Summary Report

2026 – Standing Committee Biotech SQ

Microbiome Inventions

Introduction

In recent years there has been a rapid increase in inventions, and correspondingly in patents and patent litigation, involving microbiomes, the collective of microorganisms 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 feed supplements; in agriculture; in fermentation technologies; and in environmental sustainability approaches.

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. 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.

The Reporter General and the Standing Committee on Biotechnology have received Reports from the following Groups and Independent Members in alphabetical order: Argentina, Australia, Belgium, Brazil, Bulgaria, Canada, China, Colombia, Croatia, Ecuador, Egypt, Finland, France, Germany, Hungary, India, Israel, Italy, Japan, Mexico, Netherlands, Philippines, Poland, Portugal, Singapore, Sweden, Thailand, Turkey, United Kingdom, United States, and Vietnam.

31 Reports were received in total. The Reporter General Team thanks the Groups and Independent Members for their helpful and informative Reports. All Reports may be accessed in AIPPI's library at www.aippi.org.

The Reports provide a comprehensive overview of national and regional laws, practices, and policies relating to the patentability of Microbiome Inventions, set out in three parts:

- Part I – Current law and practice
- Part II – Policy considerations and proposals for improvements of your Group's current law
- Part III – Proposals for harmonisation.

This Summary Report does not summarise Part I of the Reports received. Part I of any Report is the definitive source for an accurate description of the current state of the law in the jurisdiction in question.

This Summary Report has been prepared on the basis of a detailed review of all Reports (including Part I) but focuses on Parts II and III, given AIPPI's objective of

proposing improvements to, and promoting the harmonisation of, existing laws. As it is a summary, if any question arises as to the exact position of a particular Group in relation to Parts II or III, please refer to the relevant Report directly.

In this Summary Report:

- references to Reports of or responses by one or more "Groups" may include references to Independent Members;
- where percentages of responses are given, they are rounded to the nearest 5%; and
- in Part IV below, some conclusions have been drawn in order to provide guidance to the Study Committee for this Study Question.

I. Current law and practice

For the replies to Questions 1) to 9) for this Study Question, reference is made to the full Reports. The Reports may be accessed in AIPPI's library at www.aippi.org.

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? Please answer YES or NO and please explain your chosen view briefly.

20 of the responding Groups stated YES (approximately 65%), while 11 Groups (approximately 35%) stated NO.

Thus, a majority of the Groups considered that their current law regarding the patenting of microbiome inventions is adequate and/or sufficient. However, a significant minority identified development needs.

The Groups that answered YES generally considered that existing general patent law frameworks — including provisions implementing the EU Biotech Directive 98/44/EC, the EPC, and TRIPS — provide a sufficiently flexible and robust basis for the examination and protection of microbiome inventions, without the need for

microbiome-specific legislation. Some of the Groups, such as the UK Group raised concerns on the applicability of special legislation over time by noting that "*specific law directed to microbiomes runs the risk of being quickly outdated*."

The Groups that answered NO generally identified specific gaps or uncertainties in their current legal frameworks. The most commonly cited deficiencies included: the absence of specific examination guidelines addressing complex microbiome-related subject matter; legal uncertainty regarding the distinction between patentable inventions and non-patentable discoveries in the context of isolated microorganisms and microbial consortia; limitations on the patentability of isolated naturally occurring microorganisms; and insufficient guidance on disclosure and enablement requirements for complex microbial communities. Some of the Groups, such as the Argentine Group, also pointed out the need to ensure sufficient incentives for innovation by noting that "*new Guidelines and a more modern legislation, which effectively define the limits of what should be patentable while providing proper incentives for innovation in this greatly relevant technical field, would be beneficial*."

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?

20 of the responding Groups stated YES (approximately 65%), while 11 Groups (approximately 35%) stated NO.

The Groups that answered YES identified a range of additional policy considerations and proposals for improvement. The most frequently raised issues were as follows.

Several Groups called for the development of specific examination guidelines addressing microbiome inventions, including guidance on the distinction between patentable inventions and non-patentable discoveries, acceptable claim formats, and disclosure and reproducibility requirements (such as the level of specificity required, acceptable methods of characterisation, and requirements for reproducibility given natural microbial variability) for complex microbial communities.

Several Groups also raised concerns about the adequacy of the deposit system for complex microbiome inventions. The Japanese Group, for example, noted the need to modernise the deposit system as a result of the existing infrastructure being primarily intended for single strains and not designed to adequately

accommodate combined consortia. The Canadian Group, on the other hand, proposed modernising deposit regime to account for the practical challenges of depositing diverse, multi-component microbial communities, and to clarify when molecular data may be appropriate or required to satisfy the sufficiency of disclosure requirement. The Netherlands Group called for more guidance on microbiome-specific disclosure requirements, particularly for multi-species consortia, context-dependent microbial interactions, and dynamic ecosystems.

The US Group raised concerns about the interaction between microbiome inventions and the 2024 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, in particular with respect to any additional disclosure requirements. The Turkish Group proposed the establishment of a benefit-sharing mechanism for inventions involving genetic resources, as well as state support or tax incentives for research in this field. The Portuguese Group proposed the introduction of a rebuttable presumption of infringement based on genomic or functional similarity, combined with regulatory provenance disclosure, as an effective enforcement model for microbiome patents.

III. Proposals for harmonisation

12) Is there a need for international harmonization of patenting policies for Microbiome Inventions? Please answer YES or NO and add a brief explanation.

29 of the responding Groups stated YES (approximately 95%), while 2 Groups (approximately 5%) stated NO.

An overwhelming majority of the Groups supported international harmonisation of patenting policies for microbiome inventions. The most commonly cited justification was the need to reduce legal uncertainty arising from divergent national standards on subject-matter eligibility, disclosure requirements, and claim formats, which creates significant challenges for applicants seeking patent protection across multiple jurisdictions. These considerations were expressed consistently among the responding Groups as exemplified, e.g., by the Israeli Group noting that "*applicants face divergent approaches across jurisdictions on issues such as the treatment of naturally occurring biological material, the patentability of defined microbial communities, enablement and disclosure standards, and permissible claim formats for medical and non-medical uses*" and that "*a more*

harmonized framework would improve predictability, reduce transactional and administrative burdens, support responsible investment and innovation". In the same vein, the German Group emphasized that the differences in the subject matter eligibility "*create significant legal uncertainty for global biotechnology companies*", while the Colombian Group noted the significant legal uncertainty created by the status quo and that it "*undermine[s] incentives for cross-border research, development, and investment*".

The minority of Groups opposing harmonisation generally considered their existing framework adequate or expressed concern that harmonisation could impose unnecessary constraints.

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.

10 of the responding Groups stated YES (approximately 30%), while 19 Groups (approximately 60%) stated NO, while two (2) Groups refrained from a clear answer.

Thus, a large majority of the Groups considered that naturally occurring microorganisms should not be excluded from patentability.

The Groups that opposed exclusion generally considered that naturally occurring microorganisms should be patent-eligible where they are isolated from their natural environment by a technical process and meet the general patentability requirements. For example, the German Group stated that isolated microorganisms and microbiomes are patentable "*as long as a technical effect is achieved and not just the mere discovery of a microorganism that occurs in nature is applied for.*" The French Group raised substantial concerns concerning the exclusion of patentability for inventions relating to microorganisms by noting that "*the fact that an isolated microorganism exists in nature should not in itself justify its exclusion from patentability*". Further, the French Group noted that "*we do not believe that this criterion ('naturally occurring'), as applied in the United States, should form the basis for harmonisation, as its application would lead to the exclusion from patentability of most inventions relating to microorganisms*". While noting that "*there should not be a categorical exclusion for naturally occurring microorganisms*", the Israeli Group highlighted the importance of technical

contribution by stating that "*patent protection may be justified where the claimed subject matter reflects a genuine technical contribution, such as an inventive method of isolation, production, purification, characterization, formulation, or a novel and non-obvious use, provided that all other patentability requirements are met*". The Japanese Group referred to the previous work by AIPPI that "*naturally occurring microorganisms isolated by a technical process should not be treated as a mere 'product of nature' or found patent ineligible for that reason alone*" consistent with AIPPI Resolutions Q93 and Q259. The Finnish Group for its behalf highlighted the role of the very basics of the patent system as the criteria for determining the patentability by noting that if there is an industrial application for an isolated naturally occurring microorganism, such microorganism should be considered a patentable invention. The Canadian Group stated that identifying, isolating, and characterising a new microorganism with an attached function is an invention, and that a patent bar would disincentivise important health-related research, development, and commercialisation. The Bulgarian and Colombian Groups, among others, emphasized the technical contribution (technical process) by the Colombian Group noting that an approach treating isolated microorganisms as mere discoveries "*fails to recognize the technical contribution involved in their isolation, identification, and practical application*".

A minority of Groups considered that naturally occurring microorganisms, in their unmodified state, constitute discoveries rather than inventions and, therefore, fall outside patent-eligible subject matter. For example, the US Group stated that "n*aturally occurring microorganisms should be excluded from patentability because they clearly fall within the 'laws of nature, natural phenomena, and abstract ideas' exception to patent eligibility" and that "isolated naturally occurring microorganisms, without any further intervention, should be excluded from patentability unless they are in some way modified or changed from their naturally occurring state or possess 'markedly different characteristics' from anything found in nature and 'the potential for significant utility*". A number of Groups, such as the Chinese, Ecuadorian, Egyptian, Philippine, Thai, and Vietnamese Groups, emphasized the discovery nature of naturally occurring microorganisms as they exist in nature (unmodified state) as the reason for excluding them from patentability. However, a number of the Groups in favor of exclusion took a nuanced position acknowledging that modified versions or isolated forms with a specific purpose and clearly described isolation process should be patentable.

b. Isolated naturally occurring microbiomes should be excluded from patentability.

3 of the responding Groups stated YES (approximately 10%), while 26 Groups (approximately 90%) stated NO, while two (2) Groups refrained from a clear answer.

A majority of the responding Groups considered that isolated naturally occurring microbiomes should not be excluded from patentability, provided that the isolation involves a technical contribution and the general patentability requirements are met. A minority of Groups, including the US and the Philippine Groups, considered that isolated naturally occurring microbiomes should be excluded from patentability, on the basis that mere isolation does not transform a naturally occurring community into a human-made invention.

The Groups that opposed categorical exclusion generally considered that the isolation, characterisation, and application of a naturally occurring microbiome may involve sufficient human technical intervention to constitute a patentable invention, particularly where the isolated microbiome is reproducible, has a defined composition, and achieves a specific technical effect. For example, the Chinese Group stated that "*isolated naturally occurring microbiomes with a specific industrial application shall not be excluded from patentable subject matter, provided that strict restrictions are imposed*", noting that the isolation process constitutes a technical transformation and that the microbiome has inherent industrial application value. The Thai Group, while supporting exclusion of naturally occurring microorganisms in their unmodified state, considered that "*an isolated naturally occurring microbiome, even if composed of naturally occurring microorganisms, may represent a non-obvious and inventive arrangement of microbial species in specific proportions, selected and isolated from a complex natural environment*" and should not be excluded from patentability where the standard patentability criteria are met. The Belgian Group noted that "*isolated naturally occurring microorganisms and microbiomes should not be excluded from patentability, provided that they result from technical intervention and meet the general patentability requirements*" while acknowledging that "*particular practical challenges arise in relation to microbiomes as complex communities of microorganisms*".

The Groups that supported exclusion generally considered that a microbiome as it exists in nature constitutes a non-patentable discovery, and that mere isolation, without more, should not suffice to render it patent-eligible. The US Group stated

that "*solely separating a microbiome from its environment does not transform it into a human-made invention*" and that "*granting patents over such communities would risk giving private control over essential biological resources that researchers rely on for foundational work*". The Philippine Group similarly noted that "*microbiomes in their natural state should likewise be excluded as discoveries*" but acknowledged that "*where isolation is accompanied by a technical intervention that confers a specific, reproducible, and practical application, such subject matter may be considered patentable*".

c. Microbial consortia comprising isolated naturally occurring microorganisms should be excluded from patentability.

0 of the responding Groups stated YES (0%), while 31 Groups (100%) stated NO.

The responding Groups considered unanimously that microbial consortia comprising isolated naturally occurring microorganisms should not be excluded from patentability.

The Groups generally reasoned that a man-made microbial consortium, even if composed of individually naturally occurring microorganisms, constitutes a human technical creation rather than a mere discovery, provided that the specific combination does not exist in nature in that form and that the consortium achieves a technical effect resulting from human intervention. Many of the Groups emphasized the deliberate human activity as the source of inventive contribution. For example, the German Group noted that "*microbial consortia may be patentable where they are specifically selected, combined, or engineered to achieve a technical effect*" including synergistic or functionally interacting microorganisms. In the same vein, the Israeli Group stated that "*the inventive contribution may reside in the deliberate human selection, combination, relative proportions, conditions of use, or functional interaction of those microorganisms in a consortium that does not exist in nature in the claimed form and that achieves a technical effect not predictable from the individual components alone*". The Singapore Group further noted that "*assuming the man-made microbial consortia does not exist in nature in that specific combination of microbes, the man-made microbial consortia may be considered an invention and not a mere discovery because the specific selection and combination are products of human*

intervention". The US Group stated that "[*a]ssuming that the microbial consortia include isolated microorganisms that do not occur together in nature and are combined to form a non-natural product with 'markedly different characteristics' from anything found in nature, the microbial consortia comprising isolated naturally occurring microorganisms should not be excluded from patentability*".

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)?

19 of the responding Groups stated YES (approximately 65%), while 11 Groups (approximately 35%) stated NO. One (1) Group refrained from answering.

Thus, a majority of the Groups considered that there should be specific requirements for patent applications related to Microbiome Inventions.

The Groups that answered YES generally considered that, given the inherent complexity, variability, and reproducibility challenges of microbiome-related subject matter, clearer and more specific disclosure requirements are necessary to ensure that such inventions are defined with sufficient precision, disclosed in an enabling manner, and examined consistently. Several Groups emphasised that such requirements should be flexible and proportionate, rather than rigid or formalistic, so as not to unduly restrict innovation. With respect to defining the microorganisms with precision factors such as taxonomic identification, strain identification (strain level), genetic characterisation, sequence or marker data, functional characteristics, and quantitative parameters such as relative abundance were mentioned. The French Group proposed that it should be permissible to patent an isolated microbiome or consortium on the basis of one or more criteria, including definition by source, by method of obtaining (product-by-process claims), or by the minimum definition of the microorganisms comprising it.

A number of Groups emphasized deposit requirements. For example, the Turkish Group stated that "*where a specific strain is essential, deposit under the Budapest Treaty should be required*". However, some Groups such as the Belgian and French Groups were opposed to mandatory deposit requirements.

The Groups that answered NO generally considered that existing general patent law requirements — in particular those relating to sufficiency of disclosure, enablement, and support — are adequate to address the specific challenges of Microbiome Inventions, and that no additional microbiome-specific requirements are necessary. Some Groups, such as the Australian Group, noted that "*Microbiome Inventions should be dealt with in accordance with any other biological or non-biological invention*" with the German Group continuing that "*existing patent law requirements, in particular those relating to sufficiency of disclosure (e.g. Article 83 EPC), are generally adequate*" and that "*no additional microbiome-specific sui generis requirements appear necessary*". Giving some more nuance, the US Group noted that "*where the invention involves a microbiome and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, existing deposit requirements should suffice*". The Japanese Group further emphasized the specific characteristics of Microbiome Inventions by noting that Microbiome Inventions range from a single strain to highly complex compositions and that "*microbial analysis technology is advancing rapidly*" such that a fixed legal requirement risks not accommodating future innovation.

15) Are there any additional issues concerning any aspect of patenting Microbiome Inventions that you consider relevant to harmonisation considerations?

The responding Groups identified a range of additional issues relevant to harmonisation:

Several Groups identified the need for greater convergence on the distinction between unpatentable discovery and patentable invention in the context of biological materials derived from nature, and in particular the need to ensure that "product of nature" doctrines are not applied in an overly restrictive manner to microbiome-related inventions. The Colombian Group, e.g., proposed that international consistency in the assessment of sufficiency of disclosure for complex biological systems should be promoted. The Polish Group stated that "*[a] material isolated from nature, including microbiome inventions, should not be regarded as 'product of nature' or found patent-ineligible for that reason alone" further noting that "standard patentability criteria should be applied*".

Several Groups also raised the need for harmonisation of terminology and definitions, including shared definitions of concepts such as "microbiome," "microbial consortium," "isolated microorganism," "naturally occurring," and "engineered" or "modified." The Israeli Group, e.g., identified this as a priority area for harmonisation, noting that more consistent terminology would improve predictability and reduce legal uncertainty.

The need for greater convergence on disclosure and enablement standards — including the role of deposits, sequence or marker data, structural versus functional characterisation, and reproducibility where natural variability is inherent — was also frequently cited. The Belgian Group noted that "*differences may exist between jurisdictions regarding the evidentiary requirements for demonstrating a technical effect, which in practice is often closely linked to a specific deposited strain*" and that "*greater harmonization in the assessment of technical effect, novelty, and inventive step would therefore be beneficial*". The Chinese Group identified the need for harmonisation of deposit requirements, noting that "*there are differences among countries and regions regarding the timing and requirements for biological deposits*" and that "*harmonizing these requirements would reduce costs and procedural complexity for applicants*".

Several Groups raised the interaction between microbiome inventions and access and benefit-sharing obligations under the Nagoya Protocol and the Convention on Biological Diversity. The Chinese Group noted that countries and regions also differ in their requirements for disclosing genetic resources and that there is inconsistency among countries and regions regarding the specific content required for disclosure. The Thai Group noted that "*the harmonized framework should address the interface between patent protection for Microbiome Inventions and ABS obligations*". Moreover, the Japanese Group raised concerns about the growing legal uncertainty arising from the intersection of microbiome inventions with discussions on digital sequence information (DSI) and access and benefit-sharing obligations.

Also other themes were raised. For example, the UK Group raised a specific issue regarding the availability of prior art in the microbiome field, noting that "*isolated strains for which characteristics are reported (e.g. in a journal article) but not deposited are typically not considered publicly available*" and that "*in light of modern microbiological techniques, it may be appropriate to consider whether the existing case law should be updated*". The Japanese Group also identified the

need for harmonisation on the protection of non-medical inventions in sectors such as functional food. The Australian Group raised the possibility of a separate protection regime for Microbiome Inventions, similarly to plant-breeder rights, as an additional harmonisation consideration.

IV. Conclusions

From the Reports, the following conclusions may be drawn to provide guidance for this Study Question (kindly note that references to Groups may include different Groups):

- An overwhelming majority of the Groups considered international harmonisation of patenting policies for microbiome inventions desirable.

- The Groups were largely in favor of harmonisation of terminology and definitions in this area. Many of the Groups considered that shared definitions of key concepts, such as "microbiome," "microbial consortium," "isolated microorganism," "naturally occurring", and "engineered" or "modified", would support consistent examination, improve predictability, and reduce legal uncertainty across jurisdictions.

- As to patentability of microbiome inventions:
    - As to naturally occurring microorganisms, the Groups were divided. A number of Groups considered that naturally occurring microorganisms as they exist in nature constitute non-patentable discoveries. However, a larger number of Groups considered that isolated naturally occurring microorganisms should not be categorically excluded from patentability, provided that the isolation involves a technical contribution and the general patentability requirements are met. The Groups broadly agreed that the mere discovery of a naturally occurring microorganism, without any technical contribution, should not be patentable.
    - As to isolated naturally occurring microbiomes, a majority of the Groups considered that they should not be categorically excluded from patentability. Further, many of the Groups considered that the isolated naturally occurring microbiomes should be

patentable provided that the isolation involves a technical contribution and the general patentability requirements are met.

- As to microbial consortia comprising isolated naturally occurring microorganisms, the Groups unanimously considered that such consortia should not be excluded from patentability.

– A majority of the Groups considered that there should be specific requirements for patent applications related to Microbiome Inventions (e.g., defining microorganisms and/or microbial consortia in the Microbiome Invention). Such particulars proposed by Groups include, e.g., aspects concerning the definition and characterisation of microorganisms and microbial consortia and should be designed to improve clarity, reproducibility, and legal certainty, without imposing unnecessary formalism or unduly restricting innovation. In this regard, some of the specific requirements proposed included taxonomic identification, strain-level identification, genetic characterisation, sequence or marker data, functional characteristics, quantitative parameters such as relative abundance, definition by source, definition by method of obtaining (product-by-process claims), minimum definition of the microorganisms comprising the microbiome or consortium, and deposit of biological material under the Budapest Treaty.

– A number of Groups noted that deposit of biological material should remain available as a mechanism for satisfying sufficiency of disclosure requirements where the invention cannot be adequately described in writing, and that the Budapest Treaty framework provides an appropriate basis for such deposits. Several Groups called for the modernisation of the deposit system to better accommodate complex microbial consortia and dynamic microbial ecosystems.

– The Groups were divided on whether specific microbiome-related requirements should be introduced as mandatory legal provisions or addressed through examination guidelines and best practices.