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Datasheet for the decision of 14 September 2023

Case Number: T 1981/21 - 3.3.04
Application Number: 17174523.5
Publication Number: 3238741
IPC: A61K39/02
Language of the proceedings: EN

Title of invention:
A novel live attenuated shigella vaccine

Applicant:
EveliQure Biotechnologies GmbH

Headword:
Attenuated shigella vaccine/EVELIQURE

Relevant legal provisions:
EPC Art. 123(2)

Keyword:
Amendments - added subject-matter (no)
Case Number: T 1981/21 - 3.3.04

DECISION
of Technical Board of Appeal 3.3.04
of 14 September 2023

Appellant: EveliQure Biotechnologies GmbH
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Representative: Redl, Gerda
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Decision under appeal: Decision of the Examining Division of the European Patent Office posted on 6 July 2021 refusing European patent application No. 17174523.5 pursuant to Article 97(2) EPC.

Composition of the Board:
Chairman B. Rutz
Members: A. Chakravarty
R. Romandini
Summary of Facts and Submissions

I. The applicant (appellant) filed an appeal against the examining division's decision to refuse European patent application No. 17 174 523. This application is a divisional application of earlier (parent) application EP 13 762 423, which was granted and published as EP 2 879 700.

II. In the decision under appeal the examining division considered a main and four auxiliary requests. It held that the main request did not comply with the requirements of Article 76(1) EPC in that the subject-matter of claims 1 and 4 extended beyond the content of the earlier application as filed. Auxiliary request 1 suffered from the same deficiencies as the main request, while claim 4 of auxiliary requests 2 and 3 suffered from the same deficiencies as claim 4 of the main request. Auxiliary request 4 was not allowable because claim 1 did not comply with the requirements of Article 123(2) EPC.

III. The appellant filed a statement of grounds of appeal together with a set of claims of a main request which corresponded to auxiliary request 4 considered by the examining division. It also filed a set of claims of a first auxiliary request which had not been submitted in examination proceedings.

IV. Claim 1 of the main request reads:

"1. A live attenuated Shigella vaccine comprising a mutant Shigella strain of a rough LPS phenotype lacking LPS O-antigen, obtainable by a mutation to delete rfbF
or \textit{waal}, and which is non-invasive by a mutation of the endogenous invasion plasmid".

V. In the decision under appeal, the examining division held that claim 1 of auxiliary request 4 lacked basis under Article 123(2) EPC because the mutation to delete \textit{rfbF} was not directly and unambiguously derivable from the application as filed. Specifically, no basis could be found in the passages referred to by the appellant except for the \textit{rfbF} mutation in combination with further mutations which were not recited in present claim 1.

Definition 3 on page 31, lines 6 to 8, of the application did disclose the deletion of \textit{rfbF} alone. However, the passage in the application in question, which related to \textit{"definitions... and embodiments described (see page 30, lines 27 and 28) of which said \"definition 3\" was part"} was not seen by the examining division as disclosing the technical features of the invention because the description on page 4, lines 29 to 33 specified:

\textit{"The invention provides for ... a Shigella strain which is rough and non-invasive by a deletion of the \textit{rfbF} gene, and a deletion of the \textit{ipaB} and \textit{ipaC} genes on the invasion plasmid."}

Thus, even if any of the passages on pages 5, 10, 19, and 31 provided a potential basis for the invention as claimed, it would be in contradiction to the statement on page 4.

VI. The appellant's arguments relevant to the decision are as follows.
The examining division was wrong to hold that the passages which disclosed the claimed subject-matter on page 30 ff. of the application could not be considered because they were "in contradiction to the recited statement on page 4". In fact the application, in particular "definition 3", directly and unambiguously disclosed the claimed subject-matter. This disclosure could not be disregarded merely because other embodiments were disclosed elsewhere in the application. The various disclosures in the application as filed would not be seen as contradictory by the skilled person who would realise that they represented different aspects of the invention.

In summary, all passages of the application as filed had to be considered when assessing its disclosure.

VII. The appellant's requests as understood by the board are that the decision under appeal be set aside and that the case be remitted to the examining division for further prosecution on the basis of the set of claims of the main request (former auxiliary request 4) or alternatively, on the basis of the set of claims of the auxiliary request filed with the statement of grounds of appeal.

Reasons for the Decision

Main request - claim 1

Amendments (Article 123(2) EPC)

1. The appellant challenged the examining division's finding that claim 1 of the main request did not meet the requirements of Article 123(2) EPC.
2. In the decision under appeal, the examining division held that the application as filed lacked basis for the feature "a mutation to delete rfbF" because this mutation was only disclosed in combination with other mutations.

3. However, it also acknowledged that definition 3 on page 31, lines 6 to 8, did disclose a live attenuated Shigella vaccine comprising a mutant Shigella strain as claimed having a deletion of rfbF alone ("one or more") but considered that this passage was not a basis for the claimed subject-matter because it was in contradiction to preceding passages "disclosing the technical features of the invention".

4. According to the established case law of the Boards of Appeal, the requirements of Article 123(2) EPC that the European patent application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed are interpreted to mean that amendments 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 (see Case Law of the Boards of Appeal of the European Patent Office, 10th edition 2022, II.E.1.1).

5. Applying these principles to the case at hand leads to the conclusion that the examining division's assessment that the passage on pages 30 and 31, which is part of a section of "claim-like clauses", directly and unambiguously discloses the subject-matter of claim 1, was correct. In particular, definitions 1 to 3 disclose a live attenuated, Shigella vaccine, which is based on a non-invasive, rough Shigella strain lacking LPS O-
antigen (see definition 1), which is obtainable by deletion of rfbF (see definition 3) or waal (see definition 2).

6. However, contrary to the examining division's view, the fact that the application as originally filed, on page 4, last paragraph, also discloses "a live attenuated Shigella vaccine that is cross-protective against different serotypes and species of Shigella comprising a Shigella strain which is rough and non-invasive by a deletion of the rfbF gene, and a deletion of the ipaB and ipaC genes on the invasion plasmid" cannot, in the present case, be read to invalidate or otherwise nullify the above mentioned disclosure, even if it is preceded by the phrase "the invention provides for". There is no disclosure in the application which would lead the skilled person to the conclusion that this phrase should be understood to mean that all subsequent disclosures must be a subset of this aspect of the invention.

7. In view of the above considerations, claim 1 meets the requirements of Article 123(2) EPC.

Amendments (Article 76(1) EPC)

8. The main request in the proceedings before the examining division was found not to comply with Article 76(1) EPC in the decision under appeal. This was because the vaccine defined in claim 1 did not include the underlined features "live attenuated Shigella vaccine which is based on a rough Shigella strain lacking LPS O-antigen" present in the parent application. Furthermore, claim 4 referred to "a deletion and/or inactivation of at least one of the ipaB, ipaC or any other ipa genes", and no basis could
be found for the underlined feature in the parent application.

9. As noted by the examining division in the decision under appeal, these objections do not apply to the present main request. This is because, in the case of claim 1, the missing features have been included and, in the case of claim 4, the features objected to, have been removed.

10. In view of the above considerations, the appeal is allowable.

Remittal (Article 111(2) EPC)

11. Since the decision under appeal does not address the question of whether or not the application meets any other requirements of the EPC and in view of the fact that the primary object of the appeal proceedings is to review the decision under appeal in a judicial manner (Article 12(2) RPBA), the circumstances of the case warrant remittal of the case (Article 11 RPBA).

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the examining division for further prosecution on the basis of the set of claims of the main request.
The Registrar: I. Aperribay

The Chairman: B. Rutz

Decision electronically authenticated