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**Datasheet for the decision
of 8 May 2012**

Case Number: T 1511/09 - 3.3.02

Application Number: 01988322.2

Publication Number: 1339387

IPC: A61K 9/00

Language of the proceedings: EN

Title of invention:

Stable, aerosolizable suspensions of proteins in ethanol

Applicant:

BATTELLE MEMORIAL INSTITUTE

Opponent:

-

Headword:

Suspensions of proteins in ethanol/BATTELLE

Relevant legal provisions:

EPC Art. 123(2), 84, 54

EPC R. 137(3)

RPBA Art. 12

Relevant legal provisions (EPC 1973):

-

Keyword:

"Admissibility of requests filed with grounds of appeal: No"

"Main request not allowable"

Decisions cited:

G 0004/92

Catchword:

-



Case Number: T 1511/09 - 3.3.02

DECISION
of the Technical Board of Appeal 3.3.02
of 8 May 2012

Appellant: BATTELLE MEMORIAL INSTITUTE
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Columbus
OH 43201-2693 (US)

Representative: Turi, Michael
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 11 December 2008
refusing European patent application
No. 01988322.2 pursuant to Article 97(2) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
R. Cramer

Summary of Facts and Submissions

- I. European patent application No. 01988322.2, based on international application No. W002/43695, was filed with 33 claims.

Claim 1 as filed read as follows:

"1. A stable suspension of a biologically active protein suited for aerosol delivery to the respiratory tract of a patient in need of treatment comprising particles of said protein suspended in ethanol."

- II. The following documents *inter alia* were cited in the examination and appeal proceedings:

D1 WO 00/47203

D2 XP-001094281, A. Brown, Aerosol Science and Technology, 24:45-56 (1996))

D3 WO 00/66206

D4 XP-001093845, Won Seon Choi, PNAS, September 25, 2001, vol. 98, no. 20, 11103-11107

A1 Catalogue: "Reagenzien Diagnostica Chemikalien, Merck, 1980

A2 Catalogue: Laborchemikalien Reagenzien 1993/94, Laborat

A3 Catalogue: Analytika, 1995/96, Fluka.

- III. The present appeal lies from a decision of the examining division refusing the application (Article 97(2) EPC).

IV. The examining division rejected the main request, which was filed with the letter of 13 October 2008, since it considered that the amendments (in particular the amendment relating to the redrafting of claim 1 as a suspension "essentially consisting of") did not meet the requirements of Article 123(2) EPC.

The main request had been filed as a response to an objection of lack of novelty vis-à-vis documents D1 and D3, which had been raised in the examining division's communication sent as an annex to the summons for oral proceedings.

As regards the auxiliary requests I and II submitted at the oral proceedings before the examining division, the examining division considered that they did not meet the requirements of Article 123(2) EPC.

The examining division also cited documents D2 and D4 in its decision.

V. Claim 1 of the main request filed with the letter of 13 October 2008 read as follows:

"1. A stable suspension of a biologically active protein suited for aerosol delivery to the respiratory tract of a patient in need of treatment said suspension essentially consisting of:

- particles of said protein suspended in ethanol containing up to 3% or less of water
- optionally up to 20% (V/V) of a formulation additive selected from polyhydric alcohols, and

-optionally 0.05% to 5.0% (W/V) of a pharmaceutically acceptable excipient selected from surfactants, antioxidants, antimicrobials, and suspending agents".

- VI. The applicant (appellant) filed an appeal against the first instance decision and filed grounds thereto. The appellant filed a new main request and four auxiliary requests with the grounds of appeal. Moreover, the appellant filed a "clear copy" and a "working copy" of the main request. Additionally, the appellant filed some amended pages of the description (pages 2a, 3, 4 and 7).

The appellant stated in its grounds of appeal that auxiliary requests I and II, filed at the oral proceedings before the examining division, were no longer maintained.

- VII. A communication expressing the preliminary opinion of the board was sent pursuant to Article 15(1) RPBA as an annex to the summons for oral proceedings. The board informed the appellant that its requests as expressed with the grounds of appeal were unclear and gave the reasons why. The board also mentioned that the admissibility of the requests filed with the grounds of appeal was to be discussed at the oral proceedings, and expressed a preliminary negative opinion in this respect.

Moreover, in said communication, the board also expressed a preliminary negative opinion in relation to Articles 123(2) and 84 EPC, as well as in relation to novelty vis-à-vis document D4.

- VIII. The appellant filed a letter dated 19 April 2012 in which it informed the board that the "Applicant does not intend to attend oral proceedings". Moreover, it requested "to decide on the record". No further comments were filed in response to the board's communication sent as an annex to the summons to oral proceedings.
- IX. The board sent a brief communication dated 24 April 2012 in which it informed the appellant that the oral proceedings scheduled for 8 May 2012 would be maintained.
- X. Oral proceedings were held on 8 May 2012 in the absence of the appellant.
- XI. At the oral proceedings, the board established the following:

The appellant requested that the decision under appeal be set aside and a patent granted on the basis of the main request filed with the letter of 13 October 2008. Alternatively it requested the grant of a patent on the basis of the request entitled "Main request" filed with the grounds of appeal, or on the basis of one of the requests entitled "First-", "Second-", "Third-" and "Fourth auxiliary request" filed with the grounds of appeal.

Reasons for the Decision

1. The present appeal is admissible.
2. The oral proceedings before the board took place in the absence of the appellant, who was duly summoned but decided not to attend, as announced in its letter of 19 April 2012. Although the appellant had requested the Board "to decide on the record", it had not withdrawn its request for oral proceedings in the event that the main request was not allowed.

The present decision is based on facts and evidence put forward during the written proceedings and on which the appellant had an opportunity to comment. Therefore, the conditions set forth in decision G 4/92, OJ EPO 1994, 149 are met.

3. *Appellant's requests*
 - 3.1 The board informed the appellant with the communication sent as an annex to the summons for oral proceedings that its requests as expressed in the grounds of appeal were unclear. However, the appellant gave no reply in order to clarify the situation.
 - 3.2 The appellant had requested in its grounds of appeal that a patent be granted "on the application documents refused" and also requested that a patent be granted on the basis of "the (insignificantly amended) main request refused by the Examining Division in the appealed decision".

Thus, the board considers that the main request before the examining division (which was filed with the letter of 13 October 2008) was maintained by the appellant with its grounds of appeal. The new main request filed with the grounds of appeal, which is not insignificantly amended (see point 4.2 below), is considered as a further request.

3.3 Moreover, the appellant clearly stated on page 2 of its grounds of appeal that the first and second auxiliary requests filed during the oral proceedings before the examining division on 13 November 2008 were not being maintained.

4. *Admissibility of the requests*

4.1 The auxiliary requests filed with the grounds of appeal cannot be considered to be admissible since they do not represent a direct response to the decision under appeal but rather raise fresh issues broadening without justification the scope of the discussion in appeal proceedings to include new and complex issues. Additionally, the amended claims in auxiliary requests 1 to 4 filed with the grounds of appeal manifestly lack clarity and raise new problems in relation to lack of support (Article 84 EPC) and allowability of amendments within the meaning of Article 123(2) EPC.

The appeal proceedings are not a continuation of the examination proceedings, thus it is not an allowable response to the decision under appeal to provide completely redrafted claims opening fresh and complex issues, or to file auxiliary requests simultaneously

containing a claim intended as a purpose-related product claim within the meaning of Article 54(5) EPC 2000 and a use claim in Swiss-type form.

Therefore, the sets of claims of the auxiliary requests filed with the grounds of appeal cannot be admitted into the proceedings (Rule 137(3) and Article 111(1) EPC).

Moreover, under the circumstances set out above, the appellant's request for remittal to the department of first instance "since the auxiliary requests raise fresh issues and the appellant wishes to have the opportunity for these to be considered without loss of an instance" has also to be refused as not admissible.

- 4.2 The "main request" filed with the grounds of appeal does not correspond to an "insignificantly amended" main request as filed with the letter of 13 October 2008. The newly filed main request (clean version) incorporates *inter alia* differently drafted claims 19 and 20 (previously claim 31). Additionally, it does not contain the previously numbered claims 20 to 30.

The redrafting of claim 19 in the new main request is not caused by the decision under appeal and raises fresh issues. The unjustified incorporation of such a redrafted independent claim in the main request undermines this request's admissibility. Additionally, there is no justification why such amendments could not have been presented earlier, i.e. during the first instance proceedings.

Therefore, the main request filed with the grounds of appeal is not admitted into the proceedings (Article 12(4) RPBA).

5. *Main request*

5.1 Claim 1 of the main request before the examining division and claim 1 of the main request filed with the grounds of appeal are identical.

Claim 1 relates to

a **stable suspension**

of a **biological active protein** <suited for aerosol delivery to the respiratory tract of a patient in need of treatment>

said suspension essentially consisting of

-particles of said protein suspended in ethanol containing up to 3% or less of water

-optionally up to 20.0% (V/V) of a formulation additive selected from polyhydric alcohols, and

-optionally 0.05% to 5.0% (W/V) of a pharmaceutically acceptable excipient selected from surfactant, antioxidants, antimicrobials, and suspending agents.

5.2 As a first step it has to be assessed whether the requirements of Article 84 EPC are met.

5.2.1 The expression "essentially consisting of" finds no *verbatim* basis in the application as filed. Moreover, said expression taken within the context of the claim contrasts with the fact that other essential components (apart from protein and ethanol with water content up

to 3% or less) may also be present in the composition. The other components listed in the claim as optionally present may have an impact on the stability of the suspension and thus cannot be considered as non-essential components when they are present. Moreover, said additional components can be present in important amounts (up to 20.0% (V/V) or up to 5% (W/V), respectively).

Therefore, claim 1 lacks clarity (Article 84 EPC) since it is unclear which is the limitative character conferred by the expression "essentially consisting of" in relation to the presence or absence of components other than protein and ethanol and the value given to the relative expression "stable suspension".

5.2.2 Furthermore, it is unclear that the expression "biologically active protein" is intended to encompass polypeptides such as the enzymes and polypeptides listed on page 5, lines 14, 15 of the description.

Moreover, the claim's wording is ambiguous as to whether the protein is the active ingredient or drug for a therapeutic treatment. The compounds listed on page 5, lines 15-24, appear to encompass not only proteins and polypeptides which can be used as drugs suitable for therapeutic treatment involving administration or delivery by aerosol to the respiratory tract. Moreover, claim 1 of the main request leaves it open as to whether the protein suspension claimed is the final product ready to be administered by aerosol delivery to the respiratory tract, or also encompasses suspensions which may be further manufactured or conditioned to prepare the

aerosol composition ready for delivery (see last paragraph on page 4 of the description).

5.2.3 In view of the above, the main request fails since claim 1 does not meet the requirements of Article 84 EPC.

5.3 For the sake of completeness the following has also been considered.

5.3.1 The expression "**suited for aerosol delivery** to the respiratory tract of a patient in need of treatment" has no clear limitative character. Claim 1 concerns a product claim seeking "absolute" product protection since it is not restricted by a purpose defined by a "new" purposive medical indication, functionally linked to the product claimed. Moreover, the claim's wording merely reflects that the suspension should be suitable for aerosol delivery.

It should be recalled that for the analysis of novelty the claim has to be taken in its broadest technically meaningful sense. The expression "delivery to the respiratory tract" is not restricted to the systemic delivery of drugs through the deep lung, but it includes *inter alia* the upper airways and the possible local treatments (see page 5, first paragraph).

5.3.2 Therefore, taken in its broadest technically meaningful sense, claim 1 of the main request encompasses any thinkable suspension of a biologically active protein or polypeptide in ethanol (of water content up to 3% or less) regardless of its intended use. Such a claim manifestly lacks novelty (Article 54 EPC).

5.3.3 In particular, document D4 had been cited on page 1 of the examining division's decision and given the code [PX], i.e. meaning a document relevant for novelty and published prior to the international filing date but later than the priority date claimed. However, the examining division did not express any opinion about the validity of the priority date for the claimed subject-matter within the meaning of Articles 88 and 89 EPC. This assessment was made by the board and communicated to the appellant in the communication sent as an annex to the summons for oral proceedings.

Document D4 is a scientific publication entitled "Inhalation delivery of proteins from ethanol suspensions", published on 25 September 2001, i.e. after the priority date (1 December 2000) but before the international filing date (30 November 2001) of the application in suit.

An inspection of the priority document US 60/250,491 shows that the subject-matter claimed in the main request is not entitled to the priority date since it is not disclosed in the priority document. The priority document does not disclose *inter alia*, "a stable suspension of a biologically active protein comprising **particles of said protein suspended in ethanol containing up to 3% or less of water**". Thus, the effective filing date for the subject-matter claimed is the international filing date, and document D4 forms part of the state of the art within the meaning of Article 54(2) EPC.

5.3.4 Document D4 specifically discloses non-aqueous suspensions of proteins and polypeptides such as lysozyme and peroxidase, in both absolute ethanol and anhydrous ethanol.

It is well known to the skilled person that commercially available absolute ethanol has a water content lower than 0.2% (see, for instance, several chemical catalogues as A1 to A3, copies of which were sent to the appellant with the board's communication sent as an annex to the summons for oral proceedings).

Furthermore, anhydrous ethanol containing molecular sieves (see D4, page 11104, left hand column, first paragraph) inevitably has a water content less than 3%. The protein and polypeptide suspensions in document D4 are suitable for aerosol delivery and are indeed administered by nebulisation with a nebulizer. The suspensions disclosed in document D4 are stable. Moreover, after investigation of the effect of anhydrous ethanol on the enzymes and the positive nebulisation results of the suspensions, especially in anhydrous ethanol, document D4 further discloses that "Encouraged by the foregoing nebulisation and stability data with model enzymes, we switched to the inhalation delivery of therapeutic protein insulin" (page 11106, left column, second paragraph).

Thus, document D4 discloses insulin suspensions in ethanol with the adequate particle size for delivery to the lung. Furthermore, the ethanol used is necessarily that used in the enzyme models. Therefore, D4 specifically discloses insulin suspensions in ethanol with a water content less than 3%. Therefore, document

D4 fully anticipates the subject-matter claimed in claim 1 of the main request.

5.3.5 The appellant did not respond to the arguments in the board's assessment.

5.3.6 Consequently, the subject-matter claimed in claim 1 of the main request lacks novelty (Articles 52 and 54 EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:

N. Maslin

U. Oswald