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Datasheet for the decision of 25 July 2022

Case Number: T 0267/18 - 3.3.08

Application Number: 10008869.9

Publication Number: 2272946

IPC: C12N1/00

Language of the proceedings: EN

Title of invention:
Minicell compositions and methods

Patent Proprietor:
Vaxiion Therapeutics, LLC

Opponent:
EnGeneIC Pty Ltd.

Headword:
Minicell compositions/VAXIION THERAPEUTICS

Relevant legal provisions:
EPC R. 80
EPC Art. 84

Keyword:
Claim request with amended claims corrrectly admitted by the opposition division are part of the appeal proceedings
Main request - clarity (no)

Decisions cited:
T 0151/01, T 1273/04, T 2526/11

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0267/18 - 3.3.08

D E C I S I O N
of Technical Board of Appeal 3.3.08
of 25 July 2022

Appellant: (Opponent)	EnGeneIC Pty Ltd. Building 2 25 Sirius Road Lane Cove West, NSW 2066 (AU)
Representative:	Pohlman, Sandra M. df-mp Dörries Frank-Molnia & Pohlman Patentanwälte Rechtsanwälte PartG mbB Theatinerstrasse 16 80333 München (DE)
Respondent: (Patent Proprietor)	Vaxiion Therapeutics, LLC 11585 Sorrento Valley Road, Suite 105 San Diego, CA 92121 (US)
Representative:	Chapman, Desmond Mark Carpmaels & Ransford LLP One Southampton Row London WC1B 5HA (GB)
Decision under appeal:	**Interlocutory decision of the Opposition Division of the European Patent Office posted on 28 November 2017 concerning maintenance of the European Patent No. 2272946 in amended form.**

Composition of the Board:

Chairman	B. Stolz
Members:	D. Pilat
	A. Bacchin

Summary of Facts and Submissions

I. European patent No. 2 272 946, is based on European patent application No. 10008869.9, a divisional application of the European patent application No. 02747872.6 (EP 1 487 965) (hereinafter "the parent application") which was filed as international application PCT/US02/16877 and published as WO 03/072014. The patent was opposed on the grounds of Article 100(a) in conjunction with Articles 54 and 56 EPC, and of Articles 100(b) and (c) EPC. An opposition division considered the main request to lack novelty (Article 54(3) EPC) and decided to maintain the patent in amended form on the basis of auxiliary request 1 with a description adapted thereto.

II. Opponent (appellant) lodged an appeal against the decision of the opposition division. With its statement of grounds of appeal, it submitted new documents D43 to D46 and D48 to D50. It further submitted copies of HB-9, HB-10 and Figure 8 of document D19.

III. Respondent replied to appellant I's statement of grounds of appeal. It submitted new documents D51 and D52.

IV. The parties were summoned to oral proceedings.

V. In a communication dated 23 December 2021 sent in preparation of oral proceedings, the board provided observations on procedural issues and expressed a provisional opinion on some issues concerning Articles 84 and 76 EPC and Rule 80 EPC.

VI. Respondent withdrew its request for oral proceedings with a letter dated 14 January 2022.

VII. Appellant informed the board, with a letter dated 24 January 2022, that it would only maintain the request for oral proceedings if its request to set aside the Opposition Division's decision and to revoke the granted patent could not be granted.

VIII. None of the parties submitted substantive arguments in response to any of the issues raised in the board's communication.

IX. The oral proceedings were cancelled

X. Claim 1 of the main request read as follows:

"1. A fully intact eubacterial minicell derived from a eubacterial parent cell, wherein the minicell comprises biologically active compound *which is a therapeutic agent* and displays an antibody or antibody derivative *directed to a surface antigen of a cell for cell- or tissue-specific targeting of said eubacterial minicell*, wherein the biologically active compound and the antibody or antibody derivative are exogenous to the parent cell and distinct from each other."
(emphasis added by the board)

XI. Appellant's (opponent's) submissions, insofar as relevant to this decision, may be summarised as follows:

Main request
Exercise of discretion to admit a claim request with amended claims by the opposition division

Appellant considered that the amendments introduced in claim 1 of auxiliary Request 1, should not have been admitted into the opposition proceedings as it was not "clearly allowable" under Rule 80 EPC, Article 84 EPC and Articles 76(1) and 123(2) EPC in accordance with the EPO Guidelines for Examination, H-II 3.5 and E-VI 2.2; see also T 1273/04, reasons 3.2).

Rule 80 EPC

Even if the introduction of "which is a therapeutic agent" was intended to overcome a novelty objection in view of document D1, the introduction of the term "directed to a surface antigen of a cell for cell- or tissue-specific targeting of said minicell" served no purpose. This latter amendment was superfluous and not occasioned by a ground of opposition. It violated the provisions of Rule 80 EPC.

Article 84 EPC

The term "*which is a therapeutic agent*" introduced as amendment in claim 1 lacked clarity under Article 84 EPC.

There was no standard test for determining whether an agent is therapeutic or not. Hence, the skilled person had to test any agent for its efficacy in any possible disorder in any possible organism to determine whether said agent is therapeutic and falls under the scope of protection of claim 1.

XII. Respondent's (patent proprietor's) submissions, insofar as relevant to the present decision, may be summarized as follows:

Main request

Exercise of discretion to admit a claim request with amended claims by the opposition division

No arguments have been presented on this issue.

Article 84 EPC

The skilled person had not to determine the therapeutic efficacy of each and every agent in order to determine whether it fell within the scope of protection of claim 1 or not, as it was well-known that a competent regulatory authority had to grant its approval before a therapeutic product might be released on the market in Europe. The skilled person was able to determine with ease, from a publicly available list of approved therapeutic products, whether an agent met any therapeutic efficacy requirements or not.

XIII. Appellant (opponent) requested that the decision under appeal be set aside and the patent be revoked in toto on the grounds that it contravenes Articles 54, 56, 83, 84, 76(1) and 123(2) EPC and Rule 80 EPC. Appellant further requested that auxiliary request 1 (now the main request) not be admitted.

XIV. The respondent (proprietor) requested that the appeal be dismissed.

Reasons for the Decision

Right to be heard - Article 113(1) EPC

1. By its decision not to attend the oral proceedings and not to file substantive arguments in reply to the issues raised in the board's communication, the respondent has chosen not to make use of the opportunity to comment on the board's provisional opinion, either in writing or at the oral proceedings, although this opinion was partially to the appellant's disadvantage. According to Rule 115(2) EPC and Article 15(3) RPBA 2020, the board is not obliged to delay any step in the proceedings, including its decision, by reason only of the absence at the oral proceedings of any party duly summoned who may then be treated as relying on its written case.

2. In the light thereof, the present decision is based on the same grounds, arguments and evidence on which the provisional opinion of the board was based.

3. The main request is identical to the auxiliary request 1 underlying the decision under appeal.

Main request

4. Appellant raised objections under Articles 54, 56, 83, 84, 76(1) and 123(2) EPC and Rule 80 EPC. In view of the board's conclusion on Rule 80 and Article 84 EPC of the main and sole request (infra), there is no need to enter into a discussion of all the objections.

Exercise of discretion to admit a claim request with amended claims by the opposition division

5. Auxiliary Request 1 was filed and admitted during the oral proceedings in Opposition (see decision under appeal item 3.3.1). The amendments required no undue evaluation and complied with the requirements of Rule

80 EPC. Since the opposition division departed from its provisional opinion set out in the annex to the summons and finding on the novelty of the main request during the oral proceedings and concluded that the patent could not be maintained as granted, the filing of an auxiliary request, which intended to overcome the novelty objection, seemed justified as the subject of the proceedings had surprisingly changed for the patentee at a late stage of the proceedings.

6. Appellant considered that the amendments introduced in claim 1 contravened Rule 80 EPC, Article 84 EPC and Articles 76(1) and 123(2) EPC. Auxiliary Request 1, should not have been admitted into the proceedings as it was not "clearly allowable" in accordance with the EPO Guidelines for Examination.

7. The board cannot share appellant's view for the following reasons:

7.1 Decision T 1273/04 of 16 November 2007, mentioned by the appellant, is concerned with late amendments submitted in *ex parte* appeal proceedings and their admission under the RPBA, while the admission of auxiliary request 1 by the opposition division during the opposition proceedings need not to comply with the Rules of Procedure of the Boards of Appeal (RPBA). The findings on this issue in that decision are therefore not applicable to the present case.

7.2 In principle, a decision taken by a department of first instance in the exercise of its discretion may be overruled by a Board of Appeal only if it is concluded that the department exercised its discretion in accordance with the wrong principles, without taking the right principles into account or in an arbitrarily

or unreasonable way, thereby exceeding the proper limits of its discretion (see Case Law of the Boards of Appeal of the EPO, 9th edition, 2019, in the following "Case Law", V.A.3.5.1.b), and in particular decision G 7/93, OJ EPO 1994, 775, reasons 2.6).

7.2.1 In exercising its discretion, the division had first to consider the reasons for filing the request at such a late stage in the proceedings, the allowability of the late-filed amendments, on a *prima facie* basis, and whether the parties and the opposition division could reasonably be expected to familiarise themselves with the proposed amendments in the time available. Since the amendments introduced in claim 1 of the auxiliary request 1 were filed in reaction to a change of the opposition division's opinion regarding novelty, were intended to overcome a novelty objection, did not require any further extensive assessment for both the opposition division and the opponent, and were "prima facie" allowable, they were admitted.

7.3 Hence the board fails to see why the opposition division had exercised its discretion according to the wrong principles or in an unreasonable way.
For this reason, it will not overrule the way in which the first instance has exercised its discretion.
Furthermore, since the auxiliary request 1 was admitted by the opposition division in the proper exercise of its discretion and was decided upon by the opposition division, the board fails to see a legal basis for disregarding this request (see also Case Law, *supra*, V.A.3.5.4). It follows that since the aim of appeal proceedings is to review the decision under appeal in a judicial manner (Article 12(2) RPBA 2020), auxiliary request 1, the only request now on file, forms part of the appeal proceedings.

Rule 80 EPC

8. Even though the introduction of "which is a therapeutic agent" was intended to overcome a novelty objection in view of document D1 (see decision under appeal, item 2.2.2, last paragraph and reasoning on page 15, item 3.3.6), appellant contended that the introduction of the term "directed to a surface antigen of a cell for cell- or tissue-specific targeting of said minicell" served no purpose. This latter amendment was superfluous and not occasioned by a ground of opposition. It violated the provisions of Rule 80 EPC. Reference was made to decision T 2526/11 of 9 January 2013, reasons 3.1 to 3.4.

8.1 The board considers that the amendments in claim 1 consisting of

(a) a biologically active compound *which is a therapeutic agent* and

(b) displays an antibody or antibody derivative *directed to a surface antigen of a cell for cell- or tissue-specific targeting of said eubacterial minicell*, (amendments in italic and underlined)

are amendments which limit and define first the biologically active compound and second the antibody or antibody derivative displayed.

8.1.1 They represent a *bona fide* attempt to overcome the novelty objection raised under Article 54 EPC.

8.1.2 Amendment (b) introduced in claim 1 restricts the function of the displayed antibodies. It does not

amount to a mere reformulation of the characterizing part of claim 1. Thus, the conclusion of decision T 2526/11 not to allow a claim 1 which was also amended by completely reformulating the characterising part apparently to render the claim clearer and more concise, albeit without providing a reason for it, is as such not applicable.

9. The board considers that the amendments introduced in claim 1 satisfy the requirements of Rule 80 EPC.

Clarity (Article 84 EPC)

10. Appellant contended that the introduction into claim 1 of both terms "*which is a therapeutic agent*" and "*directed to a surface antigen of a cell for cell- or tissue-specific targeting of said eubacterial minicell*" led to a lack of clarity, since the claim no longer defined in an unambiguous manner the matter for which protection was sought (Article 84 EPC).

11. The respondent contended that the skilled person did not have to determine the therapeutic efficacy of each and every agent in order to determine whether it fell within the scope of protection of claim 1 or not, as it was well-known that a competent regulatory authority had to grant its approval before a therapeutic product might be released on the market in Europe. Thus, the skilled person was able to determine with ease, from a publicly available list of approved therapeutic products, whether any agent was a therapeutic agent or not.

12. The board considers that the term "therapeutic agent" defines an agent both by its intended use and effect. A "therapeutic agent" defines a chemical substance that

may be used for the treatment or mitigation of a disease condition or ailment.

12.1 Although a skilled person is able in most cases to decide whether a certain amount of a specifically defined product has a therapeutic effect or not (see decision T 151/01 of 9 February 2006, reasons 2.1), the "therapeutic agent" used in claim 1 defines far more than a specific class of compounds in a specific quantity having a therapeutic effect for a disease. It defines any known or yet unknown biologically active compound capable of treating or alleviating at least one disease state or condition. It is not limited to agents that are approved by a competent regulatory authority and/or are on a publicly available list of therapeutics. Hence, the respondent's argument that the skilled person would be able to determine from a list of approved therapeutic products whether any agent is a therapeutic agent or not, is not decisive in resolving the present clarity issue. Indeed, for most of the therapeutic agents, a therapeutic effect is usually first demonstrated using experimental in vitro and/or in vivo assays, long before clinical trials begin and the agent gets regulatory approval. Given the diverging definitions provided by the parties, the board must conclude that the skilled person is not in a position to establish whether the vast majority of biologically active compounds, e.g. peptides, oligonucleotides, proteins etc... are therapeutic or not and ultimately whether a fully intact eubacterial minicell comprising such an agent falls under the scope of the claim or not.

12.2 Since the term "therapeutic agent" is open to interpretation or ambiguous, claim 1 lacks clarity within the meaning of Article 84 EPC.

13. The board concludes that the main request contravenes the requirements of Article 84 EPC.

14. In the absence of an allowable request, the decision under appeal is set aside.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

L. Malécot-Grob B. Stolz

Decision electronically authenticated