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**Datasheet for the decision  
of 17 June 2025**

**Case Number:** T 0868/23 - 3.3.08

**Application Number:** 15783117.3

**Publication Number:** 3134095

**IPC:** A61K35/12, A61K35/17,  
A61K38/17, C12N5/0783,  
C12N5/16, C12N7/00, C12N15/86

**Language of the proceedings:** EN

**Title of invention:**  
Improved methods for manufacturing adoptive cell therapies

**Patent Proprietor:**  
2seventy bio, Inc.

**Opponents:**  
Dehns Limited  
GlaxoSmithKline Intellectual Property  
Development Limited  
Boult Wade Tennant LLP

**Headword:**  
CAR T-cells/2SEVENTY BIO

**Relevant legal provisions:**  
EPC Art. 123(2), 111(1)  
RPBA 2020 Art. 12(6)

**Keyword:**

Main request and auxiliary requests 1 to 8 and 12 to 15 -  
added subject-matter - (yes)

Auxiliary requests 9 to 11 and 16 to 18 - should have been  
submitted in first-instance proceedings (yes)

Remittal to the department of first instance - (no)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern**

**Boards of Appeal**

**Chambres de recours**

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**Case Number: T 0868/23 - 3.3.08**

**D E C I S I O N**  
**of Technical Board of Appeal 3.3.08**  
**of 17 June 2025**

**Appellant:**  
(Opponent 3)

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**Decision under appeal:** **Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
28 February 2023 concerning maintenance of the  
European Patent No. 3134095 in amended form**

**Composition of the Board:**

**Chair** T. Sommerfeld  
**Members:** M. Montrone  
D. Rogers

## Summary of Facts and Submissions

- I. European patent No. 3 134 095 B1 ("the patent") was granted for European patent application No. 15 783 117.3 which has been filed as International patent application published as WO 2015/164745 (the "patent application").
- II. Three oppositions were filed against the granted patent. The patent was opposed in its entirety under Article 100(a) EPC (in conjunction with Articles 53(c), 54 and 56 EPC), 100(b) and 100(c) EPC.
- III. By an interlocutory decision, the opposition division decided that the patent could be maintained in amended form on the basis of the set of claims of auxiliary request 1.
- IV. Opponent 03 ("appellant") appealed this decision. With their statement setting out the grounds of appeal ("SGA"), they *inter alia* submitted objections under added subject-matter against the subject-matter of auxiliary request 1 (i.e. the main request in appeal).
- V. In reply, the patent proprietor ("respondent") submitted counter arguments, re-submitted auxiliary requests 1 and 2 (being identical to auxiliary requests 3 and 4, respectively, already filed during the opposition proceedings) and submitted new auxiliary requests 3 to 11.
- VI. In further submissions (hereafter "rejoinder"), both parties replied to each other's submissions. The respondent submitted new auxiliary requests 12 to 18.

VII. Claims 1 and 4 of the main request read:

"1. An in vitro method for manufacturing a T cell therapeutic comprising:  
a) providing a population of human peripheral blood mononuclear cells (PBMCs) that comprises T cells and antigen presenting cells (APCs);  
b) culturing the population of PBMCs for 16 hours to 32 hours prior to transduction in a cell culture medium comprising i) interleukin-2 (IL-2), ii) an anti-CD3 antibody or CD3-binding fragment thereof, and iii) an anti-CD28 antibody or a CD28-binding fragment thereof, B7-1 or a CD28-binding fragment thereof, or B7-2 or a CD28-binding fragment thereof, wherein the culture activates and stimulates the T cells;  
c) transducing the population of PBMCs activated in step b) with a lentiviral vector encoding a chimeric antigen receptor (CAR); and  
d) culturing the population of PBMCs in a cell growth medium to expand the transduced T cells;  
thereby manufacturing the T cell therapeutic."

"4. The method of claim 1, wherein the cell culture medium;

a) is T cell growth medium (TCGM); or  
b) is T cell growth medium (TCGM) further comprising one or more additional cytokines; or  
c) is TCGM further comprising one or more additional cytokines selected from any of: IL7, IL-15, IL-9, and IL-21."

Claim 1 of auxiliary requests 6 and 12 is identical to claim 1 of the main request.

Claim 4 of auxiliary requests 1 to 5 and 13 to 15 is identical to claim 4 of the main request.

- VIII. Claim 1 of auxiliary requests 1 and 7 differs from claim 1 of the main request in that in step b) the features "*an anti-CD3 antibody*" and "*an anti-CD28 antibody*" have been replaced by "*soluble anti-CD3 antibody*" and "*soluble anti-CD28 antibody*", respectively and in that the features "*or CD3-binding fragment*" and "*or a CD28-binding fragment thereof, B7-1 or a CD28-binding fragment thereof, or B7-2 or a CD28-binding fragment thereof*" have been deleted.
- IX. Claim 1 of auxiliary requests 2 and 8 differs from claim 1 of auxiliary request 1 in that in step b) the feature "*a concentration from 45 ng/mL to 55 ng/mL of*" has been added in the context of soluble anti-CD3 and anti-CD28 antibodies.
- X. Claim 1 of auxiliary requests 3, 9, 13 and 16 differs from claim 1 of the main request in that in step b) the range "*16 hours to 32 hours*" has been replaced by "*20 hours to 24 hours*".
- XI. Claim 1 of auxiliary requests 4, 10, 14 and 17 combines the amendments of claims 1 of auxiliary requests 1 and 3.
- XII. Claim 1 of auxiliary requests 5, 11, 15 and 18 combines the amendments of claims 1 of auxiliary requests 2 and 3.
- XIII. In the letter dated 23 May 2024, opponent 02 withdrew their opposition and hence ceased to be a party to the proceedings.

- XIV. Opponent 01, being a party as of right, has remained silent in these proceedings.
- XV. In a communication pursuant to Article 15(1) RPBA, the board provided its preliminary assessment according to which none of the sets of claims on file seemed allowable or admissible.
- XVI. In reply, the respondent submitted that they would neither attend nor be represented at the oral proceedings.
- XVII. The board cancelled the scheduled oral proceedings.
- XVIII. The parties' submissions, insofar as relevant to the present decision, are dealt with in the Reasons part of this decision.
- XIX. The relevant request of the appellant for this decision is that
- the decision under appeal be set aside and amended such that the patent be revoked.
- XX. The relevant requests of the respondent for this decision are that:
- the appeal be dismissed (main request), or, alternatively, that
  - if the main request was found not to comply with the requirements of the EPC, the case be remitted to the opposition division for further prosecution,
  - alternatively that the patent be maintained on the basis of one of auxiliary requests 1 to 11 filed with their reply and
  - that auxiliary requests 12 to 18 be admitted.

## **Reasons for the Decision**

*Main request (corresponding to auxiliary request 1 as maintained by the opposition division)*

*Claim interpretation - claim 1*

1. The appellant submitted that according to its broadest sensible technical meaning the feature "*a population of human peripheral blood mononuclear cells (PBMCs) that comprises T cells and antigen presenting cells (APCs)*" in step (a) of claim 1 encompassed any human blood-derived population of cells having a round nucleus that comprised at least T-cells and APCs irrespective of their degree of purity (SGA, page 5, first paragraph and page 6, fourth paragraph to eight paragraph).
2. The board does not agree essentially for the reasons provided by the opposition division (decision under appeal, page 14, second paragraph to page 15, second paragraph) and by the respondent (reply to appeal, items 2.3, 2.4, 3.1, 3.2, 3.4 and 3.10, respondent's rejoinder, items 2.3, 2.9, 2.11 and 2.12).
3. In particular, according to the ordinary meaning of the term human PBMC population in the context of claim 1, this cell population contains an ordinary mixture of white blood cells with a round nucleus, i.e. lymphoid and myeloid cells (which excludes the presence of platelets and red blood cells (RBCs)). Such a cell population contains necessarily *inter alia* T-cells and antigen presenting cells ("APCs").

*Added subject-matter*

4. In the following, references to the application as filed are to the patent application (WO 2015/164745).
5. It is established case law that any amendment to the parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) is subject to the requirements laid down in Article 123(2) EPC. Any amendment can only be made 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 these documents as filed (Case Law of the Boards of Appeal of the EPO, 10<sup>th</sup> edition 2022 ("Case Law"), II.E.1.1).
6. The appellant raised several objections under added subject-matter against claim 1 (SGA, section 5.1 and rejoinder, section 4.1), including *inter alia*, against the combination of features mentioned therein. Further objections under added subject-matter were *inter alia* raised against claim 4 (SGA, section 5.2).
7. The respondent submitted (reply to appeal, sections 5.2 and 5.3 and rejoinder, section 5) that the following passages in the application as filed provided the basis for
  - claim 1:
    - features of steps a) and b): claims 1, 2, 5, 14, 23 and 31 as filed, G 1/03 (as regards a basis for the term "*in vitro*"), page 4, lines 9, 22 and 23, page 26, lines 3 to 5, 14, page 31, lines 12 to 14, page 32, lines 20 and 21, page 37, line 13 to page 38, line 2, Examples 1 and 2;
    - features of step c): step (b) of claims 1, 35 and 42 as filed in conjunction with the application

as filed as a whole, in particular Examples 1 and 2, page 64, lines 26 to 29;

- combination of features: all features were disclosed in the passages indicated above, in particular, in Examples 1 and 2.
- Claim 4:
  - features of claims 4a and b: page 32, lines 15, 16, 20 and 21 in conjunction with Examples 1 and 2,
  - features of claim 4c: page 4, lines 5 and 6.

*Claim 1*

8. The first issue to be assessed is thus whether or not the combination of features mentioned in claim 1 can be directly and unambiguously derived from the application as filed.
9. It is undisputed that the method of claim 1 is in essence based on claim 1 as filed.
10. The feature "*a population of human peripheral blood mononuclear cells (PBMCs) that comprises ... (APCs)*" in step a) of claim 1 differs from step a) of claim 1 as filed in that it reads instead: "*a population of cells that comprises ... (APCs)*", i.e. is limited to PBMCs contrary to any cell population that comprises T-cells and APCs. The issue of whether or not this feature in claim 1 has a basis in the application as filed needs not to be decided by the board in view of the conclusion reached on other features mentioned therein (see below).
11. As regards the issue of whether a human population of PBMCs comprises necessarily T-cells and APCs, see point 3 above.

12. The feature "*16 hours to 32 hours*" activation time in step b) of claim 1 is disclosed in claim 31 as filed. Alternative ranges are mentioned in claims 28, 30, 32 or 33 as filed (and on page 4, lines 20 to 27 of the application as filed), so that each of these ranges represents an equally preferred alternative. Most of these ranges overlap.
  - 12.1 In disagreement with the opposition division's finding (decision under appeal, page 7, second paragraph, heading "*Regarding feature (ii)*") and in agreement with the appellant (SGA, page 13, fourth to sixth paragraph), the ranges of "*at least*" 18 or 24 hours in claims 32 and 33 as filed (and on page 4, lines 24 to 27 of the application as filed) are not narrower than the range of 16 hours to 32 hours indicated in claim 1 but broader due to their open upper limit. Solely the range of "*about 12 hours to about 48 hours*" in claim 28 as filed (also page 4, lines 20 and 21 of the application as filed) comprises the narrower range of 16 hours to 32 hours mentioned in claim 1.
  - 12.2 Thus the different ranges disclosed in claims 28 and 30 to 33 as filed and in part on page 4, lines 20 to 27 of the application as filed do not constitute converging alternatives, but rather represent a list of equally preferred alternatives. A pointer in the application as filed is however missing for selecting the claimed range from this list of alternatives.
13. As regards the interleukin-2 ("*IL-2*") mentioned in step b) of claim 1, claim 1 as filed reads instead "*one or more cytokines*". The opposition division held (decision under appeal, page 7, second paragraph, heading "*Regarding feature (iii)*") that a basis for IL-2 was

found on page 31, lines 12 to 14 in conjunction with page 4, line 9 and the working examples of the application as filed. In particular, the disclosure on page 4, line 9 and in the examples provided pointers for the preferred use of IL-2. These passages of the application as filed were also referred to by the respondent (reply to appeal, sections 5.2.11 to 5.2.13).

13.1 The board does not agree, essentially for the reasons submitted by the appellant (SGA, page 13, last paragraph to page 14, last paragraph). In particular, page 31, lines 12 to 14 of the application as filed states as follows: "*The cellular compositions may further be cultured in the presence of one or more additional growth factors or cytokines, e.g., IL-2, IL7, and/or IL-15, or any suitable combination thereof*" (emphasis added). A very similar disclosure is found on page 32, lines 20 and 21 of the application as filed. Accordingly, IL-2 is one component of a list of three equal alternatives. The respective passage on page 4, line 9 has to be read in the whole context of page 4, lines 5 to 9 which states: "*In certain embodiments, the TCGM comprises one or more cytokines selected from the group consisting of: IL-2, IL7, IL-15, IL-9, and IL-21. In further embodiments, the one or more cytokines are selected from the group consisting of: IL-2, IL-7, and IL-15. In additional embodiments, the one or more cytokines comprise IL-2*" (emphasis added).

13.2 In other words, as acknowledged by the opposition division (decision under appeal, page 7, last paragraph) and contrary to the respondent's submission (reply to appeal, section 5.2.12), this passage on page 4 of the application as filed is limited to the

cytokines used in the medium "TCGM" (T cell growth medium), i.e. a feature missing from claim 1. Examples 1 and 2 of the application as filed use IL-2 but under defined experimental conditions, for example, in a TCGM that contains a specific set of activating factors at defined concentrations (page 90, lines 8 to 13 and page 95, lines 3 to 20). These features are likewise missing from claim 1.

13.3 The respondent submitted further that claims 14 and 23 as filed provided a basis for the selection of IL-2 in claim 1. This is not convincing for the reasons submitted by the appellant (rejoinder, page 9, fourth paragraph). In particular, claim 14 as filed (via dependency on claim 13 as filed) is dependent only on claim 12 as filed which relates to a wash step of cells in TCGM. Claim 12 as filed however does not relate to cell activation, i.e. the context in which IL-2 is used in step b) of claim 1. Similarly, claim 23 as filed depends on claim 21, itself dependent on claim 19 as filed. Each of claims 19 and 21 include features (use of TCGM, seeding at a specific cell density) that are absent from claim 1. Claim 23 thus cannot provide a basis for the requirement in step b) to use IL-2. Consequently, claims 14 and 23 as filed do not provide pointers for selecting IL-2 from a list of three equal alternatives either (point 13.1 above).

13.4 Owing to the considerations above, at least the features "*16 hours to 32 hours*" and "*interleukin-2 (IL-2)*" in claim 1 of the main request have been selected from different lists in the absence of a pointer. Since this artificial combination of features taken from different list generates new subject-matter that cannot be directly and unambiguously derived from

the application as filed, claim 1 comprises added subject-matter (Case Law, II.E.1.6.2 a) and b)).

*Claim 4*

14. The second issue to be assessed is whether or not the subject-matter of claim 4 can be directly and unambiguously derived from the application as filed.
15. The opposition division held that the subject-matter of claim 4 had a basis in the disclosure on page 4, lines 5 and 6 and on page 32, lines 15, 16 and 20 of the application as filed (decision under appeal, Reasons 14.11). The respondent referred in addition to Examples 1 and 2 of the application as filed (point 7 above).
16. The board does not agree essentially for the reasons submitted by the appellant (SGA, section 5.2).
  - 16.1 Claim 4 depends on claim 1, i.e. encompasses the subject-matter of both claims. Claim 4 c) requires that the TCGM comprises further *"one or more additional cytokines selected from any of: IL7, IL-15, IL-9, and IL-21"*. In other words, claim 4 c) requires that the culture medium contains IL-2 (due to step b) of claim 1) and at least one further cytokine selected from IL-7, IL-15, IL-9 or IL-21.
  - 16.2 The passage on page 4, lines 5 to 9 of the application as filed is mentioned in point 13.1, above. The passage on page 32, lines 15 to 21 reads as follows: *"In a particular embodiment, the cell culture medium is TCGM. Cell culture media contemplated herein may further comprise one or more factors including, but not limited to serum (e.g., fetal bovine or human serum),*

*interleukin-2 (IL-2), insulin, IFN- $\gamma$ , IL-4, IL-7, IL-21, GM-CSF, IL-10, IL-12, IL-15, TGF $\beta$ , and TNF- $\alpha$ . In one embodiment, the cell culture medium may comprise one or more cytokines, e.g., such as IL-2, IL-7, and/or IL-15, or any suitable combination thereof".*

16.3 It is evident that the respective sentence on page 4 of the application as filed ("*In certain embodiments, the TCGM comprises one or more cytokines selected from the group consisting of: IL-2, IL7, IL-15, IL-9, and IL-21*") reported in point 13.1 above is silent on a TCGM that specifically contains IL-2 and at least one further cytokine selected from IL-7, IL-15, IL-9 or IL-21 (as required by claim 4 c) in conjunction with claim 1). Nor is such a combination derivable from the passage on page 32 of the application as filed indicated in point 16.2 above.

16.4 For arriving at such a combination of cytokines an artificial two-fold selection has to be made, first IL-2 has to be selected and then one or more of IL-7, IL-15, IL-9, and IL-21. This generates new subject-matter that is not directly and unambiguously derivable from these pages of the application as filed (Case Law, II.E.1.6.2).

16.5 In support of their case, the respondent further relied on the disclosure of Examples 1 and 2 of the application as filed. However as set out before as well (point 13.2 above), Examples 1 and 2 disclose a specific set of experimental conditions that are all lacking from present claim 4. Accordingly the disclosure of these two working examples cannot support the respondent's case either.

17. Consequently, the subject-matter of claims 1 and 4 of the main request extends beyond the content of the application as filed, and the claims thus contravene Article 123(2) EPC.

*Auxiliary requests 1 and 2*

*Added subject-matter - claims 1 and 4*

18. Claims 1 of auxiliary requests 1 and 2 comprise the "16 hours to 32 hours" and the "IL-2" features, like claim 1 of the main request.
19. The method of claim 4 of auxiliary requests 1 and 2 is identical to claim 4 of the main request.
20. The objections under added subject-matter set out above for claims 1 and 4 of the main request apply thus equally to claims 1 and 4 of auxiliary requests 1 and 2 (Article 123(2) EPC).

*Auxiliary requests 3 to 8 and 12 to 15*

*Admittance/consideration of auxiliary requests 3 to 8 and 12 to 15*

21. Auxiliary requests 3 to 8 and 12 to 15 are new to the proceedings (sections V and VI above). These sets of claims constitute thus an amendment of the respondent's case within the meaning of Article 12(4) RPBA (auxiliary requests 3 to 8), or Article 13(1) RPBA (auxiliary requests 12 to 15) and may be admitted into the proceedings only at the board's discretion. However in view of the board's conclusion on added subject-matter as regards auxiliary requests 3 to 8 and 12 to

15 (see below), no reasons will be provided for their consideration in appeal.

*Added subject-matter*

22. Claims 1 of auxiliary requests 6 to 8 and 12 comprise the "16 hours to 32 hours" and the "IL-2" features, like claim 1 of the main request.
23. Claim 4 of auxiliary requests 3 to 5 and 13 to 15 is identical to claim 4 of the main request. Moreover, the subject-matter of claims 1 of auxiliary requests 3 to 5 and 13 to 15 requires the presence of IL-2, like claim 1 of the main request (point 16.1 above).
24. Accordingly, the objections under added subject-matter set out above for claims 1 and 4 of the main request apply equally to claims 1 of auxiliary requests 6 to 8 and 12 and to claims 4 of auxiliary requests 3 to 5 and 13 to 15 (Article 123(2) EPC).

*Auxiliary requests 9 to 11 and 16 to 18*

*Admittance/consideration of auxiliary request 9 to 11 and 16 to 18*

25. Auxiliary requests 9 to 11 and 16 to 18 are new to the proceedings (sections V and VI above). These sets of claims constitute thus an amendment of the respondent's case within the meaning of Article 12(4) RPBA (auxiliary requests 9 to 11) or Article 13(1) RPBA (auxiliary requests 16 to 18) and may be admitted into the proceedings only at the board's discretion. Pursuant to Article 12(6) RPBA, the board shall 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.

26. Claim 1 of auxiliary request 9 is identical to claim 1 of auxiliary request 3. As regards the reasons for introducing the new feature "*20 hours to 24 hours*" into claim 1 of auxiliary request 3, the respondent submitted (reply to appeal, sections 14.4.1 and 14.4.3) that this amended range addressed a new document submitted by the appellant with their SGA and the appellant's argument that the claims of the main request failed to solve the objective technical problem over the entire scope claimed.
27. The issue of considering a new document submitted by the appellant with their SGA does not pose because there is no need for the board in using such a document for arriving at a decision. As regards the other issue, i.e. whether the amended range of "*20 hours to 24 hours*" could have been introduced earlier into claim 1, the following is relevant.
28. The appellant (then opponent 03) submitted already with their notice of opposition (page 23, first to third paragraph) that the range of "*16 hours to 32 hours*" in claim 1 as granted did not solve the technical problem across the whole scope claimed. The opposition division in their preliminary opinion annexed to the summons (section 11.3) shared that view. Accordingly, this amendment in claim 1 of *inter alia* auxiliary request 9 should have been submitted during the opposition proceedings.
29. Claims 1 of auxiliary requests 10, 11 and 16 to 18 all likewise contain the amended range of "*20 hours to 24 hours*" mentioned in claim 1 of auxiliary request 9.

Thus also these sets of claims should have been submitted already during the opposition proceedings.

30. Since the respondent should have submitted auxiliary requests 9 to 11 and 16 to 18 during the opposition proceedings, these sets of claims are not admitted in the appeal (Article 12(6) RPBA).

#### *Remittal*

31. Since all sets of claims on file are either non allowable or were not admitted into the appeal proceedings, there is no case to be remitted to the opposition division for further prosecution (Article 111(1) EPC).

#### **Order**

#### **For these reasons it is decided that:**

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chair:



C. Rodríguez Rodríguez

T. Sommerfeld

Decision electronically authenticated