein said derived bacterial strain produced by the process causes less toxicity than a reference clostridial strain, and wherein the process comprises injecting the clostridial spores of *Clostridium ghonii* into an animal that supports growth of a solid tumor, and repeatedly adapting, selecting and re-isolating strains, thereby obtaining bacterial strains having oncolysis.

51. The process according to claim 50, comprising:

- (1) Preparing injectable clostridial spores from the avirulent, non-pathogenic strain of *Clostridium ghonii*.
- (2) Injecting the clostridial spores of (1) into an animal that supports growth of a solid tumor;
- (3) Assessing parameters to determine rate and degree of oncolysis and toxicity;
- (4) Collecting vegetative rods from the tumor of (2) by harvesting the tumor; and
- (5) Repeating steps (1) to (4) between about 10 to about 35 times.

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Comments: The method of claim 50 or 51 does not comprise any step of artificial chemical/physical mutagenesis, and the strain obtained therefrom will not be deemed as one randomly or occasionally produced. Since the same or similar strain can be reproduced with the method, such method is patent eligible.

Chinese Patent No. 201080034202.8

- Title: Anti-Inflammatory Bacteria
- Assignee: The Chinese University of Hong Kong

1. Use of a lactic acid bacteria in preparing a medicament for treating gastric cancer in the mammal, the lactic acid bacteria transformed to secrete biologically active cathelicidin, wherein the cathelicidin is SEQ ID NO:1 or SEQ ID NO:2, and wherein the lactic acid bacteria is selected from the group consisting of *Lactococcus* sp., *Lactobacillus* sp., and *Bifidobacterium* sp.

Comment: The medical use of a modified bacterial strain is also patent eligible.

Chinese Patent No.: 201280054515.9

- Title: Bacterium for Use as a Probiotic for Nutritional and Medical Applications
- Patentee: 4D Pharma Research Limited

1. Use of a bacterial species *Roseburia hominis* in the preparation of a medicament for treating a disease selected from an inflammatory disorder, an immune disorder and/or an intestinal disorder in a subject, wherein the immune disorder is selected from autoimmune conditions and allergies.

Comment: The medical use of a naturally occurring bacterial species is patent eligible.

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20. A pharmaceutical composition comprising the bacterial species *Roseburia hominis* and a pharmaceutically acceptable excipient, carrier or diluent, for use according to any one of claims 1–19.

21. A nutritional supplement comprising the bacterial species *Roseburia hominis* and a nutritionally acceptable excipient, carrier or diluent, for use according to any one of claims 1–19.

22. A probiotic composition comprising the bacterial species *Roseburia hominis*, for use according to any one of claims 1–19.

23. A feedstuff, food product, dietary supplement, nutritional supplement or food additive comprising the bacterial species *Roseburia hominis*, for use according to any one of claims 1–19.

Comment: A composition or preparation comprising a naturally occurring bacterial species is patent eligible.

Chinese Patent No.: 201280029881.9

- Title: Methods of Mutagenesis of *Schizochytrium* sp and Variant Strains Produced Thereof
- Patentee: ROQUETTE FRERES

1. A variant of *Schizochytrium* sp. strain identified as 2010-0321 and deposited at the Chinese Center for Type Culture Collection with the deposit reference number of CCTCC M 2011024.

Comments: A variant of a naturally occurring microorganism is patentable. However, if since such variant is occasionally obtained, it should be deposited with a competent entity under the Budapest treaty.

4. A method for producing a variant of *Schizochytrium* sp. strain comprising
- inducing mutagenesis in a *Schizochytrium* sp. strain by exposing said *Schizochytrium* sp. strain to UV radiation to produce a mutant strain;
 - contacting the mutant strain with an acetyl coenzyme A carboxylase inhibitor; and
 - selecting a variant of *Schizochytrium* sp. strain having increased DHA content and/or improved growth rate as compared with a naive *Schizochytrium* sp. strain.

Comments: The method of claim 4 is **NOT** patent eligible since each of variants obtained through performing the method will have varying characteristics, and it is deemed that the same variant cannot be reproduced with such a method. Accordingly, the above claim is not comprised in the granted claim set. However, it is our point of view that the variant having similar characteristics could be reproduced with the method as claimed, since the method comprises the steps of resistance selection with an acetyl coenzyme A carboxylase inhibitor in addition to the first mutagenesis step. Such claim is pending in a divisional application, and this argument is being presented to traverse the rejection.

11. A method of producing DHA comprising
- culturing a variant of *Schizochytrium* sp. strain according to any one of claims 1 to 3 or produced by the method of any one of claims 4-10 under conditions suitable for culturing a *Schizochytrium* sp. strain to produce DHA; and optionally
 - collecting DHA from a biomass of the cultured variant of *Schizochytrium* sp. strain, or a culture medium thereof.

Comment: A method of using a strain of a naturally occurring or modified microorganism for producing a metabolite or bio-product is patent eligible.

14. A biomass produced by the method according to any one of claims 11 to 13.

Comment: The metabolite or bio-product resulting from culturing a strain of a naturally occurring or modified microorganism is patent eligible.

EUROPE:

As reported by Caroline de Mareuil-Villette and Mathieu Porchet, of Icosa IP

The European Patent Office (EPO) generally accepts the patent eligibility of naturally occurring microorganisms, as long as their utility is recited in the claims. An example that may be of interest for new parents: did you know that we now have the secret for avoiding babies excessive crying?

Recently issued European microbiome-related patents

EP3030247

EP3030247 was granted to AB BIOTICS SA for a *Pediococcus pentosaceus* composition, which has the ability to induce the production of interleukin-10 (see claim 1) for use in the amelioration of excessive crying in infants (see claim 9).

1. A bacterial composition which comprises from 10^4 to 10^{12} cfu/g of *Pediococcus pentosaceus* viable cells **which have the ability to induce the production of interleukin-**

10, wherein the production of interleukin-10 by THP-1 macrophages in the presence of *Pediococcus pentosaceus* cells as expressed as normalized increase is higher than the production of interleukin-10 by the negative control, which are THP-1 macrophages in the absence of *Pediococcus pentosaceus* cells, when the normalized increase is determined by the following steps: {details of the specific benchmark IL-10 induction assay recited in the claim are not reproduced here}.

9. A bacterial composition as defined in any of the claims 1-8, **for use in the amelioration of excessive crying in infants**.

In this example, the language “which have the ability to induce the production of interleukin-10” is essential for the grant of the claim. The positioning of the EPO examination with regard to inventive step remains on the problem-solution approach, which also emphasizes that the solution be spelled out in the claim.

What happened in Europe in 2018 in the field of granted patents for microbiome inventions most definitely includes EP2833767 (B1) in the name of NESTEC. This may be one of the first artificial intelligence-related patents granted for microbiome inventions in Europe. Apparently, it was possible to obtain a patent on a comparison of an infant’s health status with a database containing lots of information on infants’ health statuses and their nutrition, in order to control delivery of appropriate ingredients (including probiotics) to said infant (enteral route). This opens a new door for AI and microbiome at the EPO. Claim 1 is copied below:

1. An apparatus (1) for providing metered amounts of ingredients to a nutritional composition for use in administration to an infant, such as for use in an enteral administration, the apparatus:

- comprising a plurality of containers (2), each containing one or more ingredients for the nutritional composition,
- comprising a plurality of delivery devices (3), each being connected to a container (2) and adapted to deliver from a container (2) a metered amount of the one or more ingredients, to form part of the nutritional composition, to a receptacle (4),
- comprising input means (14) adapted to receive an input from a user relating to the amounts of the one or more ingredients to be delivered from the apparatus (1),
- comprising or having access to a database (6) storing recommended intake values of nutrients as a function of health parameters of an infant,
- comprising or having access to a database (6) storing values of nutrient content(s) of the ingredients present in the containers (2),

wherein

- the input from a user relating to one or more amounts of ingredients to be delivered from the apparatus (1) is health parameters of an infant,

- the delivery devices (3) being adapted to retrieve from the data base (6) recommended intake values of nutrients corresponding to the health parameters input, and determine the amounts of ingredient to be delivered from one or more of the containers (2) accordingly,
- comprising a controller (7) being adapted to control the metered amounts of ingredients delivered individually from the containers by the delivery devices (3) in response to the input from the user and to
- retrieve from the data base (6) the amount of nutrient(s) in an ingredient,
- determine the amounts of ingredient to be delivered from the containers (2) corresponding to amounts of nutrients requested by the user through the input means (14), and
- control the delivery devices (3) to deliver into the receptacle (4) the determined amounts of ingredient from a container (2),

wherein the apparatus further comprises or has access to a database storing data of reactions of infants previous fed with a composition produced by the apparatus according to any of the preceding claims or in general.

EP2805625

EP2805625 (Nutricia) experimented with long-lasting prosecution. At the end of a process beginning in 2006, a composition comprising *Bifidobacterium breve*, a non-digestible saccharide A and a non-digestible saccharide B (see claim 1, below), and optionally *Lactobacillus paracasei*.(see claim 5) was patented as it increased the level of *Bifidobacteria* in faeces and regulated the *Bifidobacteria* population in the intestinal tract.

1. A composition having a viscosity between 1 and 60 mPa.s, as determined using a Physica Rheometer MCR 300 (Physica Messtechnik GmbH, Ostfilden, Germany) at shear rate of 95 s⁻¹ at 20 °C, a caloric density between 10 and 250 kcal per 100 ml, comprising *Bifidobacterium breve*, a non-digestible saccharide A and a non-digestible saccharide B, wherein:

- a. non-digestible saccharide A has a degree of polymerisation of 2-8 and at least 60 mol% of the total monosaccharide units of saccharide A are monosaccharides selected from the group consisting of fructose and glucose monosaccharides; and
- b. non-digestible saccharide B has a degree of polymerisation of 8-100 and at least 60 mol% of the total monosaccharide units of saccharide B are monosaccharides selected from the group consisting of fructose and glucose monosaccharides; and wherein the average degree of polymerisation of saccharide A is at least 5 monosaccharide units lower than the average degree of polymerisation of saccharide B.

Other symbiotic patents were also granted in 2018, likely indicating a trend of the EPO in regard to symbiotic combination patents.

JAPAN:

As reported by Hideki Koder and Hatsushi Shimizu, Shimizu Patent Office

The following provides some basic understanding of “subject matter eligibility” for microbiome-related inventions, and approaches for seeking patent protection for them as “a composition of matter” under current examination practice of Japan Patent Office (JPO).

Naturally occurring microorganisms and any substance from them are subject matter eligible for a patent if they have been “artificially isolated” and have any “utility.”

The main paragraph of Article 29(1) of Japanese Patent Law stipulates subject matter eligibility for a patent by stating that “Any person who has made an **invention** which is **industrially applicable** may obtain a patent therefor” (emphasis added). This provides two requirements: the subject matter as claimed must be “an invention” and must have “industrial applicability.” To be a statutory invention, it must be a “creation,” and accordingly mere discovery of any naturally occurring thing, (e.g., an ore, for which no creation of a technical idea is found) is not considered to be a statutory invention.

A naturally occurring microorganism, chemical substance, or the like, which is “artificially isolated” from nature is, however, considered to be a creation and therefore a statutory invention. In this respect, a microbe, collection thereof, or substance isolated therefrom so identified artificially meets the first requirement, “an invention.” The other requirement, “industrially applicable” (i.e., utility) would be usually met if the microbe, collection thereof or substance isolated therefrom is defined in claim(s) with a suitable format (i.e., a claim drawn to medical practice by a doctor is considered *not* to be industrially applicable), and the specification as filed provides a suitable description how the microbe, collection thereof or substance as claimed is used industrially.¹

How a patent may be sought for a naturally occurring microbe as “a composition of matter”?

Assuming an artificially-isolated microbe is novel and enabling for the patent purpose, it can be defined in a claim as “a new strain.” In addition, or in the alternative (i.e., if the microbe so isolated is a known strain), any new use of the microbe may be defined as “a composition for medical use.” A claim may read, for example, as a therapeutic or prophylactic (preventing) agent/ a medicament / a therapeutic composition / a pharmaceutical composition for treating or preventing, comprising [a microbe] for [a disease, disorder, or condition]. A similar format applies to substances isolated from such microbes.

We note that in addition, or in the alternative, current JPO practice, which was changed and made effective as of April 1, 2016, permits one to seek patent protection for any new use of a known active ingredient (e.g., microorganism such as *Chlorella vulgaris*) as “a food composition” for the new use.^{2,3} Before then, as long as the composition (i.e., component) itself is identical to the known one, a food composition defined by the intended new use was considered to be identical to the known food composition. In response to the increase in health-consciousness in society and the increased active research and development in industry regarding functional foods, a claim drawn to a food composition intended for “a new use” is now patent-eligible. For example, assuming one found that taking *Chlorella vulgaris* could strengthen a bone, such new finding can be defined in a claim to a food composition for strengthening a bone comprising *Chlorella vulgaris*.³

One example for reference of an issued microbiome-related Japanese patent that our firm has represented, for which a translation of the independent claims reads as below:

JP Pat. No. 6150312; Assignee: Meiji Holdings., Ltd.

Claim 1. A food composition for increasing muscle volume of a subject, comprising, as an active ingredient, *Lactobacillus gasseri* OLL2809 strain only, as deposited with an accession number NITE BP-72.

Claim 2. A food composition for increasing muscle volume of a subject, comprising, as an active ingredient, a processed product of *Lactobacillus gasseri* OLL2809 strain only, as deposited with an accession number NITE BP-72,

wherein said processed product is at least one selected from the group consisting of a culture, a concentrate, a paste, a spray-dried material, a freeze-dried material, a vacuum-dried material, a drum dried material, a fluid material, a diluted material, and a broken material of the strain.

- Ref. 1: Examination Guidelines for Patent and Utility Models in Japan, Part III, Chapter 1, “Eligibility for Patent and Industrial Applicability (Main Paragraph of Article 29(1) of the Japanese Patent Law), Japan Patent Office
- Ref. 2: Examination Guidelines for Patent and Utility Models in Japan, Part III, Chapter 2, Section 4, “Claims Including Specific Expressions”, Japan Patent Office
- Ref. 3: Examination Guidelines and Others in Life Sciences Field, June 2018, Japan Patent Office

Conclusion: Subject matter eligibility in international jurisdictions

While there are specific rules that apply in each jurisdiction, perhaps the most striking thing from the perspective of a U.S. patent attorney is the number of other major jurisdictions that permit composition and method of use patents on naturally occurring microorganisms. Don't let the U.S. PTO slow you down if you have a newly isolated strain or consortium that has efficacy for a given indication!! The rest of the world awaits!!

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

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