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Datasheet for the decision of 28 April 2009

Case Number: T 0347/05 - 3.3.02

Application Number: 97927754.8

Publication Number: 0907356

IPC: A61K 9/00

Language of the proceedings: EN

Title of invention:
Aerodynamically light particles for pulmonary drug delivery

Patentee:
MASSACHUSETTS INSTITUTE OF TECHNOLOGY and THE PENN STATE RESEARCH FOUNDATION

Opponent:
Inhale Therapeutic Systems, Inc.

Headword:
Aerodynamically light particles/MIT et al

Relevant legal provisions:
EPC Art. 83, 54, 56

Relevant legal provisions (EPC 1973):
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Keyword:
"In the absence of further argumentation by the appellant there is no reason to deviate from the opposition divsion's findings"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0347/05 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 28 April 2009

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 5 January 2005 rejecting the opposition filed against European patent No. 0907356 pursuant to Article 102(2) EPC 1973.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
J. Van Moer

Summary of Facts and Submissions

I. European patent No. 0 907 356, which was filed as application number 97 927 754.8, based on international application WO 97/44013, was granted on the basis of twenty one claims.

Claim 1 as granted read as follows:

"1. A particulate system for delivery to the pulmonary system comprising:

biodegradable particles with a tap density less than 0.4 g/cm^3, and wherein at least 50% of the particles have a mass mean diameter between 5 µm and 30 µm."

II. The following documents cited during the proceedings are relevant for the present decision:

(1) Product Information by "micromeritics" about The GeoPyc^R T.A.P. Density Option

(2) Ph.D. Thesis of J. Hanes, "Polymer Microspheres for Vaccine Delivery"

(2a) Copy from electronic MIT library catalogue

(4) WO 96/09814

(5) WO 95/01324

(16) Letter of MIT library services together with several annexes

(17) EP-A-0 072 046

(E1) Affidavit by Professor D. Edwards filed with the respondent's letter of 11 April 2008

(22) J. G. Weers, Current Opinion in Colloid & Interface Science, vol. 3, pages 540-544, 1998

(23) D. A. Edwards, J. Hanes, et al., Science, vol. 276, pages 1868-1869, June 1997 (cited as document (14) in document (22))

III. Opposition was filed and revocation of the patent in its entirety was requested pursuant to Articles 100(b) (insufficiency of disclosure) and 100(a) EPC (lack of novelty and inventive step).

IV. The appeal lies from a decision of the opposition division rejecting the opposition (Article 102(2) EPC 1973).

V. The opposition division was of the opinion that there was sufficiency of disclosure in relation to the parameter "tap density", since it was a well known parameter for the skilled person and there were standard methods available for measuring it.

The opposition division considered that the subject-matter claimed was not entitled to the first priority date (24 May 1996) since the priority document US 655 570 concerned "mass density" and did not disclose "tap density". Furthermore the value "30 µm" which appeared in granted claim 1 of the patent in suit was not to be found in said priority document.

However, the opposition division considered that the subject-matter claimed was entitled to the second priority date claimed (29 October 1996).

According to the opposition division's findings, the Ph.D. Thesis of J. Hanes (document (2)) had not been made available to the public before the effective filing date of the patent in suit.

Furthermore, the opposition division considered that the claimed subject-matter was novel since none of the prior art documents disclosed together the values of tap density and mass mean diameter of the particles appearing in claim 1 as granted.

As regards inventive step, the opposition division considered that document (5) represented the closest prior art. In the opposition division's view, the problem to be solved was "to improve the respirable fraction (i.e. to improve the delivery to the deep lung) of particulate systems". The solution concerned the large (in relation to their mass mean diameter) and light (in relation to the tap density) particles defined in claim 1. The opposition division was satisfied that the stated problem had been solved and that the proposed solution was not obvious in the light of the prior art.

VI. The opponent (appellant) filed an appeal to said decision and filed grounds of appeal.

VII. The respondent (patent proprietors) filed counterarguments thereto.

VIII. A communication of the board was sent to the parties on 29 January 2008.

IX. With a letter dated 9 April 2008, the appellant withdrew its request for oral proceedings.

X. The respondent filed an affidavit by Professor D. Edwards (E1) concerning the availability of the Hanes' Thesis (document (2)).

XI. A communication expressing the preliminary opinion of the board was sent on 2 May 2008.

XII. The respondent filed a response dated 28 August 2008 to the board's communication. It filed therewith an auxiliary request.

XIII. Summons for oral proceedings were sent on 17 November 2008.

XIV. The respondent filed with its letter of 12 March 2009 a second auxiliary request.

XV. With a letter dated 22 April 2009 the appellant confirmed that it had withdrawn its request for oral proceedings with its letter of 9 April 2008 and announced that it would not be attending the oral proceedings on 28 April 2009.

XVI. Oral proceedings took place on 28 April 2009 in the absence of the appellant.

XVII. The appellant's arguments filed with its grounds of appeal may be summarised as follows:

The appellant reiterated its objection to the parameter "tap density" used to characterise the biodegradable particles in granted claim 1, since this parameter could not be reproducibly measured on the basis of the information given in the patent in suit.

Moreover, the appellant maintained its novelty objection with respect to documents (2), (4), (5) and (17).

As regards the public availability of document (2) the appellant referred to the date of the doctoral thesis on its cover page and disposed of the information annexed to the MIT library letter (document (16)).

In relation to documents (4) and (17) the appellant forwarded analogous reasons to those already submitted during the opposition proceedings.

As regards the objection of lack of novelty vis-à-vis document (5), the appellant effectively argued in its grounds of appeal that the synthesis of sample 1 according to Example 1 inevitably lead to the production of salmeterol xinafoate in the form of a powder according to granted claim 1 of the patent in suit. For this purpose it filed some calculations according to the formula disclosed on page 5 of document (5), whereby it concluded that the dynamic bulk density of said sample 1 of 0.033 g/cm^3 corresponded to a maximum packed bulk density of 0.044 g/cm^3. The appellant further invoked document (17)

(page 8, line 19 to page 9, line 2) in order to make credible that "tap density" and "packed bulk density" were equivalent terms in the art. Furthermore, the appellant also referred to Example 7 and Figure 31 of document (5) in order to support its argument that it was plausible that the particles of sample 1 had a mean size falling well within the range claimed in granted claim 1 of the patent in suit.

The appellant mentioned in point 4.3.4 of its grounds of appeal that a certain argument of the opposition division's decision concerning the inventive step issue had not been discussed before the parties. Hence, the appellant contended that there was a substantial procedural violation linked to Article 113(1) EPC which made equitable to reimburse the appeal fee.

The appellant did neither counter-argue nor comment the respondent's replies dated 29 September 2005, 20 March 2008, 11 April 2008, 28 August 2008 and 12 March 2009.

XVIII. The respondent's arguments submitted in writing and at the oral proceedings can be summarised as follows:

The patent in suit mentioned in column 7 a GeoPyc^{R} device from Micrometrics Corp. for measuring tap density. It was plainly stated in document (1) (a document relied upon by the appellant) that said device was known for measuring "tap density". The fact that the device may also be used to make other density measurements did not support the appellant's argument that the "tap density" as used in the specification of the patent in suit meant something other than its

common meaning. Thus, there was sufficient disclosure in relation to tap density (Article 83 EPC).

In relation to the public availability of document (2), the respondent denied that the Thesis had been made publicly available on "September 1996". This date was the Thesis date and it had been taken over in the electronic document (2a) for copyright purposes. However, it had been proven with the MIT library letter document (16) and the accompanying annexes showing the actual date stamps (on the Thesis exemplars) of the MIT library archive and MIT Science library, that the receiving date in the MIT library was July 31, 1997. Additionally, Prof Edwards affidavit (E1) confirmed this point. Moreover, a complete copy of the MIT electronic catalogue was annexed to document (16) and it showed that the actual date (item 008) for the entry of the Thesis in the electronic catalogue was 5 December 1997. Hence, the Hanes' Thesis (document (2)) had not been made available to the public previous to 31 July 1997 and was not part of the state of the art for the patent in suit.

Document (4) did not anticipate the subject-matter claimed in view of the tap density requirement in claim 1 as granted. Document (17) did not disclose products simultaneously fulfilling all requirements in claim 1 as granted.

Document (5) did not teach or disclose any run resulting in the combination of large particle size, low density and low aerodynamic diameter as required by means of the parameters in the granted claim.

The respondent maintained that the calculations provided by the appellant were not correct. It also referred to its letter of 28 August 2008 and challenged the correctness of the appellant's arguments in relation to packed bulk density and tap density as equivalent parameters. Document (17) could not be invoked for interpreting the content of document (5) since it was an isolated patent literature (which was its own dictionary only) and did not represent the common general knowledge of the skilled person.

The particles of document (5) did not have themselves a low density, rather any low density calculation results were probably due to the retention of substantial interstitial spaces owing to the needle and flake forms of the particles. The respondent cited in this context the SEMs (Scanning Electron Microscopy) in the figures of document (5).

Document (5) was not relevant for novelty of the subject-matter claimed and its teaching referred to the problem of flowability of the products. Document (5) was silent about the problems linked to deposition and increase of respirable fractions. In fact document (5) mentioned that only 18 to 23% of the product had an aerodynamic diameter that was respirable. Hence, document (5) was also not relevant for the inventive step issue.

The respondent further pointed to the technical data contained in the patent in suit in order to support the opposition division's findings that the problem had been actually solved. It also pointed to the post-published document (22) in which the present

"invention" (post-published document (23)) was referred to as a paradigm shift in the field of formulations for inhalation.

XIX. The appellant (opponent) requested that the decision under appeal be set aside and that the European patent be revoked. It further requested reimbursement of the appeal fee.

The respondent (patentees) requested that the appeal be dismissed, or, in the alternative, to maintain the patent on the basis of the first or second auxiliary requests respectively filed with the letters of 28 August 2008 and 12 March 2009.

Reasons for the Decision

1. *Admissibility*

The appeal is admissible.

2. Main request

2.1 *Sufficiency of disclosure*

The board's communication dated 2 May 2008 expressed the opinion that a clear distinction must be drawn between the requirements of Article 84 and Article 83 EPC and that the appellant's argumentation was indeed that the scope claimed was unclear (Article 84 EPC). Having regard to the fact that the main request relates to the set of claims as granted, the requirements of

Article 84 EPC are outside the framework of the discussions.

The board's communication of 2 May 2008 remained unanswered by the appellant.

Correspondingly, the opposition division's findings in relation to the "tap density" parameter and the requirements of Article 83 EPC are endorsed by the board.

2.2 *Novelty*

On the balance of probabilities, and in the light of the data and arguments on file, document (2) was not publicly available before 31 July 1997. Hence, its content does not form part of the state of the art within the meaning of Article 54(2) EPC.

Concerning the objections with respect to documents (4) and (17), it must be emphasized that, there must be a direct and unambiguous disclosure in the state of the art which would inevitably lead to the subject-matter falling within the scope that is claimed. This is not the case for these documents and hence, the opposition division's decision can be also endorsed in this respect.

The appellant did not comment the board's communication of 2 May 2008 already expressing this opinion.

As regards the novelty analysis vis-à-vis document (5) made by the appellant in its grounds of appeal, it was based on some theoretical calculations and on arguments

of plausibility. Both had been openly contested and challenged by the respondent with its letter of 28 August 2008. These respondent's arguments have not been either contested or commented on by the appellant.

The novelty objection vis-à-vis document (5) raised in the board's communication dated 2 May 2008 was a preliminary opinion expressed before the respondent's reply of 28 August 2008.

The appellant has chosen not to comment the well founded counterarguments submitted by the respondent in its letter of 28 August 2008 and thus, the board cannot endorse anymore the questioned calculations and plausibility arguments submitted with the grounds of appeal.

Correspondingly, none of the documents of the state of the art anticipate the subject-matter of claim 1 as granted.

As regards the other granted claims of the granted set of claims, they are either dependent on claim 1 or include a clear reference thereto. Hence, the set of claims as granted meets the requirements of novelty (Articles 52 and 54 EPC).

2.3 *Inventive step*

The board of appeal endorses the opinion of the opposition division in relation to inventive step of the granted claims since document (5) does neither disclose nor teach products, having such large and light particles as defined in claim 1 as granted, to be

suitable for improving the respirable fraction (and hence the delivery to the deep lung).

The appellant has chosen not to counter-argue the respondent's arguments and hence the board sees no reason to further comment on this issue.

3. *Reimbursement of the appeal fee*

Since the appeal is not allowable, there is no basis to examine the other conditions for a reimbursement of the appeal fee (Rule 103 EPC 2000, Rule 67 EPC 1973). Hence, the request for reimbursement of the appeal fee has to be rejected.

Order

For these reasons it is decided that:

The appeal is dismissed.

The request for reimbursement of the appeal fee is rejected.

The Registrar: The Chairman:

N. Maslin U. Oswald