

[View results](#)

Respondent

27

Anonymous

09:13

Time to complete

Contact details

Kindly submit your and your groups contact details below. Please also include the authors of the reports.

1. National/Regional Group or Independent Member **(in English): ***

Netherlands

2. Contributor's name: *(name cannot be edited after submission) **

Jeroen Boelens

3. Contributor's email: *

secretariaat@aippi.nl

4. Other Contributors / Authors:

René Raggars, Steven Moonen

I. Current law and practice

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

5. **1)** Are there any specific laws or regulations in your country that address and/or regulate the patenting of Microbiome Inventions? If so, please summarize the current state of the law and patent office practice in your jurisdiction concerning the patenting of Microbiome Inventions.

Yes

No

6. **1) (continued)** You may add a brief explanation

There are no specific laws or regulations in the Netherlands that specifically address and regulate the patenting of Microbiome Inventions as defined in this Study Question. However, the general provisions of the Dutch Patent Act governing biotechnological inventions apply to Microbiome Inventions. Article 2a of the Dutch Patent Act addresses inventions relating to products consisting of or containing biological material, or processes by which biological material is produced, processed or used. This corresponds to the definition of "biotechnological inventions" in Rule 26 of the Implementing Regulations to the European Patent Convention

7. **2)** Does your jurisdiction exclude strains of isolated microorganisms and/or microbiomes from patentability?

Yes

No

8. **2) (continued)** You may add a brief explanation

Under Article 2a(2)(a) of the Dutch Patent Act, biological material that is isolated from its natural environment or obtained by means of a technical process is patentable, even if that material occurs in nature. This includes isolated microorganisms. Article 2a(2)(d) further provides that microbiological or other technical processes by which biological material is obtained, processed or used, as well as products obtained thereby, are patentable.

9. **3)** Does your jurisdiction exclude man-made microbial consortia comprising isolated naturally occurring microorganism(s) from patentability?

Yes

No

10. **3) (continued)** You may add a brief explanation

There is no specific exclusion in Dutch law for man-made microbial consortia comprising isolated naturally occurring microorganisms. Such compositions would fall under the general provisions for biotechnological inventions and would be patentable provided they meet the standard patentability requirements of novelty, inventive step, and industrial applicability.

11. **4)** Does your jurisdiction exclude man-made compositions comprising isolated naturally occurring microorganism(s) from patentability?

Yes

No

12. **4) (continued)** You may add a brief explanation

Man-made compositions comprising isolated naturally occurring microorganisms are not excluded from patentability under Dutch law.

13. **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).

No answer provided.

14. **6)** Does your jurisdiction allow for the patenting of Microbiome Inventions derived from the human microbiome? If so, please explain under what conditions this is allowed.

Yes

No

15. **6) (continued)** You may add a brief explanation

Under Article 2a(2)(b) of the Dutch Patent Act, a part of the human body that is isolated or otherwise obtained by means of a technical process is patentable, including a sequence or partial sequence of a gene, even if the structure of that part is identical to that of a natural part. This principle extends to microorganisms isolated from the human body.

However, Article 3(1)(b) excludes from patentability the human body itself at the various stages of its formation and development, as well as the mere discovery of one of its parts, including a sequence or partial sequence of a gene. The key distinction is between mere discovery (not patentable) and isolation by a technical process with a demonstrated technical effect (patentable). Additional requirements apply under Article 3(1)(e) of the Dutch Patent Act, which excludes inventions that infringe Articles 3, 8(j), 15(5), and 16(5) of the Convention on Biological Diversity, addressing issues such as biopiracy and the use of traditional knowledge without appropriate consent or compensation.

16. **7)** Are there any enablement/written disclosure/sufficiency requirements particularly pertaining to or relevant for Microbiome Inventions in your jurisdiction which must be satisfied? You may add a brief explanation. For example:

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

17. **7) a. (continued)** You may add a brief explanation

Under Article 25 (2) of the Dutch Patent Act, if an invention concerns biological material which is not available to the public and which cannot be described in the specification in such a manner as to enable the invention to be carried out by the skilled person, or when an invention implies the use of such biological material, the invention is only regarded as sufficiently disclosed if the biological material has been deposited not later than the date of filing the application with a specifically designated institution.

18. **7) b. (continued)** You may add a brief explanation

The Implementation Decree of the Dutch Patent Act 1995 stipulates in Article 18 (1) (a) that the deposition under Article 25 (2) of the Dutch Patent may be made with an institution which has the status of an International Depository Authority in accordance with article 7 of the Budapest Treaty. Article 18 (1) (b) of the Implementation Decree provides for the further possibility that the deposit is made with an institution designated by the Netherlands Patent Office. However, such an institution has not been designated.

The Implementation Decree further stipulates in Article 22 that where a deposit has been made in accordance with Article 18 (1), and where there is any conflict between the relevant provisions (Article 17-22) in the Implementation Decree and the Budapest Treaty, the provisions of the treaty prevail.

19. **7) c. (continued)** You may add a brief explanation

Under Article 17 (1) (a) of the Implementation Act it is required that the specification of inventions as referred to in Article 25 (2) of the Patent Act includes the relevant information as is available to the applicant on the characteristics of the biological material. The reference to a genetic marker is, however, not specifically required

20. **7 d. (continued)** You may add a brief explanation

The definition via structural features is not necessary. See also the answer under 7 (c).

21. **8)** Does your jurisdiction allow for the patenting of uses of and/or methods using Microbiome Inventions?

Yes

No

22. **8) a.** If YES, please explain under what conditions the patenting of uses of and/or methods using Microbiome Inventions is allowed.

Art. 2a (1) of the Dutch Patent Act stipulates that inventions relating to processes by which biological material is produced, processed or used are patentable. It is further stipulated under Art. 2a (2) (f) that such inventions in any case include microbiological or other technical processes by which biological material is obtained, processed or used, as well as products obtained thereby. Uses and methods involving microbiome-related products may be patented if they meet the normal patentability requirement of novelty, inventive step, and industrial applicability.

23. **8) b.** If YES, is there any difference between claims directed to medical vs. non-medical (e.g. cosmetic) applications?

Yes

No

24. **8) b. (continued)** You may add a brief explanation

Methods of medical treatment are excluded from patentability under Article 3 (1) (f) of the Dutch Patent Act. Product claims for medical use are nevertheless permissible (e.g. substance X for use in treating disease Y).

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

Proving infringement of microbiome claims may be technically complex. Microbiome inventions often rely on complex consortia, small strain differences, complex metagenomic signatures and/or functional characteristics. Enforcement therefore often requires deep sequencing, genotyping (to the level of a strain), and results may be ambiguous.

Under EPO case law, the identity of a strain must be clearly and reproducibly defined for a valid claim. However, competitors are often able to use a different strain with high genomic similarity, or supply only high-level taxonomic information, which makes it more difficult to prove infringement (in particular to analyze the microorganism in detail).

Finally, because of a lack of clear legal definition of what a microbial "strain" is (strain boundaries are often biologically ambiguous), this is further limiting identification and therefore enforcement.

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

Please answer the questions of this Part II below.

26. **10)** According to the opinion of your Group, is your current law regarding the patenting of Microbiome Inventions adequate and/or sufficient?

Yes

No

27. **10) (continued)** You may add a brief explanation

Relative to many other jurisdictions, the current law seems well-developed. However, the EPC relies heavily on the deposit system for biological material that cannot be fully described. In principle this system works well for single, stable microorganisms. However, it works less well for multi-species consortia or dynamic microbial ecosystems, to give an example. For example, it may very well be that not all species in a multi-species consortia are essential for the invention, whereas the reference to the biological deposit in the claim does imply all species need to be present (for infringement). In another example, the invention relies on a dynamic ecosystem, with changing composition, for example over time, whereas the deposit system relies on a static deposit of microorganism.

III) Proposals for harmonisation

Please answer the questions of this Part III below.

28. **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

29. **11) (continued)** You may add a brief explanation

It could be helpful for applicants if the EPO would provide more guidance on microbiome-specific disclosure requirements. Whereas the existing EPC rules and Guidelines provide general principles for biological material, providing more tailored guidance for, for example, multi-species consortia, context-dependent microbial interactions, or dynamic ecosystems would improve predictability of prosecution/litigation for applicants, examiners and third parties. For example, guidance on how to describe and characterize multi-species dynamic compositions, or how functional features of a microbiome can be enabled without requiring exhaustive experimental data. Such guidance should reflect modern-days microbiome science.

III) Proposals for harmonisation

Please answer the questions of this Part III below.

30. **12)** Is there a need for international harmonization of patenting policies for Microbiome Inventions?

Yes

No

31. **12) (continued)** You may add a brief explanation

Microbiome inventions, and, for example, nutritional, therapeutic or diagnostic applications using such inventions will have increasing significance for society. Differences regarding sufficiency of disclosure, deposit requirements, and functional or strain-based claims create legal uncertainty and hinder global commercialization. Harmonized standards would promote predictability and ensure that innovators receive comparable protection across jurisdictions.

32. **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 You may add a brief explanation. **YES**
- a. Naturally occurring microorganisms should be excluded from patentability You may add a brief explanation. **NO**
- b. Isolated naturally occurring microbiomes should be excluded from patentability, You may add a brief explanation. **YES**
- b. Isolated naturally occurring microbiomes should be excluded from patentability .You may add a brief explanation. **NO**
- c. Microbial consortia comprising isolated naturally occurring microorganisms should be excluded from patentability. You may add a brief explanation. **YES**
- c. Microbial consortia comprising isolated naturally occurring microorganisms should be excluded from patentability. You may add a brief explanation. **NO**

33. **13) a. (continued)** You may add a brief explanation

Excluding naturally occurring microorganisms from patentability would hinder innovation in areas such as therapeutics, diagnostics, agriculture, and environmental biotechnology. There the inventive contribution often lies not in the discovery of a microbial entity but in its purposeful isolation, characterization, and application in a technical context. Protectability of these technical advances likely stimulates research and development.

34. **13) b. (continued)** You may add a brief explanation

See above

35. **13) c. (continued)** You may add a brief explanation

See above

36. **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

37. **14) (continued)** You may add a brief explanation

In accordance with the harmonized guidelines detailed in the answer to question 12.

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

- Yes
- No

39. **15) (continued)** You may add a brief explanation

No answer provided.

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

While the reporting Study Group does not include any in-house counsel among its members, anonymous interviews were conducted with in-house professionals active in the fields of fermentation technology and nutrition.

The questionnaire and its answers have been shared and discussed within the Dutch Group, which includes representatives from large and small/medium-sized companies.