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Datasheet for the decision of 14 April 2010

Case Number: T 0041/07 - 3.3.02

Application Number: 98950826.2

Publication Number: 1019021

IPC: A61K 9/00

Language of the proceedings: EN

Title of invention:
Stabilized preparations for use in metered dose inhalers

Patentee:
Novartis AG

Opponent:
Advanced Inhalation Research Inc

Headword:
Metered dose inhalers/NOVARTIS

Relevant legal provisions:
EPC R. 68(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Procedural violation - yes: decision not reasoned for each independant subject-matter"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0041/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 14 April 2010

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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 15 November 2006 concerning maintenance of European patent No. 1019021 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: J. Riolo
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 1 019 021, based on European application No. 98 950 826.2, was granted on the basis of 29 claims.

Independent claims 1, 13 and 21 as granted read as follows:

"1. A stable respiratory dispersion for the pulmonary delivery of one or more bioactive agents comprising a suspension medium having dispersed therein a plurality of perforated microstructures with a mean aerodynamic diameter between 0.5 and 5 µm and comprising at least one bioactive agent wherein said suspension medium comprises at least one propellant and substantially permeates said perforated microstructures.

13. A method for forming a stabilized respiratory dispersion comprising the steps of:
combining a plurality of perforated microstructures having a mean aerodynamic diameter of less than 5 µm and comprising at least one bioactive agent with a predetermined volume of suspension medium comprising at least one propellant to provide a respiratory blend wherein said suspension medium substantially permeates said microstructures; and
mixing said respiratory blend to provide a substantially homogeneous respiratory dispersion.

21. A respiratory dispersion for the pulmonary delivery of one or more bioactive agents comprising a suspension medium having dispersed therein a plurality of microparticles having a mean aerodynamic diameter of

less than 5 µm and comprising greater than 20% w/w surfactant and at least one bioactive agent wherein said suspension medium comprises at least one propellant."

II. A notice of opposition was filed against the patent under Article 100 (a) EPC (lack of novelty and inventive step), Article 100 (b) EPC (insufficiency of disclosure) and Article 100 (c) EPC (added subject-matter).

The following documents *inter alia* were cited during the proceedings before the Opposition Division and the Board of Appeal:

(1) WO-A-96 26746
(2) WO-A-91 16882
(3) US-A-4 590 206
(4) US-A-5 182 097
(5) US-A-5 230 884
(6) US-A-5 354 934
(7) WO-A-96 09814
(8) WO-A-98 31346
(9) WO-A-96 40285, PP. 1-153
(10) US-A-4 009 280
(l1) US-A-4950477
(12) US-A-5 304 125
(13) US-A-5 284656
(14) Eur. Resp. J., 1989 (2), pp. 253-256
(15) Nektar Notice of Opposition against EP 939622 Bi (05.12.2003)
(16) US-A-S 126 123
(17) Product Sheet for Intal® Inhaler
(18) US-A-5 376 359

(19) US-A-4 089 120

(20) Pharmaceutical Research, 21, No. 9, 2004, pp. 1607-1614

(21) ACE professional Reference Book, 1993, p.157

III. By decision pronounced on 17 October 2006, the Opposition Division maintained the patent in amended form under Article 102(3) and 106 (3) EPC.

The main request (set of claims as granted) was rejected under Article 123 (2) EPC because the application as originally filed did not disclose the combination of microparticles with a mean aerodynamic diameter of less than 5 µm.

The auxiliary request 1 filed with letter of 18 September 2006 was considered to fulfil the requirements of the EPC.

The set of claims of this request corresponds to the set of claims as granted wherein the feature "microparticles" in independent claim 21 was replaced by the feature "perforated microstructures", which was recited in dependent claim 26.

In the Opposition Division's view this amendment overcame the objection under Article 123(2) EPC.

As to sufficiency of disclosure, the Opposition Division considered that the skilled person would obtain enough technical information, when reading the patent-in-suit which described various concrete methods and embodiments, to be able to prepare dispersions which came within the terms of the claims.

In that respect, it expressed the view that the objections raised by the opponent with regard to the interpretation of the terms "stable", "perforated", "displaced volume", "average particle volume" and "interstitial spaces" were objections which concerned lack of clarity (Art. 84 EPC) rather than insufficiency of disclosure and that the question whether the claimed scope was too broad was a question of inventive step.

With respect to novelty, the Opposition Division held that the disclosure of document (1), which related to dry hollow microparticles placed into a vial and permeated by a gaseous medium was not pertinent to the novelty of the claimed subject-matter as it concerned a different system, namely a suspension medium, with a fluid, which was a liquid, aiming at preventing sedimentation in propellant-containing drug dispersions as used in metered-dose inhalers.

As to the remaining documents, (2) to (7), cited against novelty of the claimed subject-matter, the Opposition Division concluded that none of these documents disclosed microparticles in the sense of the patent in suit, namely that they were perforated in such a manner that they are substantially permeated by the surrounding suspension medium.

The Opposition Division concluded moreover that this distinguishing feature was inventive over the available prior art because, starting from document (4) as closest prior art, wherein the suspensions were stabilized by adding a surfactant, the skilled person would not have found any guidance in the cited prior

art to modify the particle morphology by preparing perforated microstructures which are permeated by the surrounding suspension medium, as an alternative to surfactants, in order to obtain good suspension stability.

Finally, the Opposition Division considered that documents (9) to (14) and (16) and (17) mentioned in the opponent's submission of 18 September 2006 were not relevant, so that these documents were rejected as late filed.

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

V. In its grounds of appeal dated 23 March 2007, the appellant expressed surprise at the conclusions of the Opposition Division, in its decision, that the subject-matter of independent claim 21 was patentable for the same reasons as claim 1.

In that respect, it referred to the interlocutory decision of the Opposition Division. In this decision, the Opposition Division stated that "the objective technical problem was thus to provide stable propellant containing suspension formulations for inhalation". The Opposition Division was of the view that the principal distinguishing feature of the subject-matter of independent claims 1, 13, and 21 over the prior art was the specific particle morphology requiring that the microstructures possess a mean aerodynamic diameter of 0.5-5 microns or less than 5 microns and **that they are perforated in such a manner that they are substantially permeated by the surrounding suspension medium**. The

Opposition Division further stated that the term "perforated" implied certain limitations including substantial permeation of the particles by the surrounding fluid suspension medium. The Opposition Division concluded that permeation of the perforated microstructures by the surrounding suspension medium helped to improve suspension stability.

However, while claim 1 as upheld recited additional language requiring that the particles be substantially permeated by suspension medium, claim 21 made no mention of such permeation and the Opposition Division incorrectly read such limitation into claim 21.

Thus, in contradiction to the Opposition Division's position, the perforated nature of the molecules could not be a distinguishing feature necessary for the stability of the dispersion claimed therein.

As, according to the Patentee itself in its submissions of 18 September 2006, it was the high surfactant content regardless of the morphology of the particle that was responsible for achieving the solution to the stated problem in case of the subject-matter of claim 1, the appellant concluded that the Opposition Division had misinterpreted the various embodiments of the opposed patent, and that claim 21 resulted in an incorrect analysis.

The appellant filed two further documents, i.e. (18) and (19) with its grounds of appeal.

It repeated in substance its objections relating to novelty vis-à-vis documents (1), (3) and (4) and newly filed document (18).

It further held that claim 21 lacked inventive step in view of documents (4), (16) and (19) and in view of documents (18) and (16).

VI. In its reply to the grounds of appeal, the respondent (patent proprietor) mainly agreed with the Opposition Division's reasoning and favourable conclusions as to novelty and inventive step.

It considered that documents (9) to (14) and (16) filed during the proceedings before the Opposition Division, and documents (18) and (19) filed with the appellant's grounds of appeal, should be rejected as late filed.

It also filed auxiliary requests 1 to 4 and documents (20) and (21).

VII. In a communication dated 31 March 2010, the Board expressed its agreement with the appellant's written submissions that no reasons were given as to the patentability of the subject-matter of claim 21 (Rule 68 (2) EPC), so that the case should be directly remitted to the Opposition Division because the right to be heard had thus been violated (Article 113(1) EPC). The parties were invited to reconsider their request for oral proceedings.

VIII. Oral proceedings were held before the Board on 14 April 2010.

IX. The appellant did not attend the oral proceedings.

During the oral proceedings, the respondent repeated its objection that documents (9) to (14) and (16) filed during the proceedings before the Opposition Division, and documents (18) and (19) filed with the appellant's grounds of appeal, should be rejected as late filed.

It further argued that, in its view, the Opposition Division considered in fact that the wording "perforated microstructures", replacing the term "microparticles", in claim 21 implied that the structure was **substantially permeated by the surrounding suspension medium** as in claim 1, so that the Opposition Division's decision was complete.

X. The appellant requested in writing that the decision under appeal be set aside and that the patent be revoked.

The respondent requested that the appeal be dismissed or that the patent be maintained on the basis of auxiliary requests 1 to 4 filed with letter dated 8 October 2007.

Reasons for the decision

1. The appeal is admissible.

2. The function of appeal proceedings is to give a judicial decision upon the correctness of a separate earlier decision taken by a first-instance department. A **complete** reasoned decision issued by the first-

instance department meeting the requirements of Rule 68(2) EPC is accordingly mandatory.

3.1 In the present case the Opposition Division maintained the patent in amended form because it considered that auxiliary request 1 filed with letter of 18 September 2006 fulfilled the requirements of the EPC.

Thus, it held that the skilled person would obtain enough technical information, when reading the patent-in-suit which described various concrete methods and embodiments, to be able to prepare dispersions which came within the terms of the claims, so that the requirements of Article 100(b) EPC were fulfilled.

It moreover concluded that the claimed respiratory dispersion for pulmonary delivery was novel and inventive vis-à-vis the stated prior art documents because of the particular feature **"perforated microparticules"** which are "**substantially permeated by the surrounding suspension medium**".

In that respect, the Board observes that while claim 1 as upheld did indeed contain the functional limitation requiring that the particles be **substantially permeated by suspension medium**, claim 21 makes no mention of such permeation.

This is moreover in line with the fact that claim 21 of the main request was amended during the proceedings to recite "perforated microstructures" when the Opposition Division denied the main request which originally recited "microparticles" **with no perforation limitation**

at all, having an aerodynamic diameter of 5 microns or less.

This is also in line with the disclosure in the application as originally filed that the opposed patent covers two approaches for stabilization of respiratory suspensions.

The first approach which is reflected in the embodiment of claim 1 relates to density matching and requires "perforated microstructures" which are "permeated by the surrounding fluid medium" (see application as originally filed, page 3, line 30, to page 4, line 14). The second approach which is reflected in the embodiment of claim 21 is related to incorporation of increased amounts of surfactant, namely greater than 20% W/W, in the microstructures, which may be formed of particulates exhibiting low porosity or are substantially solid (see application as originally filed, page 7, lines 14 to 24).

Thus, in claim 21, it is the high surfactant content regardless of the morphology of the particle that is responsible for achieving the solution to the stated problem.
In addition, the wording "perforated microstructures" in claim 1 does not have the same restrictive meaning for the assessment of novelty as in claim 1, since the limiting functional feature **"substantially permeated by the surrounding suspension medium"** is not present.

Accordingly, the Board concludes that the Opposition Division's decision is totally silent on the issues of novelty and inventive step as regards the subject-

matter of independent claim 21 as defined above, so that the decision maintaining the patent in amended form is not reasoned, which is contrary to the requirements of Rule 68(2) EPC .

3.2 The Board agrees with the respondent's submission that in accordance with the description "perforated microstructures" are defined as comprising a solid structural matrix that exhibits pores, voids, hollows, defects, apertures, perforations, holes or other interstitial spaces that allow the fluid suspension medium to freely permeate, fill, pervade or perfuse the microstructure (see the patent-in- suit, paragraphs [0019], [0032], [0048]).

The Board cannot however conclude therefrom that this definition also applies to claim 21, for two reasons:

– firstly, because the same description recites that when the suspension medium comprises greater than 20% W/W surfactant, as reflected in claim 21, the microstructures may be formed of particulates exhibiting low porosity or be substantially solid (see the patent-in- suit, paragraph [0028]), and,

– secondly, because claim 21 is drafted as an independent claim, which indicates, as a rule, that the features of independent claim 1 are not comprised in said claim, so that the limiting functional feature "**substantially permeated by the surrounding suspension medium**" of claim 1 cannot be read implicitly in claim 21, contrary to the respondent's submission.

5. The duty to provide substantiated reasons in administrative decisions is a fundamental principle in all contracting states, Rule 68(2) EPC simply being an expression of that principle. Furthermore, from the point of view of the practical functioning of the system envisaged in the EPC, in the absence of the documents and an adequately related reasoned decision within the meaning of Rule 68(2) EPC the Board cannot examine the appeal as to its merits in an adequate manner.

6. In accordance with the established case law of the Boards of Appeal, the case is remitted to the department of first instance for further prosecution.

Under these circumstances, documents (9) to (14) and (16) to (19) filed by the appellant and documents (20) and (21) filed by the respondent are introduced into the proceedings since, as shown above, their relevance vis-à-vis the subject-matter of claim 21 has yet not been assessed by the Opposition Division.

The respondent's argument that documents (9) to (14) and (16) and (17) should be rejected because they have been not been considered relevant thus does not hold good.

The respondent's argument that documents (18) and (19) should be rejected as late filed is not accepted by the Board as these documents were filed together with the grounds of appeal and should be considered prima facie as an attempt to show that the Opposition Division's favourable conclusions were not correct.

In conclusion, the appeal is allowed to the extent that the decision under appeal is set aside and the appeal fee is reimbursed pursuant to Rule 67 EPC on account of the substantial procedural violation constituted by non-compliance with Rule 68(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance for further prosecution.

3. The appeal fee is reimbursed.

The Registrar: The Chairman:

N. Maslin U. Oswald