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**Datasheet for the decision
of 29 August 2023**

Case Number: T 0505/20 - 3.3.08

Application Number: 09731866.1

Publication Number: 2279254

IPC: C12N15/113, C12N15/88,
A61K31/712, A61K31/713,
A61K9/127, A61P35/00

Language of the proceedings: EN

Title of invention:

Novel lipid formulations for nucleic acid delivery

Patent Proprietor:

Arbutus Biopharma Corporation

Opponents:

Merck Sharp & Dohme Corporation
Moderna Therapeutics, Inc.

Headword:

Lipid formulations for nucleic acid delivery/ARBUTUS BIOPHARMA
CORPORATION

Relevant legal provisions:

EPC Art. 113(1)
EPC R. 111(2)
RPBA 2020 Art. 11

Keyword:

Appealed decision - reasoned (no)

Right to be heard - substantial procedural violation (yes)

Remittal - fundamental deficiency in first-instance proceedings (yes)

Decisions cited:

T 2475/17



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Case Number: T 0505/20 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 29 August 2023

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
20 December 2019 concerning maintenance of the
European Patent No. 2279254 in amended form**

Composition of the Board:

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

Summary of Facts and Submissions

- I. European patent No. 2 279 254 ("the patent") is based on European patent application No. 09 731 866.1. The patent is entitled "*Novel lipid formulations for nucleic acid delivery*".
- II. Two oppositions to the granted patent were filed. The patent was opposed under Article 100(a) EPC on the grounds of lack of novelty (Article 54 EPC), exceptions to patentability (Article 53(c) EPC) and lack of inventive step (Article 56 EPC), and under Article 100(b) and (c) EPC.
- III. By an interlocutory decision, the opposition division decided that the patent in amended form on the basis of the set of claims of auxiliary request 1 submitted at the oral proceedings, and the invention to which it relates met the requirements of the EPC. The opposition division also held that the subject-matter of claims 1, 8 and 10 of the main request (patent as granted) extended beyond the content of the application as filed (Article 100(c) EPC).
- IV. The patent proprietor, opponent 1 and opponent 2 filed notice of appeal against the opposition division's decision.
- V. By letter dated 28 April 2020, the patent proprietor withdrew its appeal and thus assumed the procedural status of respondent to the opponents' appeals. It also requested the reimbursement of its appeal fee (Rule 103(1)(b) EPC).

- VI. With its statement setting out the grounds of appeal, opponent 1 (appellant I) submitted, *inter alia*, that the opposition division's decision suffered from a substantial procedural violation as it was not based on the correct wording of claim 1 of auxiliary request 1. Appellant I requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution and that the appeal fee be reimbursed (Rule 103(1)(a) EPC), or alternatively, the patent be revoked. Oral proceedings were requested as an auxiliary measure only.
- VII. With its statement setting out the grounds of appeal, opponent 2 (appellant II) submitted, *inter alia*, that suitability "for systemic delivery" was not a requirement of claim 1 of auxiliary request 1 submitted at the oral proceedings before the opposition division. Appellant II requested that the decision under appeal be set aside and the patent be revoked; that the main request be held inadmissible and that oral proceedings be held if the board did not revoke the patent in written proceedings.
- VIII. In reply to the opponents' appeals, the respondent submitted a set of claims of a new main request (identical to auxiliary request 1 submitted during oral proceedings before the opposition division and held allowable in the decision under appeal) and auxiliary requests 1, 1a, 2 and 3 and arguments, *inter alia*, to the effect that the opposition division's decision did not suffer from a substantial procedural violation. The respondent requested that the patent be maintained in amended form on the basis of the main request (implying that the appeals be dismissed), or alternatively on the basis of the auxiliary requests 1, 1a, 2 or 3, and that oral proceedings be held if the patent cannot be

maintained on the basis of the main request on the written submissions alone. Additionally, should the board decide that the decision under appeal suffered from a substantial procedural violation, that the case be remitted to the opposition division for further prosecution.

- IX. With letter dated 22 March 2022, appellant II submitted arguments, *inter alia*, to the effect that it concurred with appellant I 's analysis that the opposition division's failure to base its decision on the correct wording of the claims materially affected the opposition division's decision.

- X. With letters dated 10 June 2022, 3 August 2022 and 18 April 2023, respectively, the respondent withdrew auxiliary requests 2 and 3; auxiliary request 1; and auxiliary request 1a.

- XI. The board scheduled oral proceedings and issued a communication under Article 15(1) RPBA in which it indicated, *inter alia*, that it was of the preliminary opinion that the decision under appeal suffered from defects which it considered to constitute substantial procedural violations, that it intended to set the decision under appeal aside and to remit the case to the opposition division for further prosecution. Appellant II and the respondent were invited to inform the board if they maintained their respective requests for oral proceedings.

- XII. In response, the respondent withdrew with letter dated 26 June 2023 its request for oral proceedings in the appeal proceedings "*specifically in the scenario that both (a) neither Opponent amends its appeal by altering its requests with respect to the allegation of a*

substantial procedural violation and (b) the Board of Appeal remains of the view that the decision of the Opposition Division should be set aside and the case should be remitted to the Opposition Division for further prosecution".

- XIII. With letter dated 12 July 2023, appellant II submitted that it *"agrees that no oral proceedings are necessary prior to a decision by the Board that remits the case to the Opposition Division due to a finding of a substantial procedural violation, as envisaged in the preliminary opinion. Prior to that specific decision, we thus do not request oral proceedings."* Appellant II also requested the reimbursement of the appeal fee (Rule 103(1) (a) EPC).
- XIV. By communication dated 26 July 2023, oral proceedings were cancelled.
- XV. The appellants' arguments relevant to the decision are summarised below.

The opposition division did not consider the actual wording of claim 1 according to auxiliary request 1 as filed during oral proceedings but, by mistake, based its decision on a differently worded claim 1.

The opposition division's error of reading "systemically" into the amended claim language in claim 1 appeared to have materially affected the impugned decision with respect to Rule 80 EPC and the assessment of inventive step and consequently the decision to maintain the patent in amended form.

Contrary to the respondent's submissions it was not correct that nothing turned on the error of the

opposition division. In the relevant passage of the decision the opposition division had recognised that a particular, "efficient" level of systemic delivery was not a requirement of the claim.

The feature "systemic" was neither an explicit nor an implied limitation of claim 1. It had been inappropriate, and indeed misleading for the remainder of the problem-solution approach, for the opposition division to include the feature "systemically" in the formulation of the objective technical problem, considering that the scope of claim 1 was not limited to particles that were suitable particularly for "systemic" administration.

The reasons for the appealed decision did not relate to the claims which were actually at stake and which were maintained by the opposition division. As a consequence, the decision was not reasoned, contrary to the requirements of Rule 111(2) EPC. This constituted a substantial procedural violation, which justified the reversal of the impugned decision and the remittal of the present case to the opposition division for reconsideration as well as the reimbursement of the appeal fee in accordance with Rule 103(1) (a) EPC.

XVI. The respondent's arguments relevant to the decision are summarised below.

The decision under appeal did not turn on whether or not the word "systemically" was explicitly written in claim 1 because the opposition division viewed systemic delivery as an implicit feature of the claim (decision under appeal, Reasons 4.10.4). The decision under appeal therefore did not suffer from a substantial

procedural violation.

XVII. The final requests of the parties, in so far as relevant for the present decision, are set out below.

Appellant I requested that the decision under appeal be set aside and the case be remitted to the opposition division for further prosecution and the appeal fee be reimbursed (Rule 103(1)(a) EPC).

Appellant II requested the reimbursement of its appeal fee (Rule 103(1)(a) EPC).

The respondent requested that the case be remitted to the opposition division for further prosecution, should the board decide that the decision under appeal suffered from a substantial procedural violation and the reimbursement of its appeal fee (Rule 103(1)(b) EPC).

Reasons for the Decision

1. The decision to set aside the decision under appeal and to remit the case to the opposition division for further prosecution (see Order, below) could be taken without holding oral proceedings (see sections VI., XII. and XIII. above).

Substantial procedural violation

2. Claim 1 of auxiliary request 1 submitted at the oral proceedings before the opposition division reads as follows:

"1. A nucleic acid-lipid particle comprising:
(a) a nucleic acid;

(b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle;
(c) a non-cationic lipid comprising up to 49.5 mol % of the total lipid present in the particle and comprising a mixture of: (i) a phospholipid of from 4 mol % to 10 mol % of the total lipid present in the particle; and (ii) cholesterol or a derivative thereof of from 30 mol % to 40 mol % of the total lipid present in the particle; and
(d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle,
for use in a method for the in vivo delivery of a nucleic acid, the method comprising administering said nucleic acid-lipid particle to a mammalian subject."

3. The opposition division based its decision on a differently worded claim 1 which contains the term "systemically" as part of the "for use" clause as follows: "*for use in a method for the in vivo delivery of a nucleic acid, the method comprising systemically administering said nucleic acid-lipid particle to a mammalian subject.*" (underlining added by the board).
4. This is apparent from the quotation of claim 1 of auxiliary request 1 in the decision under appeal (see Reasons, 4.2 and 4.5.1) and further confirmed by the fact that the opposition division, when deciding on the admission of auxiliary request 1 into the proceedings held that claim 1 was "identical" to claim 1 of a previous auxiliary request 1 filed on 3 September 2018 (see decision under appeal, Reasons 3.2.3). Amended claim 1 of that previous auxiliary request 1 filed on 3 September 2018 contained indeed the term "*systemically*" as part of the "for use" clause.

5. The impugned decision is therefore not based on the text submitted by the patent proprietor, contrary to the requirements of Article 113(2) EPC.
6. On the merits, the opposition division considered that the amendment in the "for use" clause of claim 1 of auxiliary request 1 submitted at the oral proceedings was occasioned by a ground of opposition (Rule 80 EPC) and had been introduced "*in relation to inventive step*" (see decision under appeal, Reasons 4.3).
7. How the opposition division understood the amendment to be "*in relation to inventive step*", becomes clear from the assessment of inventive step in the decision under appeal. The opposition division included the feature "systemic" in the formulation of the objective technical problem to be solved which it formulated as "*the provision of alternative particles suitable for systemic delivery of nucleic acids in cells in vivo.*" (underlining added by the board, see decision under appeal, Reasons 4.10.4). With respect to the question of obviousness vis-à-vis document D1, taken to represent the closest prior art, the opposition division held that "*There is no guidance in D1 as to which compositions falling within said ranges [of lipid components in the nucleic acid-lipid particles of document D1] would be suitable for systemic delivery of nucleic acids in cells in vivo.*" (underlining added by the board, see Reasons, 4.10.5) and concluded that the subject-matter of claim 1 and its dependent claims and hence auxiliary request 1 met the requirements of Article 56 EPC.
8. In light of the opposition division's reasoning in the decision under appeal (see points 6. and 7. above) it appears that the opposition division's erroneous

consideration of a wrong wording of claim 1 was decisive for the opposition division's findings with respect to at least allowability of auxiliary request 1 under Rule 80 EPC and Article 56 EPC and consequently the decision to maintain the patent in amended form.

9. In this respect, the board is not persuaded by the patent proprietor's line of argument that the impugned decision did not turn on whether or not the word "systemically" was explicitly written in claim 1 of auxiliary request 1 because the opposition division viewed systemic delivery as an implicit feature of the claim.

10. At the beginning of the passage relied on by the patent proprietor's in this context (see decision under appeal, Reasons 4.10.4) the opposition division noted that *"The proprietor identified the objective technical problem as the provision of nucleic acid-lipid particle formulations for the efficient systemic delivery of nucleic acids in cells in vivo. However, in view of the interpretation of the feature "for use ..." (see above), efficient systemic delivery of nucleic acids in cells in vivo is not an explicit feature of claim 1"* (underlining added by the board). It then held that *"In view of the examples of the patent, this can be considered to be an implicit feature of the particles claim 1 [sic]. The examples of the patent show in vivo efficacy of siRNA-lipid particles containing lipid compounds which fall in the centre of the ranges of claim 1."* (underlining added by the board).

11. Against the backdrop that the opposition division (erroneously) considered claim 1 of auxiliary request 1 to explicitly contain the feature "systemically administering" (see point 3. above) and in view of the

opposition division's justification for acknowledging an implicit feature of the particles, namely "*in vivo efficacy*" the board is not persuaded that this passage of the decision under appeal indicates that the opposition division viewed "*systemic delivery*" to constitute an implicit feature of claim 1.

12. Instead, the board agrees with the appellants that in this passage the opposition division was rebutting the patent proprietor's argument that the claimed subject matter was characterized by a particularly "efficient" level of systemic delivery and recognised that a particular, "efficient" level of systemic delivery is not a requirement of the claim.
13. Based on the above observations and considering that claim 1 of auxiliary request 1 as actually maintained by the opposition division (see point 2. above) does not contain the term "*systemically*" in the "for use" clause and is not limited to particles that are suitable particularly for "systemic" administration, the board concludes that the reasons given by the opposition division for holding auxiliary request 1 filed at the oral proceedings allowable do not relate to claim 1 of auxiliary request 1 as actually maintained by the opposition division. As a consequence, at least the conclusions reached by the opposition division with respect to Rule 80 and Article 56 EPC are not duly supported by the reasons given for the decision, i.e. the decision is not reasoned, contrary to the requirements of Rule 111(2) EPC.
14. As a further consequence of the opposition division's failure to consider the valid claim 1 of auxiliary request 1 submitted at the oral proceedings, the

appellants right to be heard (Article 113(1) EPC) was violated because the opposition division decided that the patent could be maintained in amended form on the basis of this claim request for reasons that the appellants were not given the opportunity to comment on.

15. The defects set out in points 13. and 14. above are considered by the board to constitute substantial procedural violations (see also T 2475/17, Reasons 1.1 and 1.4).

Remittal of the case (Article 111(1) EPC and Article 11 RPBA)

16. Pursuant to Article 111(1), second sentence, EPC, the board may either exercise any power within the competence of the department responsible for the decision appealed or remit the case to that department for further prosecution.
17. Remitting a case to the department of first instance requires special reasons (Article 11 RPBA). As a rule, fundamental deficiencies in first instance proceedings constitute such special reasons. A substantial procedural violation is a fundamental deficiency within the meaning of Article 11 RPBA.
18. Furthermore, as set out in Article 12(2) RPBA, the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner. This principle would not be observed if the board were to give a first decision on the valid version of auxiliary request 1, i.e. the main request on appeal.

19. Thus, special reasons are present to remit the case to the opposition division for further prosecution.
20. In view of the substantial procedural violations noted above, the appeal fees of the opponents are to be reimbursed in full (Rule 103(1)(a) EPC).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the opposition division for further prosecution.
3. The appeal fees of appellants I and II are reimbursed under Rule 103(1)(a) EPC. The appeal fee of the respondent is reimbursed under Rule 103(1)(b) EPC.

The Registrar:

The Chairwoman:



L. Malécot-Grob

T. Sommerfeld

Decision electronically authenticated