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**Datasheet for the decision
of 12 February 2026**

Case Number: T 0630/24 - 3.3.08

Application Number: 20169573.1

Publication Number: 3750549

IPC: A61K35/74, C12N1/00, C12Q1/02,
G01N33/50

Language of the proceedings: EN

Title of invention:

Composition for inducing proliferation or accumulation of regulatory T cells

Applicant:

The University of Tokyo

Headword:

Composition for inducing proliferation or accumulation of regulatory T cells/THE UNIVERSITY OF TOKYO

Relevant legal provisions:

EPC Art. 123(2)
RPBA 2020 Art. 12(4), 12(6)

Keyword:

Amendments - added subject-matter (yes)
Late-filed request - should have been submitted in first-
instance proceedings (yes) - admitted (no)

Decisions cited:

G 0002/10



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Case Number: T 0630/24 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 12 February 2026

Appellant: The University of Tokyo
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Decision under appeal: **Decision of the Examining Division of the
European Patent Office posted on 18 December
2023 refusing European patent application No.
20169573.1 pursuant to Article 97(2) EPC**

Composition of the Board:

Chairwoman T. Sommerfeld
Members: R. Morawetz
D. Rogers

Summary of Facts and Submissions

- I. The appeal lodged by the applicant (appellant) lies from the decision of the examining division refusing European patent application No. 20 169 573.1 which was filed as a divisional application in respect of earlier (parent) European patent application No. 16 188 203.0. The letter had been filed as a divisional application in respect of earlier (grandparent) European patent application No. 11 728 077.6 which was filed as an international application, published as WO 2011/152566.
- II. The decision under appeal was issued as a so-called "decision on the state of the file" in response to a corresponding request by the appellant. For the reasons for the refusal, the decision referred to the examining division's communication of 12 April 2023.
- III. In that communication, the examining division considered a single set of claims, filed under cover of a letter dated 3 January 2023, and came to the conclusion that claim 1 contravened Article 123(2) EPC.
- IV. With the statement setting out the grounds of appeal, the appellant re-submitted the set of claims considered in the decision under appeal as its main request and a new set of claims as auxiliary request 1.
- V. The board appointed oral proceedings and, in a communication pursuant to Article 15(1) RPBA, provided its preliminary appreciation on some matters concerning the appeal.
- VI. The appellant's submissions and arguments, in so far as they are relevant to the present decision, are

discussed in the Reasons for the Decision.

- VII. The appellant requested that the decision under appeal be set aside and a patent be granted upon the basis of the set of claims of the main request or, alternatively, on the basis of the set of claims of auxiliary request 1.

Reasons for the Decision

Main request

Amendments (Article 123(2) EPC) - claim 1

1. Reference is made below to the divisional application as filed, which is referred to as the application as filed.
2. The standard for assessing compliance with the requirements of Article 123(2) EPC is the standard set out in decision G 2/10 (OJ EPO 2012, 376, Reasons 4.3), also known as the gold standard. Amendments are only permitted within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of the application as filed. After the amendment, the skilled person may not be presented with new technical information (ibid., Reasons 4.5.1).
3. Claim 1 reads as follows:
"A pharmaceutical composition for use in a method of treating or preventing an infectious disease by inducing proliferation or accumulation of transcription factor Foxp3-positive regulatory T cells, the composition comprising bacteria belonging to

Clostridium cluster XIVa and/or cluster IV, wherein the bacteria induce said proliferation or accumulation of transcription factor Foxp3-positive regulatory T cells, and wherein the infectious disease is a Clostridium difficile infection, a Salmonella infection, a Shigella infection, tuberculosis, malaria, filariasis, schistosomiasis, toxoplasmosis, leishmaniasis, hepatitis C, hepatitis B or herpes."

4. This decision concerns solely the question of whether the definition of the active agent being "*bacteria belonging to Clostridium cluster XIVa and/or cluster IV, wherein the bacteria induce said proliferation or accumulation of transcription factor Foxp3-positive regulatory T cells*", without the further qualification that these bacteria also belong to the genus *Clostridium*, has a basis in the application as filed.
5. The examining division held that there was no single basis in the original application referring in general to bacteria belonging to *Clostridium* clusters IV/XIV as part of the invention without further limitation of such bacteria to the genus *Clostridium*. In particular, it held that the passage on page 28, line 12 ff of the application as filed discloses that the phylogenetic classification of the bacteria into clusters IV/XIVa was done additionally and based on an already limited group of bacteria belonging to the genus *Clostridium*.
6. The appellant submitted that the definition of the bacteria in claim 1 was based on page 28, lines 16 to 17, of the application as filed while the continuation of that passage to page 29, line 1, of the application as filed provided the basis for the conjunction "*and*" in the expression "*belonging to Clostridium cluster*

XIVa and/or cluster IV".

7. On page 28, lines 12 to 17, the application as filed defines the active ingredient in the composition of the invention as follows "*[t]he 'bacteria belonging to the genus Clostridium,' which are the active ingredient in the composition of the present invention, is not particularly limited as long as the bacteria have the effect of inducing proliferation or accumulation of regulatory T cells. The bacteria preferably belong to the cluster XIVa or the cluster IV.*"
8. The skilled person reads the second sentence (page 28, lines 16 to 17, of the application as filed) in its context, i.e., in conjunction with the first sentence (page 28, lines 12 to 16, of the application as filed). The information conveyed to the skilled person by the application as filed is therefore that the active ingredient consists of bacteria belonging to the genus Clostridium that induce the proliferation or accumulation of Treg cells, and that bacteria belonging to the cluster XIVa or the cluster IV constitute a preferred subgroup of these bacteria.
9. In agreement with the examining division, the board considers that the phylogenetic classification in cluster IV or cluster XIVa on page 28, lines 16 to 17, of the application as filed, defines a subset of the bacteria of the taxonomic group genus Clostridium.
10. The appellant's argument that page 28, lines 16 to 17, of the application as filed provided a definition of effective bacteria as such can therefore not be accepted.

11. The appellant's further argument that "*Clostridium clusters XIVa and IV as such are, de facto, evidently not a subgroup of the taxonomic group 'genus Clostridium'. These 'clusters' are a broader, phylogenetically defined group of bacteria and encompass various taxonomic genera other than 'the genus Clostridium'" (grounds of appeal, point 12) does not assist its case.*
12. As set out in points 8. to 9. above, the application as filed discloses on page 28, lines 12 ff that the active agent is bacteria which belong to both genus *Clostridium* and cluster IV or cluster XIVa. Since the clusters are a broader group of bacteria and encompass various taxonomic genera other than the "*genus Clostridium*", omission of the limitation to the "*genus Clostridium*" extends the subject-matter to bacteria of all taxonomic genera within cluster IV or cluster XIVa and hence beyond the disclosure in the passage on page 28, line 12 ff of the application as filed.
13. The appellant's argument that the reference to '*Clostridium clusters XIVa and/or IV*' in claim 1 was a justified intermediate generalisation over the disclosure of page 28, lines 12 to 17, of the application as filed, because taxonomic/phenetic classification of organisms based on phenotypes in the genus *Clostridium* and phylogenetic classification in cluster IV or XIVa neither had a clearly recognisable functional or structural relationship nor were they inextricably linked, likewise fails.
14. Reference is made to points 8. to 9. above. The group of bacteria disclosed on page 28, lines 12 to 17, of the application as filed corresponds to the intersection resulting from different characterisations

of the bacteria. This involves a taxonomic-phenotypic classification based on the phenotype of the bacteria, a functional limitation to bacteria that induce Treg cells, as well as a phylogenetic classification based on the sequence of the 16S rRNA gene of the bacteria.

15. Omission of the classification into the genus *Clostridium* is therefore not an intermediate generalisation. Instead, it is a simple generalisation which extends the claimed subject-matter to bacteria of all taxonomic genera within the phylogenetic classification and hence beyond the disclosure on page 28, lines 12 to 17, of the application as filed (see also point 12. above). The question of whether taxonomic/phenetic classification and phylogenetic classification have a clearly recognisable functional or structural relationship or are inextricably linked does not arise in the circumstances of the present situation and there is no need to address the appellant's arguments regarding the case law on allowable intermediate generalisations.

16. In yet a further line of argument, the appellant submitted that the term "genus" could be omitted because, in the broadest sense, on page 6, lines 10 to 20, the application as filed aimed to provide intestinal commensal bacteria which induce Treg cells and which bacteria may (i) belong to the genus *Clostridium*, or (ii) be a chloroform-treated fraction or (iii) be a spore-forming fraction of mammalian faeces. The disclosure of page 28, lines 16 to 21, of the application as filed merely provided a further way of identifying the intestinal commensal bacteria of the invention.

17. This argument fails for two reasons. First, as explained above (points 8. to 9. above), the disclosure of page 28, lines 16 to 21, of the application as filed further defines (limits) bacteria which belong to the genus *Clostridium* and induce Treg cells. These bacteria already represent a subset of the intestinal commensal bacteria disclosed on page 6, lines 10 to 20, of the application as filed (point 16. above). However, it is not explicitly stated on page 28, lines 16 to 21, of the application as filed that the phylogenetic classification into cluster IV or XIVa applies to intestinal commensal bacteria in general, and the appellant has not explained why a person skilled in the art would nevertheless infer this implicitly, yet directly and unambiguously, from this passage. Second, the appellant's argument cannot in any event provide a basis for the disputed feature in connection with claim 1, since that claim is not even limited to intestinal commensal bacteria.

18. In yet another line of argument, the appellant relied on the passage on page 44, lines 10 to 21, of the application as filed and submitted that it supported the conclusion that the invention could be defined by the phylogenetic categorisation of the bacteria in *Clostridium* clusters IV and/or XIVa in combination with the immunological effect of inducing Treg cells.

19. The board disagrees. On page 44, lines 10 to 21, the application as filed speculates on the potential utility of "*the composition of the present invention*" for promoting body weight gain. This proposed utility is said to be based on the fact that *Clostridium* clusters IV and XIVa belong to the group Firmicutes. The passage is silent about the effect, if any, of bacteria belonging to *Clostridium* clusters IV or XIVa

on the induction of transcription factor Foxp3-positive Treg cells and such an effect cannot be derived from what is disclosed explicitly on page 44, lines 10 to 21, of the application as filed either.

20. At oral proceedings before the board, the appellant expanded on this argument and submitted that the passage on page 44, lines 10 to 21, was part of a section beginning on page 25, line 23, of the application as filed, and that for this reason "*the composition of the present invention*" on page 44, lines 11 to 21, and thus bacteria belonging to Clostridium clusters IV or XIVa, had the effect of inducing Treg cells.
21. The board does not find this argument convincing either. In the section beginning on page 25, line 23, of the application as filed, the compositions of the present invention having an effect of inducing proliferation or accumulation of Treg cells are disclosed to comprise as an active ingredient, (a) bacteria belonging to the genus Clostridium, (b) a spore-forming fraction of a fecal sample obtained from a mammal or (c) a chloroform-treated fraction of a fecal sample obtained from a mammal (page 25, line 25 to page 26, line 12, of the application as filed). On page 28, lines 12 ff, the bacteria inducing Treg cells are further defined (points 7. to 9. above).
22. A person skilled in that art reading page 44, lines 10 to 21, of the application as filed in conjunction with the section beginning on page 25, line 23, of the application as filed would therefore not infer that all bacteria belonging to clusters IV or XIVa have the immunological effect of inducing Treg cells. Instead, they would directly and unambiguously infer that it is

bacteria belonging to clusters IV or XIVa and also to the genus *Clostridium* that induce Treg cells.

23. The appellant's further argument, that consideration of the application as filed as a whole led to the conclusion that in the application as filed bacteria were defined solely by the phylogenetic classification in cluster IV or cluster XIVa, also fails.
24. As explained at oral proceedings, all passages relied on by the appellant as disclosing bacteria belonging to clusters IV or XIVa refer to bacteria that are further defined as either belonging to genus *Clostridium* (Example 7, page 83, lines 8 to 26; Example 17, page 105, line 23; Figure 49), as belonging to a spore-forming fraction of a fecal sample (Example 18), or as belonging to the microbiota of a subject (page 14, lines 13 to 19; page 55, lines 1 to 8). The appellant's argument fails for this reason alone. Under these circumstances, there is no need to address the question whether these passages are even relevant to the subject-matter of claim 1.
25. Finally, for the reasons set out above and contrary to the appellant's assertion, it is also not clear from the application as filed that bacteria characterised phylogenetically as belonging to *Clostridium* cluster IV or XIVa are disclosed in the application as filed as providing a complete solution to a technical problem unambiguously recognisable from the application. In any event, the only relevant criterion for the assessment of Article 123(2) EPC is the one set out in point 2. above.
26. In sum, the board concludes from the above that the definition of the active agent being "*bacteria*

belonging to Clostridium cluster XIVa and/or cluster IV, wherein the bacteria induce said proliferation or accumulation of transcription factor Foxp3-positive regulatory T cells", without the further qualification that these bacteria also belong to the genus Clostridium is not directly and unambiguously derivable from the application as filed.

27. The question of whether page 28, line 17 to page 29, line 1 of the application as filed makes it clear that bacteria of cluster XIVa and cluster IV can be used in combination (point 6. above) can therefore be left open.
28. On the basis of the above observations, the board sees no reason to set aside the decision under appeal as regards the main request.

Auxiliary request 1

Admittance and consideration

29. Auxiliary request 1 differs from the main request in that claim 1 has been amended and now specifies that the bacteria also belong to the genus Clostridium.
30. Auxiliary request 1 was newly filed on appeal and constitutes an amendment of the appellant's case within the meaning of Article 12(4) RPBA, which may be admitted into the proceedings only at the board's discretion. Pursuant to Article 12(6) RPBA, the board shall not admit claim requests which should have been submitted, or which were no longer maintained, in the proceedings leading to the decision under appeal, unless the circumstances of the appeal case justify their admittance.

31. The appellant submitted that auxiliary request 1 had been filed in response to the examining division's decision and directly addressed that decision by including the feature that the examining division had deemed necessary for the claims to comply with Article 123(2) EPC.
32. However, the set of claims underlying the decision under appeal is the same as the one considered in the examining division's communication of 12 April 2023 and the reasons given in the examining division's decision are also the same as set out in the examining division's communication of 12 April 2023 (sections II. to V. above). The examining division moreover explicitly indicated which feature was missing from claim 1 (communication of 12 April 2023, point 2). The appellant was therefore in a position to address this objection earlier, i.e. in response to the examining division's communication of 12 April 2023.
33. The board concludes from the above considerations that auxiliary request 1 could and should have been submitted in the first-instance proceedings. Instead, the appellant requested a decision according to the state of the file.
34. Appeal proceedings are however not a continuation of examination proceedings and introducing subject-matter the examination of which was deliberately foregone in the first-instance proceedings is at odds with the purpose of the appeal proceedings as a review instance, as stipulated in Article 12(2) RPBA.
35. On the basis of the above observations, the board sees no reason to admit and consider auxiliary request 1 in the appeal proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairwoman:



C. Rodríguez Rodríguez

T. Sommerfeld

Decision electronically authenticated