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Datasheet for the decision of 23 September 2025

Case Number: T 0911/23 - 3.3.08

Application Number: 18215469.0

Publication Number: 3483276

IPC: C12N15/86, C12N15/87

Language of the proceedings: EN

Title of invention:
Improved methods of genetically modifying animal cells

Patent Proprietor:
Wilson Wolf Manufacturing Corporation

Opponents:
GRUND IPG Patentanwälte und Solicitor PartG mbB
European Oppositions Limited

Headword:
Methods of genetically modifying animal cells/WILSON WOLF

Relevant legal provisions:
EPC Art. 76(1)

Keyword:
Divisional application - subject-matter extends beyond content of earlier application (yes)

Decisions cited:
G 0001/05, G 0002/10

Europäisches Patentamt
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Beschwerdekammern

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Case Number: T 0911/23 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 23 September 2025

Appellant: (Opponent 2)	European Oppositions Limited Lacon London 84 Theobalds Road London WC1X 8NL (GB)
Representative:	Maiwald GmbH Elisenhof Elisenstraße 3 80335 München (DE)
Respondent: (Patent Proprietor)	Wilson Wolf Manufacturing Corporation 33-5th Avenue NW Suite 700 New Brighton, MN 55112 (US)
Representative:	Barker Brettell LLP 100 Hagley Road Edgbaston Birmingham B16 8QQ (GB)
Party as of right: (Opponent 1)	GRUND IPG Patentanwälte und Solicitor PartG mbB Steinsdorfstrasse 2 80538 München (DE)
Representative:	Grund, Martin Grund Intellectual Property Group Patentanwälte und Solicitor PartG mbB Steinsdorfstraße 2 80538 München (DE)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 16 March 2023 concerning maintenance of the European Patent No. 3483276 in amended form**

Composition of the Board:

Chairwoman	T. Sommerfeld
Members:	R. Morawetz
	L. Bühler

Summary of Facts and Submissions

I. The appeal lodged by opponent 2 (appellant) is against the opposition division's interlocutory decision according to which European patent No. 3 483 276 ("the patent") as amended in the form of the main request submitted on 30 May 2022 and the invention to which it relates met the requirements of the EPC.

II. The patent was granted on the basis of European patent application No. 18 215 469.0 which was filed as a divisional application in respect of earlier European patent application No. 14 845 082.8, which was itself filed as an international application under the PCT and published as WO 2015/042595 ("the earlier application", document D20 in the proceedings).

III. The patent 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.

IV. In the decision under appeal, the opposition division considered one claim request, the main request. It held, *inter alia*, that the main request met the requirements of Article 76(1) EPC.

V. In their statement of grounds of appeal, the appellant maintained, *inter alia*, objections under Article 76(1) EPC against independent claims 1 and 7 of the main request considered in the decision under appeal.

VI. In reply to the appeal, the patent proprietor (respondent) submitted sets of claims of a main request

and auxiliary requests 1 to 14. The main request was identical to the main request before the opposition division, auxiliary requests 1 to 9 were identical to auxiliary requests 6 to 14 filed during the opposition proceedings on 1 February 2023, and auxiliary requests 10 to 14 were new.

VII. In a further submission, the appellant questioned the admissibility of auxiliary requests 10 to 14 and raised objections under, *inter alia*, Article 76(1) EPC against claim 1 of auxiliary requests 13 and 14.

VIII. In response, the respondent submitted comments on, *inter alia*, the admissibility of auxiliary requests 10 to 14.

IX. The board scheduled oral proceedings in accordance with the parties' requests and, in a communication pursuant to Article 15(1) RPBA, set out its preliminary opinion that claim 1 of the main request contravened Article 76(1) EPC and that auxiliary requests 1 to 12 also contravened Article 76(1) EPC for the same reasons as the main request.

X. Oral proceedings took place as scheduled, in the absence of opponent 1.

XI. The parties' submissions and arguments, in so far as they are relevant to the present decision, are discussed in the Reasons for the Decision set out below.

XII. The parties' requests, in so far as they are relevant to the present decision, are as follows.

The appellant requests:

- that the decision under appeal be set aside and that the patent be revoked in its entirety

- that auxiliary requests 10 to 14 not be admitted into the appeal proceedings

The respondent requests:

- that the decision under appeal be upheld (i.e. that the appeal be dismissed) or, alternatively, that the patent be maintained in amended form on the basis of one of auxiliary requests 1 to 14 filed as with the reply to the statement of grounds of appeal

- that auxiliary requests 1 to 14 be admitted into the appeal proceedings

Reasons for the Decision

Main request - claim 1
Added subject-matter (Article 100(c) in conjunction with Article 76(1) EPC)

1. Reference is made in the following to the pages and line numbering of document D20, referred to herein as the "earlier application as filed" (section II. above).

2. The standard for assessing compliance with the requirements of Articles 123(2) and 76(1) EPC is the same (G 1/05, OJ EPO 2008, 271, Reasons 5.1), namely the standard set out in decision G 2/10 (OJ EPO 2012, 376, Reasons 4.3), also referred to 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 earlier application as filed. After the amendment, the skilled person may not be presented with new technical information (ibid., Reasons 4.5.1).

3. It is also 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 separate sections 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, for the person skilled in the art, emerge clearly and unambiguously from the content of the application as filed (Case Law of the Boards of Appeal of the European Patent Office, 11th edition 2025 ("Case Law"), II.E.1.6.1 a) and I.E.1.6.2 a)).

4. Claim 1 reads as follows (with amendments as compared to claim 1 of the earlier application as filed indicated by underlining and strikethrough).

"A method of transducing and then culturing ~~animal~~ T cells comprising:
adding a media, ~~animal~~ T cells, and genetic modification agents comprised of lentivirus into a device ~~that includes~~ with rigid walls and a bottom comprised of gas permeable, liquid impermeable material, said ~~animal~~ T cells are at a concentration of ~~3~~ greater than 2 million and up to ~~20~~ 30 million cells per millilitre of media, ~~said animal cells in contact with said gas permeable, liquid impermeable material~~, said gas permeable, liquid impermeable material being

~~in a horizontal position~~ in contact with ambient gas, and
allowing a period of time whereby said genetic modification agents act to transduce at least a portion of said cells~~.~~, and
adding a volume of media into the device and allowing a period of time for the T cells to be cultured when gas permeable material is in a horizontal position and ambient gas suitable for cell culture is in contact with the gas permeable, liquid impermeable material."

5. It is common ground that claim 1 of the main request is based on claim 1 of the earlier application as filed, to which, *inter alia*, the features "*and then culturing*" and "*and adding a volume of media ... liquid impermeable material*" were added prior to grant.

6. The question to be considered concerning claim 1 of the main request is whether the addition of the culturing step results in subject-matter which extends beyond the content of the earlier application as filed within the meaning of Article 76(1) EPC.

7. Claim 1 of the earlier application as filed relates exclusively to the transduction of animal cells. In the appealed decision, the opposition division found that page 6, lines 5 to 10, of the earlier application as filed provided a basis for adding a cultivation step after cell transduction in the method according to claim 1.

8. On page 4, line 2, to page 6, line 10, the earlier application as filed discloses various alternative embodiments intended to improve the process of transducing animal cells. The first to fourth of these embodiments do not include a culturing step after the

transduction step. The fourth embodiment corresponds to the method according to claim 1 of the earlier application as filed.

9. In the context of the fifth embodiment, disclosed on page 5, line 15, to page 6, line 10, the earlier application as filed discloses that in addition to the transduction step "[a] *subsequent step can be performed to expand the population size of the transduced cells by adding a volume of media into the device and allowing a period of time for cells to be cultured with the media when the device is oriented in a position such that at least a portion of the cells reside upon the cell growth surface and the cell growth surface is oriented in a horizontal position and ambient gas suitable for cell culture is in contact with the gas permeable liquid impermeable material*" (earlier application as filed, page 6, lines 5 to 10).

10. This embodiment of the earlier application as filed, which corresponds to the method of independent claim 9 of the earlier application as filed, also includes a step of removing media from the device prior to transduction in order to increase the cell concentration from a first cell concentration to a second cell concentration, which is greater than the first cell concentration (earlier application as filed, page 5, line 21, to page 6, line 1), while the cell concentration as such is not defined.

11. The board shares the appellant's view that the disclosure of a culturing step on page 6, lines 5 to 10, of the earlier application does not relate to an embodiment of the method according to claim 1 of the earlier application as filed, but to a separate

embodiment altogether.

12. Neither on page 6 nor elsewhere in the earlier application as filed is it stated that the culturing step disclosed on page 6, lines 5 to 10, of the earlier application is generally applicable to all embodiments of transducing animal cells disclosed in the earlier application as filed.

13. In line with the established case law of the boards of appeal (point 3. above), it is therefore required that the earlier application as filed provides a pointer to the claimed combination of features for it to meet the requirements of Article 76(1) EPC.

14. The respondent did not dispute that the statement on page 6, lines 5 to 10, of the earlier application as filed is made in the context of a different embodiment but they asserted that the skilled person would understand that an expansion step is an option available to all embodiments recited in the description.

15. Yet this is not persuasive, because when assessing compliance with the requirements of Article 76(1) EPC, there is no room for speculation as to which features of the disclosed invention the skilled person might upon reflection understand as being combinable because this concerns matters related to obviousness. It is also well established in the case law of the boards of appeal that the results of the skilled person's thoughts and reflections do not constitute matter that is a clear and unambiguous consequence of what is explicitly mentioned (Case Law, II.E.1.3.4 b)). An assessment under Article 76(1) EPC must be based on the features that are directly and unambiguously disclosed

in combination in the earlier application as filed, and not on the features that might be conceivably combinable.

16. The respondent's related argument that "[t]*he skilled person would clearly understand that a previous media-removal step would be entirely unnecessary in the method of claim 1, because it is already starting at position of a high cell density*" (reply, page 50, penultimate paragraph) misses the point.

17. The question to be addressed in the case at hand is not whether the skilled person would recognise that they could dispense with features disclosed in the context of one embodiment (in this case the embodiment disclosed on page 5, line 15, to page 6, line 10, of the earlier application as filed) when combining this embodiment with features from a second, unrelated embodiment (in this case the method of claim 1 of the earlier application as filed). That question would only arise if the earlier application as filed provided any indication at all as to the combination of features from the two embodiments in the first place.

18. The respondent's additional argument that page 13, lines 4 to 8, of the earlier application as filed explicitly discloses that a step for removing the media can be omitted is therefore also irrelevant. In addition, the board notes that page 13, lines 4 to 8, of the earlier application as filed refers to cultivation prior to transduction, not to cultivation after transduction and is therefore irrelevant to the question at issue.

19. The respondent also submitted that the skilled person would clearly contemplate the subsequent expansion of

transduced cells as a next natural step in the method of claim 1 in view of the benefits of an expansion step following transduction as discussed on page 21, lines 17 to 21, of the earlier application as filed.

20. On page 21, lines 17 to 21, the earlier application discloses that "[s]*killed artisans should also recognize that the benefits obtained by expanding cells from any number of unconventionally low cell surface densities to any number of unconventionally high cell surface densities, as described in described in* [sic] *Vera '700* [U.S. patent application 13/475,700]*. For example, Vera '700 described numerous examples including CAR T expansion in EXAMPLE 14, which can be beneficial in the present invention when transducing and expanding a population of CAR T cells.*"

21. However, claim 1 of the earlier application as filed does not relate to unconventionally low cell surface densities or to their expansion to any number of unconventionally high cell surface densities. Nor does it relate to Chimeric Antigen Receptor (CAR) T cells. The board is therefore not persuaded that the skilled person would derive directly and unambiguously from page 21, lines 17 to 21, of the earlier application as filed that the transduction method of claim 1 of the earlier application as filed is to be combined with the culturing step disclosed on page 6, lines 5 to 10, of the earlier application as filed.

22. The respondent's further argument that page 10, lines 14 to 18, of the earlier application as filed taught the subsequent expansion/culture of cells that have been transduced at a high concentration, as per the method of claim 1, is not convincing either.

23. The relevant passage discloses that "[i]*n the gas permeable device, after a period of time wherein the cells are in their increased concentration in the media and are in the presence of genetic modification agents, the cell population can be moved from a state of transduction to a state of cell culture. Thus, media can be restored to a greater height or the cells can be washed of the genetic modification agents and re-suspended in one or more gas permeable devices for population expansion*" (earlier application as filed, page 10, lines 14 to 18).

24. In the board's view, the statement that "*media can be restored to a greater height*" implies that media had previously been removed. Since the method according to claim 1 of the earlier application as filed does not include such a media removal step - unlike the method of independent claim 9 of the earlier application as filed, for example -, the disclosure on page 10, lines 14 to 18, of the earlier application as filed does not relate to the method of transduction of claim 1 of the earlier application as filed, but to a different method. It does not provide any indication of the claimed combination of features, either.

25. The respondent's related argument that a feature of reducing the media height was not essential in the method of claim 1 is not convincing either, for analogous reasons to those set out in point 17. above. In addition, the board notes that the respondent's reliance on the alleged non-essentiality of features is misplaced, since the so-called essentiality test cannot replace the standard set out in G 2/10 (Case Law, II.E. 1.4.4 c) and e)).

26. The appellant is therefore right that all of the passages in the earlier application as filed on which the respondent relied as a basis for adding the cultivation step to the method according to claim 1 refer to embodiments that are not embodiments of the method according to claim 1 of the earlier application as filed. They are also right that nothing in the earlier application as filed indicates to a person skilled in the art that the inclusion of a cultivation step after cell transduction in the method according to claim 1 was envisaged in the earlier application as filed.

27. For the reasons set out above, the board concludes that the skilled person would not directly and unambiguously derive from the whole of the earlier application as filed the combination of the method of claim 1 of the earlier application as filed and the culturing step disclosed on page 6, lines 5 to 10, of the earlier application as filed.

28. The decision under appeal is thus not correct on this point and the subject-matter of claim 1 of the main request contravenes Article 76(1) EPC.

Auxiliary requests 1 to 12 - claim 1
Article 76(1) EPC

29. Claim 1 of each of auxiliary requests 1 to 12 is based on claim 1 of the earlier application as filed to which, *inter alia*, the following features were added: "*and then culturing*"; "*and adding a volume of media into the device and allowing a period of time for the T cells to be cultured when gas permeable material is in a horizontal position and ambient gas suitable for cell culture is in contact with the gas permeable, liquid*

impermeable material".

30. The reasons set out above for holding that claim 1 of the main request contravenes Article 76(1) EPC also apply to claim 1 of each of auxiliary requests 1 to 12. This was not disputed by the respondent.

31. Thus, auxiliary requests 1 to 12 contravene Article 76(1) EPC.

Auxiliary request 13 - claim 1
Article 76(1) EPC

32. Claim 1 of auxiliary request 13 reads as follows (with amendments as compared to claim 9 of the earlier application as filed indicated by underlining and strikethrough).

"A method of culturing and transducing ~~animal~~ T cells comprising:
a) adding media and a quantity of ~~animal~~ T cells into a gas permeable device ~~including~~ with rigid walls and includes a horizontal cell growth surface comprised of gas permeable, liquid impermeable material, and allowing ~~animal~~ T cells to gravitate to the gas permeable, liquid impermeable material, whereby the ~~animal~~ T cells are at a first cell concentration, media is a first media height, and media is at a first media volume, said first cell concentration being the quantity of ~~animal~~ T cells divided by said first media volume, said first media height being defined by the distance from the uppermost location of said media to the lowest location of said media when said cell growth surface is in a horizontal position,
b) culturing the T cells when the device is oriented in a position such that at least a portion of the T cells

reside upon the cell growth surface and the cell growth surface is oriented in a horizontal position and ambient gas suitable for cell culture is in contact with the gas permeable, liquid impermeable material,
~~b)~~ c) removing a portion of said first media volume from said device leaving a second media volume in said device wherein ~~animal~~ T cells are at a second cell concentration, said second cell concentration is greater than 3 million and up to 20 million cells per millilitre of media and is greater than said first cell concentration, media is at a second media height which is defined by the distance from the uppermost location of said media to the lowermost location of said media when said cell growth surface is in a horizontal position,
~~c)~~ d) adding ~~genetic modification agents~~ lentivirus into said device,
~~d)~~ e) allowing a period of time for said genetic modification agents to transduce at least a portion of said ~~animal~~ T cells,
~~e)~~ f) adding ~~a volume of~~ more media ~~into said device~~ to raise the height of the media to a new level, and
~~f)~~ g) ~~allowing a period of culture time for animal cells to be expanded in quantity when said device is oriented in a position such that at least a portion of said animal cells reside upon said cell growth surface and said cell growth surface is oriented in a horizontal position and ambient gas suitable for cell culture is in contact with said gas permeable liquid impermeable material.~~ culturing the T cells to expand the quantity of the transduced T cells."

33. The respondent submitted that claim 1 of auxiliary request 13 was based on claim 9 of the earlier application as filed and that a basis for the addition of new step b), the definition of the cell

concentration in step c) and the replacement of steps e) and f) by new steps f) and g) was provided in the earlier application as filed.

Step b)

34. With respect to step b) of claim 1 of auxiliary request 13, the respondent argued that page 13, lines 4 to 8, of the earlier application as filed disclosed, as one option, a first step of culturing cells. Moreover, page 17, lines 5 to 20, of the earlier application as filed taught that the method of transducing cells could be embodied by any of steps a) to g) including, as one option, a prior culturing step c). In addition, page 8, lines 12 to 14, of the earlier application as filed taught a culturing step prior to media height reduction.

35. The respondent did not argue, however, that the earlier application as filed provided any incentive to include a culturing step in the method of claim 9 of the earlier application as filed.

Second cell concentration is greater than 3 million and up to 20 million cells per millilitre of media

36. With respect to the cell concentration being "*greater than 3 million and up to 20 million cells per millilitre of media*", the respondent's main argument was, that the person skilled in the art would recognise that the method according to claim 1 of the earlier application as filed represented a reduced version of the method according to claim 9 of the earlier application as filed. Therefore, the concentration disclosed in connection with the method in claim 1 of the earlier application as filed could be combined with

the method according to claim 9 of the earlier application as filed.

37. The appellant, however, is right that the method of claim 1 of the earlier application as filed is not a reduced version of the method of claim 9 of the earlier application as filed but a different method altogether. Thus, while claim 1 discloses a method of transducing wherein the animal cells are at a defined concentration of 3 million to 20 million cells per millilitre of media, claim 9 discloses a method of transducing animal cells in which the cells gravitate in the device and in which, prior to transduction, part of the media volume is removed to increase the cell concentration from an undefined first concentration to a greater, likewise undefined second cell concentration.

38. There is thus no reason why the skilled person would derive directly and unambiguously from the earlier application as filed that the cell concentration disclosed in the context of the method of claim 1 of the earlier application as filed is applicable to the second concentration in step b) of the method in claim 9 of the earlier application as filed.

39. As an alternative argument, the respondent submitted that the cell concentration of "*greater than 3 million and up to 20 million cells per millilitre of media*" was a selection from a single list on page 13, lines 8, to 17, in particular on page 13, lines 9 and 10, of the earlier application as filed.

40. The passage on page 13, lines 8 to 17, of the earlier application as filed does not relate to the method of claim 9 of the earlier application as filed and it does not mention second cell concentrations. The respondent

has not explained why the earlier application as filed provided any incentive to include that particular cell concentration in step b) of the method of claim 9 of the earlier application as filed.

41. A consideration of the earlier application as filed as a whole, as is required in order to assess compliance with the requirements of Article 76(1) EPC, reveals, moreover, that dependent claims 10 and 11 of the earlier application as filed disclose different second cell concentrations for the method of claim 9, i.e. from 4 or 5 million to 20 million animal cells per millilitre of media.

42. Also, on page 11, line 12, to page 12, line 5, the earlier application as filed explains that the duration at which cells in the gas permeable device can be sustained at an elevated concentration is dependent on cell metabolism. None of the possible cell concentrations disclosed for T cells - to which claim 1 of auxiliary request 13 is restricted - corresponds to a cell concentration of "*greater than 3 million and up to 20 million cells per millilitre of media*".

43. These issues (in points 41. and 42. above) were pointed out by the board during the oral proceedings and were not disputed by the respondent.

Steps f) and g)

44. Lastly, the respondent submitted that page 17, lines 19 and 20, of the earlier application as filed provided the basis for steps f) and g).

45. The appellant is right that page 17, lines 5 to 6, of the earlier application as filed discloses that the

processes of increasing transduction efficiency can be embodied in any of the steps a) to g) as set out on page 17 of the earlier application as filed. The appellant is also right that these steps are not identical to the steps of the method of claim 9 of the earlier application as filed.

46. The respondent did not explain why steps f) and g) on page 17 of the earlier application as filed could be extracted and combined with the method of claim 9 of the earlier application, from which steps e) and f) had been deleted.

47. In view of points 34. to 46. above, the appellant is also right that the subject-matter of claim 1 of auxiliary request 13 results from multiple selections of features disclosed in separate passages of the earlier application as filed. None of these passages demonstrates that the claimed combination of features is envisaged in the earlier application as filed.

48. Indeed, the respondent has not indicated a single passage, example or embodiment of the earlier application as filed that discloses - in combination - the features of claim 1 of auxiliary request 13 or that would provide any incentive or pointer to combine exactly these features.

49. The board therefore agrees with the appellant that the respondent has treated the earlier application as filed as a reservoir from which features were cherry-picked and that due to the absence of a pointer to the claimed combination of features in the earlier application as filed, claim 1 of auxiliary request 13 also contravenes Article 76(1) EPC.

Auxiliary request 14 - claim 1
Article 76(1) EPC

50. Claim 1 of auxiliary request 14 is also based on claim 9 of the earlier application as filed and it differs from claim 1 of auxiliary request 13 merely in that step a) has been amended to read "*a gas permeable device that has walls, wherein the walls are rigid*" instead of "*a gas permeable device with rigid walls*". Claim 1 of auxiliary requests 14 therefore also contravenes Article 76(1) EPC for the same reasons as those set out above with respect to claim 1 of auxiliary request 13. This was not disputed by the respondent.

Auxiliary requests 10 to 14
Admittance and consideration

51. The appellant requested that auxiliary requests 10 to 14 not be admitted into the proceedings. However, the board has decided to admit them into the proceedings pursuant to Article 12(4) RPBA. In view of the conclusions reached under Article 76(1) EPC (see above), there is no need to provide reasons for this part of the decision.

Conclusion

52. None of the requests on file is allowable. The decision under appeal must therefore 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:

C. Rodríguez Rodríguez T. Sommerfeld

Decision electronically authenticated