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**Datasheet for the decision
of 29 July 2008**

Case Number: T 0114/06 - 3.3.02

Application Number: 04013422.3

Publication Number: 1452171

IPC: A61K 9/16

Language of the proceedings: EN

Title of invention:

Pharmaceutical liquid suspensions

Applicant:

Cambridge Biostability Limited

Opponent:

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Headword:

Pharmaceutical liquid suspensions/CAMBRIDGE BIOSTABILITY
LIMITED

Relevant legal provisions:

EPC Art. 76, 84, 123(2), 111(1)
EPC R. 103

Relevant legal provisions (EPC 1973):

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Keyword:

"Articles 76 and 123(2) - (yes): basis for claim 1 in the
parent application and in the divisional application as
originally filed"

"Clarity (yes): no ambiguous terms in claim 1"

"Reimbursement of the appeal fee - (no): no substantial
procedural violations"

"Remittal - (yes): undecided issues"

Decisions cited:

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Catchword:

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Case Number: T 0114/06 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 29 July 2008

Appellant: Cambridge Biostability Limited
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 9 August 2005
refusing European application No. 04013422.3
pursuant to Article 97(1) EPC 1973.

Composition of the Board:

Chairman: U. Oswald
Members: A. Lindner
J. Van Moer

Summary of Facts and Submissions

I. European patent application No. 04 013 422.3 was refused by a decision of the examining division dated 9 August 2005 on the basis of Article 97 EPC on the grounds that the main and sole request contained subject-matter that extends beyond the content of the parent application as filed (Article 76 EPC) and, in addition, lacked clarity (Article 84 EPC).

II. The decision was based on claims 1-10 of the main and sole request filed with letter dated 13 July 2005.

Independent claim 1 of the main request before the examining division reads as follows:

"1. A pharmaceutical composition comprising an active ingredient carried by particles containing a glass, these particles being suspended in a biocompatible liquid, characterised in that the densities of the particles and biocompatible liquid are sufficiently similar that the particles remain in suspension."

III. The arguments in the decision may be summarised as follows:

In connection with the requirements of Article 76 EPC, it was reasoned that the subject-matter of present claim 1 contained several features that had not been disclosed in the divisional application as originally filed. In addition, objections concerning "double-patenting" in connection with the parent application were raised.

Furthermore, the examining division came to the conclusion that the feature "the densities of the particles and biocompatible liquid are sufficiently similar that the particles remain in suspension" did not meet the requirements of Article 84 EPC.

IV. The appellant (applicant) lodged an appeal against said decision.

V. At the oral proceedings of 29 July 2008, the appellant filed a new main request. Independent claim 1 reads as follows:

"1. A pharmaceutical composition comprising an active ingredient carried by particles of sugar glass having a diameter in the range of 0.1 to 100 micrometers these particles being suspended in a biocompatible perfluorocarbon liquid, characterized in that the densities of the particles and biocompatible liquid are matched such that the particles remain in a stable suspension."

VI. The appellant's submissions can essentially be summarised as follows:

As regards the alleged procedural violations of the examining division, the direct refusal after only one official communication was "contrary to reasonable expectation" and thus surprising for the appellant. The first and only official communication of the examining division contained two contradictory statements: on the one hand, it was stated that the substantive examination of the requirements defined in Article 52(1) EPC would be postponed, which clearly implied that it

would take place at a later stage of the procedure; on the other hand, the official communication contained the statement that the refusal of the European patent application was to be expected "at the next stage of prosecution", unless the objections raised under Articles 76 and 84 EPC were "convincingly overcome". As neither the EPC nor the Guidelines contained a definition of the term "next stage of prosecution", the content of the official communication was ambiguous. Furthermore, a straight refusal after the first and only official communication was not possible after only a partial examination of the application, in particular if the applicant had submitted a *bona fide* response to the objections raised in the official communication, as had been the case.

The further objections raised in the statement of the grounds of appeal were not reiterated.

- VII. The appellant requested that the decision under appeal be set aside and that the case be remitted to the first instance for further prosecution on the basis of the request submitted during the oral proceedings. He also requested reimbursement of the appeal fee.

Reasons for the decision

1. The appeal is admissible.
2. Basis for the subject-matter of claim 1 in the parent application as originally filed (Article 76 EPC):

The subject-matter of claim 1 is based on claims 1 and 6 as well as page 8, lines 9-15 of the parent application as originally filed.

In this context, it is noted that the "sugar glass microparticles" according to claim 6 in combination with claim 1 of the parent application are identical to the "particles of sugar glass" mentioned in present claim 1, as both types of particles are further defined by a diameter range of 0.1 to 100 micrometers.

Furthermore, the parent application does not specifically mention **pharmaceutical** compositions. However, the fact that the compositions of the parent application are indeed pharmaceutical compositions can be derived from claim 18; the passage on page 8, lines 9-11, as well as the disclosure of the parent application as a whole.

As a consequence, the subject-matter of present claim 1 meets the requirements of Article 76 EPC.

3. Basis for the subject-matter of claim 1 in the divisional application as originally filed (Article 123(2) EPC):

The basis for the subject-matter of present claim 1 can be found in claims 1, 7-8 and page 12, lines 1-13 of the divisional application as originally filed.

Although the divisional application as originally filed does not specifically mention **biocompatible** perfluorocarbon liquids as presently claimed, the biocompatibility of the perfluorocarbon liquids is

implicitly disclosed by the passage on page 13, lines 18-21.

As a consequence, the subject-matter of present claim 1 meets the requirements of Article 123(2) EPC.

4. Clarity:

The wording "the densities of the particles and biocompatible liquid are **sufficiently similar...**", which in the decision under appeal had been objected to under Article 84 EPC, was replaced by the feature "the densities of the particles and biocompatible liquid are **matched...**", which does no longer contain any ambiguity. As a consequence, the subject-matter of present claim 1 meets the requirements of Article 84 EPC.

5. Double patenting:

In the decision under appeal, the examining division also raised objections with regard to double patenting in connection with the parent application. It is, however, noted that the parent application was withdrawn with letter dated 13 August 2004. As a consequence, the question of double patenting does not arise.

6. Procedural violations:

In the official communication of the examining division dated 18 April 2005, the examining division raised several objections under Article 76 EPC and 84 EPC. In paragraph 3 of the communication, the examining division informed the applicant that substantive

examination as regards the requirements defined in Article 52(1) EPC would be postponed until the objections raised under Articles 76 and 84 EPC had been convincingly dealt with. Finally, the second sentence in paragraph 5 reads as follows:

"Should the objections raised above not be convincingly overcome, refusal of the application under Article 97(1) EPC is to be expected at the next stage of the prosecution."

The board is of the opinion that the warning in paragraph 5 of the official communication dated 18 April 2005 is clear and unambiguous: the application will be refused at the next stage of the prosecution, i.e. when the examining division carries out its next action, unless the objections raised under Articles 76 and 84 EPC are overcome. This warning given by the examining division is not in contradiction to the statement given in paragraph 3 of the official communication dated 18 April 2005. On the contrary, these two passages clearly define the sequence of further procedural steps: if the objections raised under Articles 76 and 84 EPC are not overcome, then the application will be refused; if they are overcome, then the substantive examination of the application will continue and will include the examination of the requirements defined in Article 52(1) EPC. It follows therefrom that the content of the official communication dated 18 April 2005 was neither contradictory nor ambiguous, nor was the subsequent refusal contrary to reasonable expectation in view of the warning mentioned above. As a consequence, the examining division did not commit substantial procedural violations.

7. Remittal to the first instance:

7.1. Although Article 111(1) EPC does not guarantee an absolute right to have all the issues in the case considered by two instances, it is well recognised that any party should where appropriate be given the opportunity to have two readings of the important elements of the case. Hence, a case is normally referred back if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

7.2. Thus, the Board has reached the conclusion that, in the circumstances of the present case, the case should be remitted to the examining division for further prosecution on the basis of the main request filed at the oral proceedings of 29 July 2008.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution.
3. The request for reimbursement of the appeal fee is refused.

The Registrar:

The Chairman

N. Maslin

U. Oswald