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2026 AIPPI World Congress – Hamburg
Adopted Resolution
10 October 2026

Standing Committee on Biotech Resolution

Microbiome-Based Inventions

Background:

1) In recent years there has been a rapid increase in inventions, and correspondingly in patents and patent litigation, involving "microbiomes", defined as "the collective of microorganisms that exist naturally in a particular environment, such as in the gut or the skin of a host organism". Microbiome-based inventions also encompass isolated bacterial consortia, isolated individual bacterial strains, and/or genetically engineered bacterial strains. Microbiome-based inventions hold substantial promise for revolutionising approaches across a broad range of industries, including health, agriculture, fermentation technologies, production of "functional foods", environmental sustainability, etc.

2) There is a lack of harmonisation between jurisdictions as to the requirements for patent protection for microbiome-based inventions, and, in particular for subject matter eligibility and enablement requirements.

3) Article 27(1) of the Trade-Related Aspects of Intellectual Property Rights Agreement (hereinafter "TRIPS") indicates that patents shall be available for inventions, whether products or processes, in all fields of technology provided they are new, involve an inventive step, and are capable of an industrial application.

4) TRIPS Article 8(1) 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*."

5) TRIPS Articles 27(2) allows – but does not require – members to 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*."

6) 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.

7) 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 process 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 patentability by virtue of TRIPS Articles 27(2) and (3) and 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.

8) For microbiome-based inventions, uncertainty over requirements and lack of harmonisation pose significant challenges to the development of this important field, which may chill investment and hinder the potential of this technology to positively impact healthcare, nutrition, agriculture, and environmental sustainability.

9) AIPPI Standing Committee on Biotechnology initiated a study on microbiome-based inventions. 31 Reports were received from AIPPI's National and Regional Groups and Independent Members providing detailed information and analysis regarding national and regional laws relating to this Resolution. These Reports were reviewed by the Standing Committee on Biotechnology and by the Reporter General Team of AIPPI and distilled into a Summary Report (which can be found at www.aippi.org).

10) At the AIPPI World Congress in Hamburg in 2026, the subject matter of this Resolution was further discussed within a dedicated Study Committee, and again in a full Plenary Session, following which the present Resolution was adopted by the Executive Committee of AIPPI.

AIPPI resolves that:

1) There should be no categorical exclusion from patenting microbiome-based inventions solely because they concern microorganisms, microbial consortia, or microbiomes isolated from natural environments; or biological material derived therefrom.

2) Patentability requirements for microbiome-based inventions should be assessed under ordinary principles applicable to biotechnology inventions (if applicable) rather than through technology-specific exclusions or prohibitive requirements.

3) Subject matter eligibility for microbiome-based inventions should not take into account other patentability requirements, including novelty, inventive step, enablement, or sufficiency.

4) Technical intervention should confer subject matter eligibility to microbiome-based inventions. Such technical intervention may include for example isolating, modifying, formulating, engineering, or using microorganisms, microbial consortia, or microbiomes originating from natural environments, or biological material derived therefrom.

5) Microbial consortia and other microbiome-based compositions should be assessed for patentability requirements as compositions of matter. This assessment should at least include consideration of formulation, functional interaction, and/or synergistic technical effect. Microbial consortia and microbiome-based compositions should not *per se* be ineligible for patent protection solely because their constituent organisms individually occur in nature.

6) Assessment of disclosure, enablement, sufficiency, and reproducibility of microbiome-based inventions should be internationally consistent and predictable. It should be possible to satisfy requirements with one or more of:
   - deposit of biological material, including microbial consortia;
   - technical characterisation of microorganisms and/or microbial consortia;
   - genomic, proteomic, phenotypic, functional, and/or compositional data;
   - validated analytical methods;
   - the source or the process of obtaining the microbiome-based invention; and
   - other information enabling the skilled person to reproduce the invention.

7) Deposition of biological material under the *Budapest Treaty* and other systems that accept deposits of biological material to support patent filings should be optional but, when a deposit is duly made and disclosed in the patent

application, the biological material should be considered to be sufficiently disclosed.

8) Depository Authorities under the *Budapest Treaty* and other systems that accept deposits of biological material to support patent filings should accept deposits of individual microorganisms, microbiomes and mixed microbial consortia to the extent technically possible.