**Standing Committee Study Question**

by the AIPPI Standing Committee on Biotechnology

# 2026 – Standing Committee Study Question

# Patentability of Microbiomes

## Introduction

1) In recent years there has been a rapid increase in inventions, and correspondingly in patents and patent litigation, involving microbiomes, the collective of microoganisms that exist naturally in a particular environment, such as in the gut or the skin of a host organism. These microbiomes (which may also exist in the form of isolated bacterial consortia, isolated individual bacterial strains, and/or genetically engineered bacterial strains) have shown promising applications in health and well-being, such as the use of microbiomes or isolated microorganisms in the treatment of specific diseases and disorders; in the provision of "functional foods", engineered foodstuff, or animal fed supplements; in agriculture; in fermentation technologies; and in environmental sustainability approaches.

2) This Study Question by the AIPPI Standing Committee on Biotechnology examines various issues stemming from the present lack of international harmonisation on the patentability of inventions related to microbiomes/microbiological consortia and isolated bacteria as well as their medical and technical applications. Whereas most jurisdictions provide sound patent protection for such inventions, there are still some major jurisdictions that significantly limit the IP protection available for these important inventions.

3) For the purposes of this Study Question, a microbiome-related invention (hereafter referred to as "Microbiome Invention") may encompass:
    a. an isolated naturally occurring microorganism;
    b. a modified and/or engineered microorganism;
    c. an isolated naturally occurring microbiome or a microbial consortium comprising isolated naturally occurring microorganism(s);
    d. a modified and/or engineered microbial consortium;
    e. a composition comprising a naturally occurring microbiome and/or a microbial consortium comprising isolated naturally occurring microorganism(s);
    f. a composition comprising a modified and/or engineered microbial consortium; or
    g. a composition comprising a) an isolated naturally occurring microbiome and/or a microbial consortium comprising isolated naturally occurring microorganism(s), and b) a modified and/or engineered microbial consortium;

    wherein (a) to (g) do not encompass any plant or animal organisms or parts thereof.

**Why AIPPI considers this an important area of study**

4) Microbiomes, microbial consortia and individual, isolated bacteria comprised in such microbiomes hold substantial promise in revolutionising approaches across a broad range of industries, including health, agriculture, fermentation technologies, production of “functional foods”, environmental sustainability, etc.

5) Uncertainty over, or the unavailability of patent eligibility of Microbiome Inventions, especially in jurisdictions with restrictive views on the patentability of natural products or biotechnological methods is a significant hurdle to the development of this important field, which may chill investment and hinder the realisation of the potential of this technology.
6) Ensuring the reproducibility and enablement of Microbiome Inventions, given the variability in microbial communities across different environments and/or hosts, is also crucial.

7) Establishing a harmonized framework for the patentability of Microbiome Inventions is therefore critical in fostering investments in research and development in this emerging and crucial field.

**Relevant treaty provisions**

8) Article 8 (1) of the TRIPs Agreement states:

*"Members may, in formulating or amending their laws and regulations, adopt measures necessary to **protect public health and nutrition**, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."*

9) Further, Article 27 (2) and (3) of the TRIPs Agreement state:

*2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect **human, animal or plant life or health** or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*

*3. Members may also exclude from patentability:*

*(a) **diagnostic, therapeutic and surgical methods for the treatment of humans or animals**; (…)*

*(b) plants and animals **other than micro-organisms**, and essentially biological processes for the production of plants or animals **other than non-biological and microbiological processes**. (…)*

**Scope of this Study Question**

10) This Study Question the need for international harmonisation on the patentability of inventions related to microbiomes/microbiological

consortia and isolated bacteria as well as their medical and technical applications.

**Previous work of AIPPI**

11) In Resolution Q93 (1994) on Biotechnology, AIPPI reaffirmed the broad principle that inventions involving living organisms (microorganisms, plants, animals, parts thereof, biological material, and processes to obtain or use them) should be patentable provided they meet the patentability criteria. The Resolution rejected narrowing "biotechnological inventions" to particular techniques and emphasized the beneficial role of patent protection for technological, economic and social progress. AIPPI also stated that moral and ethical issues arising from biotechnology should be dealt with by laws specifically addressing those concerns (and by existing patent exclusions for inventions contrary to ordre public or morality), rather than by introducing blanket prohibitions into patent law.

12) In Resolution Q259 (2017) on Gene Patenting AIPPI reaffirmed that, as a matter of principle clearly reflected in TRIPS Agreement, patents should be granted for any inventions in all fields of technology including genes or parts thereof isolated from nature by a technical pro-cess or nucleic acid molecules artificially synthesized, provided an industrial, agricultural, diagnostic and/or therapeutic application is identified and other patentability criteria are met. Furthermore, genetic materials should not be regarded as subject matter excluded from pa-tentability by virtue of TRIPS Article 27(2) and (3), and in particular, should not be regarded as inventions contrary to ordre public or morality. AIPPI also resolved that genetic material "isolated" from nature by a technical process should not be treated as a mere "product of nature" or found patent ineligible for that reason alone. AIPPI strongly supported the implementation of the necessary legislative measures to ensure that genetic materials, when isolated from nature or artificially synthesized, constitute patent eligible subject matter.

13) This Study Question shall focus on the patentability of the various types of Microbiome Inventions. Novelty, inventive step, utility, and enablement requirements for Microbiome Inventions will be considered.

**You are invited to submit a Report addressing the questions below. Please refer to the 'Protocol for the preparation of Reports'.**

## Questions

### I. Current law and practice

Please answer all questions in Part I on the basis of your Group's current law.

For each question that follows, please answer YES or NO AND provide a brief explanation.

1) Are there any specific laws or regulations in your country that address and/or regulate the patenting of Microbiome Inventions? [YES/NO] If so, please summarize the current state of the law and patent office practice in your jurisdiction concerning the patenting of Microbiome Inventions.

2) Does your jurisdiction exclude strains of isolated microorganisms and/or microbiomes from patentability? [YES/NO] You may add a brief explanation.

3) Does your jurisdiction exclude man-made microbial consortia comprising isolated naturally occurring microorganism(s) from patentability? [YES/NO] You may add a brief explanation.

4) Does your jurisdiction exclude man-made compositions comprising isolated naturally occurring microorganism(s) from patentability? [YES/NO] You may add a brief explanation.

5) If you have answered yes to any of questions 2 to 4 above, please provide a brief explanation of the basis for the exclusion from patentability. In particular, please identify whether the exclusion is based on the issue of lack of eligible subject matter (e.g., such as the 101 provisions in the US) and/or based on lack of substantive patentability requirements (i.e. novelty, lack of inventive step obviousness and/or insufficiency of disclosure/enablement).

6) Does your jurisdiction allow for the patenting of Microbiome Inventions derived from the human microbiome? [YES/NO] If so, please explain under what conditions this is allowed.

7) Are there any enablement/written disclosure/sufficiency requirements particularly pertaining to or relevant for Microbiome Inventions in your jurisdiction which must be satisfied? [YES/NO] You may add a brief explanation. For example:

   a. Is a deposit necessary? [YES/NO] You may add a brief explanation.
   b. If a deposit is necessary, does this deposit need to be under the Budapest Treaty? [YES/NO/NOT APPLICABLE] You may add a brief explanation.
   c. Is reference to a genetic marker necessary? [YES/NO/NOT APPLICABLE] You may add a brief explanation.
   d. Is definition via structural features necessary, such as 16s RNA? [YES/NO/NOT APPLICABLE] You may add a brief explanation.

8) Does your jurisdiction allow for the patenting of uses of and/or methods using Microbiome Inventions? [YES/NO] You may add a brief explanation.
   a. If YES, please explain under what conditions the patenting of uses of and/or methods using Microbiome Inventions is allowed.
   b. If YES, is there any difference between claims directed to medical vs. non-medical (e.g. cosmetic) applications?

9) What are the key issues or challenges that arise when enforcing patent rights related to Microbiome Inventions in your jurisdiction?

## II. Policy considerations and proposals for improvements of your Group's current law

10) According to the opinion of your Group, is your current law regarding the patenting of Microbiome Inventions adequate and/or sufficient? [YES/NO] You may add a brief explanation.

11) Are there any other policy considerations and/or proposals for improvement to your Group's current law falling within the scope of this Study Question? [YES/NO] You may add a brief explanation.

## III. Proposals for harmonisation

12) Is there a need for international harmonization of patenting policies for Microbiome Inventions? [YES/NO] You may add a brief explanation.

13) Should isolated naturally occurring microorganisms, isolated naturally occurring microbiomes, and/or microbial consortia comprising isolated naturally occurring microorganisms be excluded from patentability?

    a. Naturally occurring microorganisms should be excluded from patentability [YES/NO] You may add a brief explanation.
    b. Isolated naturally occurring microbiomes should be excluded from patentability [YES/NO] You may add a brief explanation.
    c. Microbial consortia comprising isolated naturally occurring microorganisms should be excluded from patentability [YES/NO] You may add a brief explanation.

14) Should there be specific requirements for patent applications related to Microbiome Inventions (e.g., defining microorganisms and/or microbial consortia in the Microbiome Invention)? [YES/NO] You may add a brief explanation.

15) Are there any additional issues concerning any aspect of patenting Microbiome Inventions that you consider relevant to harmonisation considerations? [YES/NO] You may add a brief explanation.

16) Please indicate which industry sector views provided by in-house counsels are included in your Group's answers to Part III.