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**Datasheet for the decision of 24 September 2024**

**Case Number:** T 1032/22 - 3.3.08

**Application Number:** 15721601.1

**Publication Number:** 3134512

**IPC:** C12M1/26, B01D15/38, C12N5/0783, C12N5/00

**Language of the proceedings:** EN

**Title of invention:**
Method for automated generation of genetically modified T cells

**Patent Proprietor:**
Miltenyi Biotec B.V. & Co. KG

**Opponents:**
GE Healthcare Bio-Sciences AB
D Young & Co LLP
James Poole Limited

**Headword:**
Method for automated generation of genetically modified T cells/MILTENYI

**Relevant legal provisions:**
EPC Art. 100(a), 54(2), 123(2)
RPBA 2020 Art. 12(4), 12(6)

**Keyword:**

Grounds for opposition
Novelty - (no)
Amendment to case - detrimental to procedural economy (yes)
Late-filed request - should have been submitted in first-instance proceedings (yes)
Amendments - allowable (no)

**Decisions cited:**

G 0002/10, T 0951/92, T 0727/00, T 0233/18, T 0545/18, T 0914/18, T 1024/19, T 0317/20, T 0439/22

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**Case Number: T 1032/22 - 3.3.08**

# D E C I S I O N
# of Technical Board of Appeal 3.3.08
# of 24 September 2024

| | |
|---|---|
| **Appellant I:**<br>(Patent Proprietor) | Miltenyi Biotec B.V. & Co. KG<br>Friedrich-Ebert-Strasse 68<br>51429 Bergisch Gladbach (DE) |
| **Representative:** | Heide, Anna Katharina<br>ambidex IP<br>Jägerhofstraße 31<br>45478 Mühlheim an der Ruhr (DE) |
| **Appellant II:**<br>(Opponent 1) | GE Healthcare Bio-Sciences AB<br>Björkgatan 30<br>751-84 Uppsala (SE) |
| **Representative:** | Kilburn & Strode LLP<br>Lacon London<br>84 Theobalds Road<br>Holborn<br>London WC1X 8NL (GB) |
| **Appellant III:**<br>(Opponent 3) | James Poole Limited<br>One Southampton Row<br>London WC1B 5HA (GB) |
| **Representative:** | Carpmaels & Ransford LLP<br>One Southampton Row<br>London WC1B 5HA (GB) |
| **Party as of right:**<br>(Opponent 2) | D Young & Co LLP<br>120 Holborn<br>London EC1N 2DY (GB) |
| **Representative:** | D Young & Co LLP<br>3 Noble Street<br>London EC2V 7BQ (GB) |

**Decision under appeal:** **Interlocutory decision of the Opposition Division of the European Patent Office posted on 1 March 2022 concerning maintenance of the European Patent No. 3134512 in amended form**

**Composition of the Board:**

**Chairwoman** T. Sommerfeld
**Members:** R. Morawetz
A. Bacchin

## Summary of Facts and Submissions

I. European patent No. 3 134 512 ("the patent") was granted on European patent application No. 15 721 601.1, which was filed as an international application published as WO 2015/162211 ("application as filed") claiming priority from US application 61/983,543 ("priority application" or "P1"), filed on 24 April 2014.

II. Three oppositions were filed against the granted patent, which was opposed in its entirety under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC) and lack of inventive step (Article 56 EPC) and under Article 100(b) and (c) EPC.

III. By way of an interlocutory decision, the opposition division decided that the patent in amended form on the basis of auxiliary request 2 submitted on 11 February 2022, and the invention to which it relates, met the requirements of the EPC. The opposition division also held that claim 1 of the main request (claims as granted) was not entitled to priority and lacked novelty (Article 54 EPC) and that claims 3, 4, 5, 7, 8, 10, 11 and 12 to 15 of auxiliary request 1 submitted on 10 February 2022 were not entitled to priority and that claims 3, 4 and 14 lacked novelty (Article 54 EPC).

IV. The patent proprietor (appellant I), opponent 1 (appellant II) and opponent 3 (appellant III) lodged appeals against the interlocutory decision of the opposition division. For ease of reference, the board refers to the appellants as patent proprietor and

opponents 1 and 3, respectively.

V. With the statement setting out the grounds of appeal ("SGA"), the patent proprietor maintained the main request considered in the decision under appeal as its main request and auxiliary request 2 held allowable in the decision under appeal as auxiliary request 22 and submitted sets of claims of new auxiliary requests 1a/1b to 18a/18b and 19 to 21. The patent proprietor also maintained various auxiliary requests filed during the opposition proceedings as auxiliary requests 23 to 30 and filed, *inter alia*, documents A058 and A059.

VI. In their statements setting out the grounds of appeal, opponent 1 and opponent 3 maintained, *inter alia*, their objections under Article 123(2) EPC against claim 1 of the set of claims of the auxiliary request found allowable by the opposition division.

VII. With its reply to the opponents' statements of grounds of appeal ("reply"), the patent proprietor submitted sets of claims of auxiliary requests 23a and 23b.

VIII. The board scheduled oral proceedings in accordance with the parties' requests and subsequently issued a communication under Article 15(1) RPBA setting out its preliminary opinion.

IX. By letter dated 23 August 2024, the patent proprietor withdrew auxiliary requests 1a/1b to 18a/18b and 24 to 30.

X. With a further letter, dated 18 September 2024, the patent proprietor requested a stay of the proceedings because of the pending referral G 1/24 to the Enlarged

Board of Appeal.

XI. By letter dated 20 September 2024, opponent 3 submitted arguments why the patent proprietor's request for a stay of proceedings should not be admitted and, if admitted, should be rejected.

XII. The board informed the parties of its opinion that there was no need to stay the proceedings and that the issue would be further discussed during oral proceedings if it became relevant.

XIII. During the oral proceedings, the patent proprietor withdrew auxiliary requests 23, 23a and 23b.

XIV. Claims 1, 3, 4 and 14 of the main request read as follows:

"1. An automated process for generation of genetically modified T cells, T cell subsets and/or T cell progenitors comprising the steps:

a) providing a cell sample comprising T cells, T cell subsets and/or T cell progenitors
b) preparation of the cell sample by centrifugation
c) magnetic separation of the T cells, T cell subsets and/or T cell progenitors
d) activation of the enriched T cells, T cell subsets and/or T cell progenitors using modulatory agents
e) genetic modification of the T cells, T cell subsets and/or T cell progenitors
f) expansion of the genetically modified T cells, T cell subsets and/or T cell progenitors in a cultivation chamber
g) washing of the cultured T cells, T cell subsets and/or T cell progenitors **characterized in that** all steps

are performed in a closed and sterile cell culture system."

"3. The process according to claim 1 or 2, wherein said modulatory agents are anti-CD3 and anti-CD28 antibodies or fragments thereof coupled to beads or nanostructures.

4. The process according to any one of claims 1 to 3, wherein said nanostructures are a nanomatrix, the nanomatrix comprising a) a matrix of mobile polymer chains, and b) attached to said matrix of mobile polymer chains anti-CD3 and anti-CD28 antibodies or fragments thereof, wherein the nanomatrix is 1 to 500 nm in size."

"14. The process according to any one of claims 1 to 13, wherein said genetic modification of the T cells, T cell subsets and/or T cell progenitors is the introduction of a polynucleotide sequence encoding for a chimeric antigen receptor (CAR) or a T cell receptor (TCR)."

Claim 1 of auxiliary request 19 differs from claim 1 of the main request in that the feature "*and wherein all steps mentioned above are performed automatically*" is added at the end of the claim.

Claim 1 of auxiliary request 20 differs from claim 1 of the main request in that the features "*and wherein all steps mentioned above are performed automatically and wherein said activation, genetic modification and/or said expansion of T cells, T cell subsets and/or T cell progenitors are performed by shaking conditions*" are added at the end of the claim.

Claim 1 of auxiliary request 21 differs from claim 1 of the main request in that the features "*and wherein all steps mentioned above are performed automatically and wherein said modulatory agents are selected from agonistic antibodies*" are added at the end of the claim.

The wording of claim 1 of auxiliary request 22 is set out in the Reasons for the Decision.

XV. The decision refers to the following documents:

D2c MACS & more (2014), vol 16, pages 1 to 40

D5a Drechsel K. *et al.*, Journal for ImmunoTherapy of Cancer (2014), vol 2 (Suppl 3), P21

A058 Expert report of Dr Aigner (5 July 2022), pages 1 to 25

A059 Oxford Advanced Learners Dictionary (2010), pages 89 and 1380

XVI. Opponent 2, a party as of right, did not make any requests or substantive submissions during the appeal proceedings.

XVII. The arguments of the patent proprietor, opponent 1 and opponent 3 relevant for the decision are dealt with in detail in the Reasons for the Decision.

XVIII. The parties' requests relevant for the decision of the board are set out below.

The appellant-patent proprietor requested a stay of the appeal proceedings in view of the pending referral to

the Enlarged Board of Appeal G 1/24; further, it requested that:
- the decision under appeal be set aside and that the patent be maintained as granted (main request) or, alternatively, that the patent be maintained in amended form on the basis of the set of claims of one of auxiliary requests 19 to 21; or, further alternatively, that the patent be maintained on the basis of auxiliary request 22 being identical to auxiliary request 2 considered allowable in the decision under appeal (i.e. that the opponents' appeals be dismissed);
- documents A052 to A059 and A063 be admitted into the appeal proceedings and that if not the whole of A058 was admitted, admissibility for each question addressed in A058 be decided individually;
- the opponents' objection that the combination of features in claim 1 of auxiliary request 22 required multiple selections not be admitted into the appeal proceedings.

Appellant-opponent 1 requested that:
- the decision under appeal be set aside and that the patent be revoked;
- none of auxiliary requests 19 to 21 be admitted into the appeal proceedings;
- documents A052 to A059 and A063 not be admitted into the appeal proceedings.

Appellant-opponent 3 requested that:
- the decision under appeal be set aside and that the patent be revoked;
- none of auxiliary requests 19 to 21 be admitted into the appeal proceedings;
- the patent proprietor's request to stay the appeal proceedings not be admitted into the appeal proceedings and further, should the board decide to admit the

request, that the request be denied;
- documents A052 to A059 and A063 not be admitted into the appeal proceedings.

## Reasons for the Decision

*Admittance and consideration of documents*

1. The patent proprietor requested that documents A058 and A059 be admitted into the appeal proceedings in support of its arguments on the interpretation of the term "*automated*" in claim 1 of the main request and auxiliary request 22.

2. The issues decided by the board do not turn on the interpretation of the term "*automated*" (see below). Therefore, the content of documents A058 and A059 and the arguments of the patent proprietor based on it were not considered in this decision, and there was no need for the board to decide on the admittance of these documents.

3. There was also no need to decide on the admittance of documents A052 to A057 and A063, as the patent proprietor did not rely on any of these documents in the context of the issues decided by the board.

*Main request (patent as granted)*
*Claim construction - claim 1*

4. Claim 1 of the main request relates to "[a]*n automated process for generation of genetically modified T cells, T cell subsets and/or T cell progenitors comprising the steps: a) ... g) ...* ***characterized in that*** *all steps are performed in a closed and sterile cell culture*

*system*" (emphasis in the original).

5. The opposition division found that claim 1 of the main request could not be understood as referring exclusively to a "fully" automated process and concluded that it had to be interpreted in accordance with the definition in paragraph [0027] of the patent as referring to a process in which at least one step of the method was performed without any human support or intervention (decision under appeal, Reasons 5.1), i.e., to encompass not only a semi-automated process but even the automation of only one step (hereinafter "broad interpretation").

6. The patent proprietor disputes this broad interpretation and submits that the skilled person reading claim 1 understands that each of the recited steps a) to g) is automated, while other steps not mentioned in claim 1 but comprised in the automated process can be performed manually and, indeed, that it is necessary that some steps such as connecting tubing sets, media, reagents, etc. be performed manually (hereinafter "narrow interpretation").

7. The board does not need to decide on the interpretation of claim 1 because the main request lacks novelty, regardless of whether claim 1 is interpreted broadly or narrowly (see below).

*Priority (Article 87(1) EPC) - dependent claims 3, 4, 5, 7, 8 and 10 to 15*

8. The opposition division found that the features of dependent claims 3, 4, 5, 7, 8 and 10 to 15 of auxiliary request 1 filed on 10 February 2022 were not disclosed in priority document P1 and that, therefore,

these claims were not entitled to the claimed priority.

9. Dependent claims 3, 4, 5, 7, 8 and 10 to 15 of the main request include the features which the opposition division considered not to be disclosed in priority document P1.

10. The patent proprietor did not contest, either in written proceedings or at the oral proceedings before the board (see minutes of the oral proceedings, page 4), the findings of the opposition division on the lack of priority of dependent claims 3, 4, 5, 7, 8 and 10 to 15 of auxiliary request 1 filed on 10 February 2022. Nor did it contest that these findings apply to the subject-matter of the corresponding claims of the main request, i.e. dependent claims 3, 4, 5, 7, 8 and 10 to 15, irrespective of the priority entitlement of claim 1.

11. Against this backdrop, the board concludes that the effective date of the subject-matter of dependent claims 3, 4, 5, 7, 8 and 10 to 15 of the main request is the filing date. Documents D2c and D5 are therefore prior art within the meaning of Article 54(2) EPC for these claims.

*Novelty over documents D2c and D5a*

12. The opposition division held that document D2c disclosed the subject-matter of dependent claims 3, 4 and 14 of auxiliary request 1 filed on 10 February 2022 and that document D5a disclosed the subject-matter of dependent claims 3 and 4 of auxiliary request 1 filed on 10 February 2022.

13. The patent proprietor did not contest, either in written proceedings or at the oral proceedings before the board, these findings of the opposition division on the lack of novelty of dependent claims 3, 4 and 14 of auxiliary request 1 filed on 10 February 2022.

14. The board shares the view of opponent 3 that the findings of the opposition division on lack of novelty (point 12. above) apply to dependent claims 3, 4 and 14 of the main request irrespective of how claim 1 of the main request is construed, i.e. narrowly or broadly.

15. Thus, even applying the patent proprietor's narrow construction of claim 1 of the main request (point 6. above), the subject-matter of dependent claims 3, 4 and 14 of the main request is identical to the subject-matter of dependent claims 3, 4 and 14 of auxiliary request 1 filed on 10 February 2022, and the opposition division's reasons for finding that these claims lack novelty over documents D2c and D5a apply, *mutatis mutandis*.

16. With the broader construction of claim 1 of the main request (point 5. above), i.e. that at least one of steps a) to g) is carried out without any human support or intervention, the subject-matter of dependent claims 3, 4 and 14 of the main request necessarily also lacks novelty over documents D2c and D5a.

17. This was not disputed by the patent proprietor, either in written proceedings or at the oral proceedings before the board (see minutes of the oral proceedings, top of page 5).

18. The board concludes from the above observations that dependent claims 3, 4 and 14 of the main request lack

novelty. Article 100(a) in conjunction with Article 54 EPC therefore prejudices the maintenance of the patent as granted.

*Admittance and consideration of auxiliary requests 19 to 21*

19. Auxiliary requests 19 to 21 were first submitted with the patent proprietor's appeal. Claim 1 of these requests omits restrictions present in claim 1 of the auxiliary request upheld by the opposition division, i.e. auxiliary request 22 in the appeal proceedings. In addition, dependent claims comprising features found by the opposition division not to be entitled to the claimed priority have been deleted from these requests.

20. Opponents 1 and 3 requested that auxiliary requests 19 to 21 not be admitted on the grounds that they constituted an amendment of the patent proprietor's case, they could and should have been filed in opposition proceedings, and admitting them would lead to a new substantive debate contrary to the requirement of procedural economy.

21. The patent proprietor's main argument in support of the admittance of auxiliary requests 19 to 21 was that, in accordance with T 914/18 (Reasons 4.1), the deletion of an alternative and the deletion of dependent claims did not constitute an amendment of a party's case within the meaning of Article 13(2) RPBA. This argument fails for the following reasons.

22. First, the relevant provision under which admittance of auxiliary requests 19 to 21 is to be considered is Article 12(4) RPBA, not Article 13(2) RPBA. Since the decision under appeal is not based on any of the auxiliary requests 19 to 21 and since the patent

proprietor has not demonstrated that any of these requests was admissibly raised and maintained in the proceedings leading to the decision under appeal, the board shares the view of opponents 1 and 3 that auxiliary requests 19 to 21 constitute, by definition, an amendment of the patent proprietor's case within the meaning of Article 12(4) RPBA.

23. Second, contrary to the assertion by the patent proprietor, the deletion of an alternative in a claim and the deletion of dependent claims are in principle considered not to be amendments of the appeal case within the meaning of Article 13 RPBA only if they do not lead to a fresh case (T 914/18, Reasons 4.1).

24. In the present case, however, it is not alternative features but limiting features which were deleted from claim 1 of auxiliary requests 19 to 21. Claim 1 of each of auxiliary requests 19 to 21 is therefore broader than claim 1 of the auxiliary request upheld by the opposition division. Inventive step of claim 1 of auxiliary requests 19 to 21 was not assessed by the opposition division. Consequently, auxiliary requests 19 to 21 change the factual and legal framework of the case as compared to the case considered by the opposition division.

25. The patent proprietor's further argument that the deletion of the dependent claims only eliminated a point of dispute of lack of priority and did not change the discussion of inventive step of the remaining independent claims therefore also fails.

26. At the oral proceedings before the board, the patent proprietor submitted that auxiliary request 19 did not constitute an amendment within the meaning of Article

12(4) RPBA because its claim 1 was identical to claim 1 of auxiliary request 1 filed on 10 February 2022, thus it had been discussed and considered by the opposition division, whereas dependent claims not entitled to the claimed priority had been deleted, as in the auxiliary request upheld by the opposition division. It further submitted that auxiliary request 21 did not constitute an amendment either, because the features "*and wherein all steps mentioned above are performed automatically*" and "*wherein said modulatory agents are selected from agonistic antibodies*" had already been considered in the decision under appeal in the context of the auxiliary request upheld by the opposition division.

27. None of these arguments are persuasive, for the following reasons.

28. First, auxiliary request 19 is not the same as auxiliary request 1 filed on 10 February 2022 or the auxiliary request upheld by the opposition division. Although claim 1 of auxiliary request 19 is indeed identical to claim 1 of auxiliary request 1 filed on 10 February 2022, contrary to the patent proprietor's assertion, the subject-matter at stake had not already been fully discussed in opposition. Indeed, claim 1 of auxiliary request 1 filed on 10 February 2022 was not fully examined by the opposition division, because e.g. inventive step was not considered (decision under appeal, Reasons, items 7 to 11). In addition, the subject-matter of the dependent claims of auxiliary request 19 is different from the subject-matter of the dependent claims in auxiliary request 22. For example, dependent claim 2 of auxiliary request 19 is directed to a list of modulatory agents, whereas in auxiliary request 22, that list has been limited to agonistic

antibodies and incorporated into claim 1.

29. Second, claim 1 of auxiliary request 21 lacks the feature "*wherein said activation and said expansion of T cells, T cell subsets and/or T cell progenitors are performed by shaking conditions*" present in claim 1 of the auxiliary request upheld by the opposition division, and the findings of the opposition division cannot therefore be extended to the subject-matter of auxiliary request 21.

30. To conclude, auxiliary requests 19 to 21 constitute an amendment of the patent proprietor's case within the meaning of Article 12(4) RPBA, and it is therefore at the discretion of the board whether to admit them into the proceedings (Article 12(4) RPBA). Pursuant to the non-exhaustive list of criteria in Article 12(4) RPBA, the Boards are to exercise their discretion in view of, *inter alia*, the complexity of the amendment, the suitability of the amendment to address the issues which led to the decision under appeal, and the need for procedural economy.

31. Furthermore, pursuant to Article 12(6) RPBA, the board must not admit requests, facts, objections or evidence which should have been submitted in the proceedings leading to the decision under appeal unless the circumstances of the appeal case justify their admittance.

32. The patent proprietor put forward two lines of argument to justify the submission of auxiliary requests 19 to 21 on appeal. First, with respect to the deletion of the dependent claims in those requests, it argued that this was a direct response to the opposition division's surprising denial, on the evening of the first day of

oral proceedings, of entitlement to priority to the dependent claims of auxiliary request 1 filed on 10 February 2022. Second, with regard to the amendments to claim 1 in auxiliary requests 19 and 21, it submitted that it was its legitimate right to defend auxiliary requests directed to the automation of the process alone, irrespective of shaking, since in the decision under appeal, the opposition division had acknowledged inventive step on the basis of automation alone, and it was therefore clear that it had unnecessarily limited itself.

33. As regards the first line of argument, the board notes that, at the outset of the opposition proceedings, an objection of lack of priority was raised against each of dependent claims 3 to 15 as granted, for reasons additional to those raised in connection with the lack of priority of independent claim 1 (opponent 3's notice of opposition, section 3).

34. In reply to the notices of opposition, the patent proprietor submitted auxiliary requests 1 to 9 and argued that granted claim 1 and its dependent claims 5 and 6 were entitled to priority (letter dated 26 February 2020, section E). However, the patent proprietor did not address the lack of priority objections against the other dependent claims as granted or submit fall-back positions in case the dependent claims were considered to lack novelty or inventive step as a consequence of lack of priority.

35. In a first communication, the opposition division noted the lack of priority objections raised by the opponents and also that the patent proprietor had commented on the priority of two dependent claims, and announced that, depending on the circumstances, priority would be

discussed at oral proceedings (communication dated 8 April 2020, paragraph 12.5). The opposition division also noted that, if priority were not considered validly claimed, at least documents D2c, D4 and D16 would be highly relevant for the assessment of novelty and inventive step (ibid., paragraphs 13.2.1 to 13.2.7).

36. In its response to the first communication of the opposition division, the patent proprietor did not further address the lack of priority objections against the dependent claims as granted nor submit fall-back positions in case these claims were considered to lack priority.

37. The opposition division issued a summons to oral proceedings accompanied by a further communication in which it reiterated what it had said in the first communication on entitlement to priority, novelty and inventive step of the dependent claims of the main request (communication dated 20 November 2020, paragraphs 17.5, 18.2.1 and 18.2.7).

38. Within the time limit under Rule 116(2) EPC, the patent proprietor submitted new auxiliary requests 1 to 9, none of which addressed the potential lack of priority of the dependent claims of the main request. The patent proprietor merely submitted, as regards entitlement to priority of dependent claims 3 to 15 of the main request, that the priority document disclosed reagents capable of inducing T cell proliferation, such as agonistic antibodies, e.g. anti-CD3 and anti-CD28 (letter dated 10 December 2021, section E.4).

39. As it turned out, the opposition division concluded in the afternoon of the first day of the oral proceedings

(10 February 2022) that most of the dependent claims of auxiliary request 1 filed on the same day were not entitled to the claimed priority. It then found that dependent claims 3, 4 and 14 of auxiliary request 1 lacked novelty over documents D2c and D5a (minutes of oral proceedings before the opposition division ("minutes"), sections 9 and 10).

40. Although this may have come as a surprise to the patent proprietor, it cannot be considered surprising from an objective point of view since it followed the objections raised by opponent 3 at the beginning of the opposition proceedings (point 33. above).

41. Any fall-back position addressing the lack of priority of the dependent claims could and should therefore have been filed during the opposition proceedings, at the latest at the oral proceedings, once the opposition division had announced its opinion on the priority and novelty of auxiliary request 1.

42. However, instead of submitting auxiliary requests 19, 20 and/or 21 during opposition proceedings, the patent proprietor pursued a different combination of features before the opposition division, i.e. auxiliary request 2 (auxiliary request 22 on appeal).

43. The patent proprietor's explanation for filing auxiliary request 2 on the second day of the oral proceedings before the opposition division, i.e. that it had decided to file an immediately recognisable admissible request, does not help its case.

44. In this context, the board does not disregard the fact that it may not always be possible to properly address objections by amending claims at such a late stage as

during the oral proceedings. The board also recognises that, depending on the circumstances, the patent proprietor may not be expected to file auxiliary requests for each and every objection raised in the opposition proceedings. Nevertheless, the board recalls that in the present case the objection of lack of priority, to which the then auxiliary request 2 and present auxiliary requests 19, 20 and 21 respond, was not raised by the opposition division at the oral proceedings, but was raised at the beginning of the opposition proceedings by an opponent. Moreover, the opposition division had twice indicated, following the opponents' submissions, that novelty might become an issue if the dependent claims were found to lack priority, namely in its communications of 8 April 2020 and of 20 November 2020.

45. The board therefore agrees with opponents 1 and 3 that the patent proprietor had had reason - and several opportunities - to present its fall-back positions on this objection before the oral proceedings in opposition proceedings. The need to submit a fall-back position only at the oral proceedings, the last stage of the opposition proceedings, where the criteria for admissibility are stricter, was therefore entirely due to the decision of the patent proprietor to submit its fall-back positions only at the last stage of the opposition proceedings. It cannot justify the filing of further fall-back positions dealing with the objection of lack of priority at an even later stage, i.e. in the appeal proceedings.

46. As regards the patent proprietor's second line of argument (point 32. above), the board is unable to deduce from the patent proprietor's submissions any reasons why auxiliary requests directed only to the

automation of the process, independently of shaking, could not have been filed during opposition proceedings.

47. It is well established in the case law of the Boards of Appeal that Article 12(6), second sentence, RPBA expresses and codifies the principle that each party should submit all facts, evidence, arguments and requests that appear relevant as early as possible so as to ensure a fair, speedy and efficient procedure. A party is not at liberty to bring about the shifting of the case to the appeal proceedings as it pleases and so compel the board either to give a first ruling on the critical issues or to remit the case to the opposition division (Case Law of the Boards of Appeal of the EPO, 10th ed., 2022 ("Case Law"), V.A.4.3.1). The choices the patent proprietor made during the first instance proceedings, i.e. to limit the claimed subject-matter to an automated process in which "*all steps mentioned above are performed automatically and wherein said activation and said expansion of T cells, T cell subsets and/or T cell progenitors are performed by shaking conditions*" (claim 1 of auxiliary request 2 filed during oral proceedings on 11 February 2022) – even if it now considers them to be unduly limiting – cannot therefore justify broadening its case on appeal.

48. For the following reasons, the case law relied on by the patent proprietor does not support its case either. In brief, T 951/92 (Reasons 3), T 233/18 (Reasons 1 to 6) and T 545/18 (Reasons 2.3 to 2.6) concern situations where the first instance decision was taken in violation of the appellant's right to be heard (Article 113(1) EPC). In T 545/18 (Reasons 1), an auxiliary request filed in reaction to a new objection raised by the board was considered admissible. In

T 1024/19 (Reasons 4.5), the board was satisfied that the patent proprietor could not have filed the auxiliary request in the oral proceedings before the opposition division. Finally, in T 317/20, the board did not admit the auxiliary requests at issue (Reasons 28 to 44), and the board is unable to understand how that case would assist the patent proprietor.

49. In the case in hand, the patent proprietor does not even assert that its right to be heard was infringed during the opposition proceedings; no new objection was raised by the opposition division, and there is no objective reason why auxiliary requests 19 to 21 could not have been filed during the opposition proceedings.

50. At the oral proceedings before the board, the patent proprietor furthermore referred to the notice from the European Patent Office dated 1 July 2024 on the President's decision that proceedings before the examining and opposition divisions should continue despite the pending referral G 1/24. This meant that examining and opposition divisions are to continue to apply the practice set out in the Guidelines for Examination in the EPO (Guidelines F-IV, 4.2) and are to thus, as far as possible, require a claim to be amended such that - in cases where the description gives a specific meaning to words used in the claims - the meaning be clear from the wording of the claims alone. On this basis, the patent proprietor argued that amendments aimed at bringing the claims in agreement with the description must be allowed, and therefore auxiliary requests 19 to 21 should be admitted.

51. The board disagrees for the following reasons.

52. First, as a matter of principle, the admissibility of auxiliary request 19 to 21, which were filed with the patent proprietor's statement of grounds of appeal, cannot be justified by reference to something that occurred years after those requests were first filed.

53. Second, the Decision of the President of the EPO to continue examination and opposition proceedings despite the pending referral concerns only proceedings before the departments of first instance and is not binding on the Boards of Appeal. Most importantly, this Decision does not contain any information on the exercise of discretion to admit auxiliary requests into the proceedings, not even before the departments of first instance. Therefore, nothing can be inferred from it as to the admittance of auxiliary requests in appeal proceedings.

54. Third, the patent proprietor's argument provides at best a justification for the inclusion of the feature "*and wherein all steps mentioned above are performed automatically*" in claim 1 of auxiliary requests 19 to 21, but not for any of the other amendments sought by these requests, which, as set out above, could and should have been submitted earlier, i.e. during the opposition proceedings.

55. Finally, the board shares the view of opponents 1 and 3 that auxiliary requests 19 to 21 required further discussion and were therefore, contrary to the assertion of the patent proprietor, also not clearly allowable. Thus, inventive step had to be discussed for all requests. For auxiliary requests 19 and 20, sufficiency of disclosure had to be discussed in addition, because dependent claim 2 contains a list of modulatory agents, which was objected to from the

outset of the opposition proceedings under Article 83 EPC (opponent 3's notice of opposition, section 6) but was not decided on by the opposition division, because in the auxiliary request upheld by the opposition division, the modulatory agents had been limited to agonistic antibodies. As submitted by opponents 1 and 3, these considerations also belong to the assessment of admittance of auxiliary requests, to be taken into account in the exercise of the board's discretion in view of the need for procedural economy.

56. The patent proprietor has foregone an examination by the opposition division of subject-matter added in auxiliary requests 19 to 21. Adding this subject-matter on appeal is at odds with the purpose of appeal proceedings referred to in Article 12(2) RPBA. It would also require the board to assess for the first time the inventive step of the claimed combination of features and the sufficiency of disclosure of modulatory agents other than agonistic antibodies or remit the case to the opposition division. Neither of these options would be consistent with procedural economy.

57. For these reasons, the board decided not to admit any of auxiliary requests 19 to 21 into the proceedings.

*Auxiliary request 22*
*Added subject-matter*

58. The opposition division found that the subject-matter of claim 1 met the requirements of Article 123(2) EPC. This part of the decision under appeal was disputed by opponents 1 and 3, which maintained, *inter alia*, that the combination of features in claim 1 required multiple selections from different lists of options to

which the application as filed provided no pointer.

59. As its main line of argument, the patent proprietor submitted that the opponents' objection that the combination of features in claim 1 required multiple selections was new and requested that it not be admitted into the appeal proceedings.

60. For the following reasons, the board disagrees.

61. Auxiliary request 22 was filed as auxiliary request 2 during the oral proceedings before the opposition division, and the opponents objected at the oral proceedings that the combination of features in claim 1 required multiple selections from several lists (minutes, paragraph 13).

62. The objection was dealt with in the decision under appeal (Reasons 14.2.3), and it therefore forms part of the appeal proceedings (Article 12(1)(a) and 12(2) RPBA). The EPC does not provide any legal basis for retroactively excluding on appeal submissions admitted by opposition divisions (Case Law, V.A.3.4.4).

63. Claim 1 reads as follows (with feature annotation [F1], [F2], [F3] as used by opponent 1):

"An automated process for generation of genetically modified T cells, T cell subsets and/or T cell progenitors comprising the steps:
a) providing a cell sample comprising T cells, T cell subsets and/or T cell progenitors
b) preparation of the cell sample by centrifugation
c) magnetic separation of the T cells, T cell subsets and/or T cell progenitors
d) activation of the enriched T cells, T cell subsets

and/or T cell progenitors using modulatory agents,
e) genetic modification of the T cells, T cell subsets and/or T cell progenitors
f) expansion of the genetically modified T cells, T cell subsets and/or T cell progenitors in a cultivation chamber
g) washing of the cultured T cells, T cell subsets and/or T cell progenitors
characterized in that all steps are performed in a closed and sterile cell culture system and
[F1] wherein all steps mentioned above are performed automatically and
[F2] wherein said activation and said expansion of T cells, T cell subsets and/or T cell progenitors are performed by shaking conditions and
[F3] wherein said modulatory agents are selected from agonistic antibodies."

64. It is common ground that claim 1 is based on claim 1 as granted, to which features F1, F2 and F3 have been added.

65. 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 can not be presented with new technical information (ibid., Reasons 4.5.1).

66. It is moreover well established in the case law of the boards of appeal that the content of an application must not be considered to be a reservoir from which features pertaining to separate embodiments or lists can be combined in order to artificially create a particular embodiment. In the absence of any pointer to that particular combination, this combined selection of features does not emerge clearly and unambiguously from the content of the application as filed for the person skilled in the art (Case Law, II.E.1.6.1(a)).

67. Reference is made below to the page and line numbering of the application as filed.

*Combination of features F2 and F3*

68. The opposition division found that a basis for the combination of features F2 and F3 could be found in granted claims 2 and 9 (identical to claims 2 and 9 as filed) for two reasons. First, it considered that the combination of features was not a selection of independent features from different lists, but a further specification of features already present in combination in claim 1, i.e. the use of modulatory agents and both the activation and expansion of T cells, T cell subsets and/or T cell progenitors ("T cells"). Second, the opposition division found that the application as filed provided a pointer to the claimed combination of features because feature F2 was disclosed as preferred on page 5, lines 9 to 10 and lines 27 to 30 and in Examples 3 and 4 of the application as filed, whereas feature F3 was disclosed as preferred on page 4, lines 15 to 24 and in Example 3 of the application as filed.

69. In view of the arguments of the parties, the question to be answered is whether a selection from several lists occurred and, if so, whether the application as filed supports the selection.

70. Claim 2 as filed reads "[t]*he process according to claim 1, wherein said modulatory agents are selected from the group consisting of agonistic antibodies, cytokines, recombinant costimulatory molecules and small drug inhibitors*", whereas claim 9 as filed reads "[t]*he process according to any one of claims 1 to 8, wherein said activation, genetic modification and/or said expansion of T cells, T cell subsets and/or T cell progenitors are performed by shaking conditions.*"

71. The board shares the view of opponents 1 and 3 that claim 2 provides a list of four equally preferred alternatives of modulatory agents from which "*agonistic antibodies*" need to be selected to arrive at feature F2, while claim 9 provides a further list of seven equally preferred options from which activation and expansion of T cells under shaking conditions need to be selected to arrive at feature F3.

72. The combination of features F2 and F3 in claim 1 thus represents one of 28 possible combinations of features resulting from selections within the separate lists of claims 2 and 9. It is well established in the case law that the combination of one item from each of two lists, in the absence of any pointer that supports the combination, results in subject-matter, which although conceptually comprised in the content of the application as filed, can not be considered to be directly and unambiguously disclosed in this individualised form (T 727/00, Reasons 1.1.4). The fact that features F2 and F3 further specify features

already present in combination in claim 1 does not alter the fact that selections from separate lists are required and is therefore irrelevant. The first line of reasoning of the opposition division must therefore be rejected.

73. The patent proprietor's argument that the skilled person would seriously consider combining features F2 and F3 because claim 2 points to agonistic antibodies and claim 9 points to T cell activation and expansion under shaking conditions must also be rejected. No pointer to combining specifically agonistic antibodies and T cell activation and expansion under shaking conditions can be derived from claims 2 and 9, respectively, because these features are presented as equivalent alternatives among other options in those claims (points 70. and 71. above).

74. With respect to the second line of reasoning of the opposition division (point 58. above), it is noted that page 5, lines 9 to 10 of the application as filed discloses a preference for shaking conditions during expansion of T cells, but not during activation.

75. On page 5, lines 27 to 30, the application as filed discloses that "[t]*herefore surprisingly, synergistic effects can be observed when high T cell, T cell subsets and/or T cell progenitor densities are activated and then expanded under shaking conditions (possibly before or after genetic modification of said cells) within the process of the present invention*".

76. The opposition division held that this passage had to be read in the context of the two preceding sentences on page 5 of the application as filed and concluded that the use of high T cell densities was not limiting

but that the application as filed disclosed "*that with the method claimed, i.e. with an activation and expansion under shaking conditions, also high T cell densities can be used*" (decision under appeal, Reasons 14.2.3, emphasis in the original).

77. However, the board shares the view of opponents 1 and 3 that the passage on page 5, lines 27 to 30 of the application as filed discloses activation and expansion of T cells under shaking conditions in the context of high T cell densities only and that there is no indication on page 5 of the application as filed that the disclosure can be generalised.

78. Furthermore, as noted by opponent 3 at the oral proceedings before the board, this understanding of the teaching of page 5, lines 27 to 30 of the application as filed is confirmed by the disclosure on page 10, lines 19 to 29, page 13, lines 23 to 30 and Example 3 of the application as filed where the use of shaking conditions during activation and expansion of T cells is consistently disclosed in the context of high T cell densities only.

79. The board therefore also shares the view of opponent 3 that if there is a pointer in the application as filed to use shaking conditions for both activation and expansion of T cells, it is only in the context of high T cell densities. However, claim 1 is not limited to a method which uses high T cell densities.

80. The patent proprietor's argument that in light of page 5, lines 30 to 31 of the application as filed, which reads "[t]*his rapidly leads to very high cell numbers of genetically-modified cells (see FIG 9)*", achieving high densities of gene-modified T cells was

the technical effect, whereas the relevant technical features were the defined steps under shaking conditions, must also be rejected because the defined steps are only disclosed in the context of using high T cell densities in the first place (point 74. above).

81. None of the further passages of the application as filed referred to by the patent proprietor at the oral proceedings before the board provide a pointer to the use of shaking conditions during the T cell activation and expansion either.

82. Thus, as noted by opponents 1 and 3, the disclosure on page 5, lines 8 to 9 of the application as filed is the same as in claim 9 as filed and, as set out above (points 70. to 73.), no preference for T cell activation and expansion under shaking conditions is derivable from that disclosure.

83. Page 8, lines 1 to 3 of the application as filed reads: "[a]*ccordingly, in the process of the invention, T cell activation, gene modifying and/or cultivation steps can be performed under steady or shaking conditions of the centrifugation or the cultivation chamber*". The board shares the view of opponents 1 and 3 that even more selections are required to arrive at feature F2 from this disclosure than from the disclosure on page 5, lines 8 and 9 of the application as filed, and that no pointer to the use of shaking conditions during T cell activation and expansion in the context of the method of claim 1 can be inferred from this disclosure.

84. Finally, in the embodiment disclosed on page 13, line 32 to page 14, line 1 of the application as filed, shaking conditions are used not only during T cell activation and expansion, but also during genetic

modification. Furthermore, shaking conditions are said to be used to keep the high-density cell culture in suspension, and therefore no pointer to the use of shaking conditions in the context of the method of claim 1, which is not directed to a high-density T cell culture, can be inferred from this disclosure either.

85. With respect to the opposition division's reliance on Example 3 as providing a pointer to performing the activation and expansion of T cells under shaking conditions, the board shares the view of opponent 3 that Example 3 is missing at least the genetic modification of step (e) of claim 1 and cannot therefore provide any pointer to the combination of feature F2 with the remaining features of the method of claim 1.

86. Thus, as noted by opponent 3, no genetic modification step is described in Example 3 or in the legend for Figure 9 on page 10, lines 19 to 29 of the application as filed. Instead, Example 3 states that starting from a leukapheresis, T cells were enriched similarly to Example 2 (page 24, lines 4 to 5 of the application as filed). Subsequent to enrichment and transfer of the cells into the chamber of the closed sterile tubing set, Example 3 describes an activation step (page 24, lines 7 to 9) and an expansion step (page 24, lines 9 to 11). The absence of a genetic modification step is consistent with the conclusion in Example 3 that the "*results show that it is possible to activate and expand T cells*" (page 24, lines 11 to 12) and that "*it is possible to very rapidly generate large numbers of T cells*" (page 24, lines 13 to 14) without any reference to "*genetic modification*" or "*gene-modified T cells*". The board therefore shares the view of opponent 3 that the reference to "*gene-modified T cells*" in the title

of Example 3 appears to be in error.

87. The counter-argument of the patent proprietor that Example 3 discloses a step of genetic modification by reference to Figure 4 has to be rejected. Figure 4 shows the impact of culture shaking during the manufacture of gene-engineered T cells according to the method of Example 2, not Example 3 (page 2, line 31; page 23, lines 28 to 31 of the application as filed). In the context of Example 3, Figure 4 is merely referred to for comparison (see page 24, lines 13 to 15 of the application as filed) and does not instruct the skilled person to perform a genetic modification.

88. The patent proprietor's further argument that the skilled person considering the whole content of the application as filed would understand the procedural instructions for genetic modification of T cells provided in the context of the description of Figure 4 to apply for all examples of the application as filed is not persuasive either. The skilled person has no reason to read a step of genetic modification into Example 3 of the application as filed merely because genetic modification of T cells is described for a different example in the application as filed.

89. The board moreover recalls that as set out above (points 78. and 79. above) Example 3 discloses the use of shaking conditions during activation and expansion of T cells in the context of high T cell densities only. Also for this reason, no pointer to the use of shaking conditions during T cell activation and expansion in the context of the method of claim 1 can be inferred from Example 3.

90. With respect to the opposition division's reliance on Example 4, the board also shares the view of opponent 3 that no pointer to performing the activation and expansion of T cells under shaking conditions can be derived from Example 4 because the manufacturing process in Example 4 is carried out as in Example 2 (page 24, lines 23 to 24 of the application as filed) and hence without shaking conditions during activation (see page 23, lines 18 and 19 and line 25 of the application as filed).

91. The opposition division's further argument that the disclosure of anti-CD3/anti-CD28 antibodies, particularly TransAct, as preferred options on page 4, lines 15 to 24 and in Example 3 of the application as filed provided a pointer to the selection of agonistic antibodies must also be rejected.

92. The board concurs with opponents 1 and 3 that any disclosure in the application as filed on specific forms of antibodies - i.e. anti-CD3 and anti-CD28 antibodies coupled to beads or nanostructures (page 4, lines 15 to 17 of the application as filed), or the TransAct CD3/CD28 kit in Example 3 - cannot provide a pointer to generally using "*agonistic antibodies*", let alone in combination with shaking conditions during T cell activation and expansion in the context of the method of claim 1.

93. The patent proprietor's argument that all examples were performed with agonistic antibodies likewise fails, because all examples use the TransAct CD3/CD28 kit, i.e. specific antibodies not agonistic antibodies generally (page 22, line 21; page 23, line 6; page 24, line 9; page 24, lines 23 and 24 of the application as filed). Therefore, the patent proprietor's further

argument that Examples 2 and 3 disclose the use of agonistic antibodies in combination with shaking conditions during the activation and expansion of T cells also fails for this reason alone, although in Example 2 the activation is not even performed under shaking conditions (see page 23, lines 18 and 19 and line 25).

94. The patent proprietor's final argument that the claimed combination of agonistic antibodies with shaking conditions during activation and expansion of T cells was explicitly disclosed on page 9, lines 8 to 28 and page 11, lines 17 to 31 of the application as filed also fails to persuade.

95. Contrary to the patent proprietor's submissions, page 9, lines 8 to 28 of the application as filed does not explicitly disclose the use of agonistic antibodies in combination with shaking conditions during T cell activation and expansion. Page 9, lines 10 and 11 instead discloses the use of a kit comprising specific antibodies for activation, i.e. TransAct CD3/CD28 and then the use of "*3 different types of sporadic shaking modes*" after T cell activation (page 9, lines 13 and 14).

96. Contrary to the patent proprietor's submission, page 11, lines 17 to 31 of the application as filed also does not disclose features F2 and F3 in combination. Instead, the use of shaking conditions during T cell activation and expansion is disclosed as being optional, and agonistic antibodies are mentioned only in a list of equally preferred alternatives. Therefore, the disclosure on page 11, lines 17 to 31 requires a first selection to arrive at the combination of shaking conditions during T cell activation and expansion and a

further selection to arrive at the use of agonistic antibodies.

97. In conclusion, multiple selections are required to arrive at the claimed combination of the use of shaking conditions during T cell activation and expansion (feature F2) and the use of agonistic antibodies as modulatory agents (feature F3) in the context of the method of claim 1, and the application as filed as a whole provides no pointer to this combination of features.

98. Absent any pointer in the application as filed as a whole to the claimed combination of features F2 and F3, the subject-matter of claim 1 provides the skilled person with new technical information which they cannot directly and unambiguously derive from the application as filed.

99. Consequently, there is no need to decide whether the further combination of features F2 and F3 with feature F1 in claim 1 also adds subject-matter. The decision on auxiliary request 22 could therefore also be taken independently of documents A058 and A059 and independently of the request for stay of the proceedings, as indicated below.

100. The subject-matter of claim 1 of auxiliary request 22 contravenes the requirements of Article 123(2) EPC.

*The patent proprietor's request for a stay of proceedings*

101. With decision T439/22 (OJ EPO 2024, 104), a referral was made to the Enlarged Board of Appeal, pending as G 1/24, on the legal basis for interpreting patent claims for the purpose of assessing patentability,

whether and under which circumstances the description and figures may be consulted when interpreting a patent claim and, finally, the extent to which a patent can serve as its own dictionary (T 439/22, Questions 1 to 3).

102. Shortly before the date of the oral proceedings, the patent proprietor requested that the appeal proceedings be stayed in view of pending referral G 1/24.

103. In support of its request, the patent proprietor argued that the interpretation of claim 1 of the main request was decisive for the question of entitlement to priority and thus novelty and inventive step of the main request. In its view, the outcome of the present case therefore depended on the answer to the questions referred to the Enlarged Board of Appeal in G 1/24.

104. As set out above (points 14. to 16.), the board considers that the main request lacks novelty, regardless of how claim 1 is interpreted and regardless of whether claim 1 is entitled to priority.

105. The board also decided on the auxiliary requests without the need for a ruling on the questions currently pending before the Enlarged Board of Appeal (points 19. to 100. above).

106. Accordingly, the board saw no reason to grant the patent proprietor's request for a stay of proceedings.

*Conclusion*

107. The main request and auxiliary request 22 are not allowable, and auxiliary requests 19 to 21 are not admitted into the appeal proceedings. In the absence of

an allowable claim request in the proceedings before the board, the decision under appeal must be set aside, and the patent must be revoked.

## Order

## For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairwoman:

L. Stridde T. Sommerfeld

Decision electronically authenticated