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Datasheet for the decision of 20 January 2011

Case Number: T 0894/07 - 3.3.02

Application Number: 01917326.9

Publication Number: 1267833

IPC: A61K 9/113

Language of the proceedings: EN

Title of invention:
Pharmaceutical preparations and their manufacture

Patentee:
Vectura Limited

Opponent:
Advanced Inhalation Research Inc

Headword:
Pharmaceutical Preparations/VECTURA

Relevant legal provisions:
EPC Art. 123(2)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Amendments - added subject-matter (yes)"
"All requests: claimed subject-matter not individualised in the original application"

Decisions cited:
-

Catchword:
-

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Case Number: T 0894/07 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 20 January 2011

Appellant: (Opponent)
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Decision under appeal: **Interlocutory decision of the Opposition Division of the European Patent Office posted 30 March 2007 concerning maintenance of European patent No. 1267833 in amended form.**

Composition of the Board:

Chairman: U. Oswald
Members: H. Kellner
D. S. Rogers

Summary of Facts and Submissions

I. European patent No. 1 267 833, based on international application PCT/GB2001/001562, published as WO 2001/074332 and having application No. 01 917 326.9 in the EPO, was granted with 26 claims.

Independent claim 18 as granted read as follows:

"A composition comprising active particles comprising an active substance and having a median diameter of less than 100µm, a normalised Kurtosis of at least 5 or 6 and, optionally, a median diameter of not more than 50µm."

II. Opposition was filed against the granted patent under Article 100(a) EPC, novelty and inventive step, and Article 100(b) EPC, sufficiency of disclosure.

The opposition division held that the main request before the opposition division did not fulfil the requirements of Article 123(2) EPC, since the application as filed disclosed a mass median aerodynamic diameter of less than 5µm only in connection with inhalable compositions and the claim was not limited to such compositions.

The subject-matter of the first auxiliary request was found to meet the requirements of the EPC.

Independent claim 16 of this first auxiliary request before the opposition division, corresponding to claim 18 as granted, reads (added text in bold):

"A composition comprising **therapeutically** active particles **for inhalation** comprising a **therapeutically** active substance and having a **mass** median **aerodynamic** diameter of less than **5µm and** a normalised Kurtosis of at least 5 or 6."

III. Both the opponent and the patentee filed appeals against the decision of the opposition division.

IV. With its grounds of appeal, the patentee submitted six sets of claims in addition to a main request, claim 16 of the sixth auxiliary request having the same text as claim 16 as maintained by the opposition division.

The wording of the corresponding claim 16 of the patentee's main request reads (additions with respect to the corresponding claim 18 as granted in bold):

"A composition comprising **therapeutically** active particles comprising a **therapeutically** active substance and having a median diameter of not more than 50µm and a normalised Kurtosis of at least 5 or 6."

Claim 16 of the first auxiliary request is worded in the same way as claim 16 as maintained by the opposition division with the exception that the words "for inhalation" are missing and that the value 10µm is inserted instead of 5µm; it reads (additions with respect to the corresponding claim 18 as granted in bold):

"A composition comprising **therapeutically** active particles comprising a **therapeutically** active substance and having a **mass** median **aerodynamic** diameter of less

than **10µm and** a normalised Kurtosis of at least 5 or 6."

In claim 16 of the second auxiliary request the value of 5µm appears instead of 10µm. Thus, these two requests correspond to the main request before the opposition division, (that was found not to fulfil the requirements of Article 123(2) EPC), with, however, a differing value for the mass median aerodynamic diameter in one of the two cases (less than 10µm and less than 5µm respectively).

In claim 16 of the third auxiliary request, the words "suitable for inhalation" are inserted and the value for the mass median aerodynamic diameter is less than 10µm; the claim reads (additions with respect to claim 18 as granted in bold):

"A composition **suitable for inhalation,** comprising **therapeutically** active particles comprising a **therapeutically** active substance and having a **mass** median **aerodynamic** diameter of less than **10µm and** a normalised Kurtosis of at least 5 or 6."

In claim 16 of the fourth auxiliary request, the single amendment with respect to claim 16 of the third auxiliary request is the value for the mass median aerodynamic diameter of less than 5µm.

Claim 16 of the fifth auxiliary request differs from claim 16 as maintained by the opposition division in the value for the mass median aerodynamic diameter of less than 10µm while less than 5µm are found again in claim 16 of the sixth auxiliary request resulting in

textual identity to claim 16 as maintained; both claims refer to therapeutically active particles **for inhalation**.

V. With letter of 22 December 2010, the patentee informed the board that it would not attend the oral proceedings scheduled for 20 January 2011 and that it withdrew its request for oral proceedings but maintained all claim-requests on file.

Dated 13 January 2011, the opponent filed a letter indicating that, maintaining all its requests as filed in writing, it would not join the oral proceedings either.

VI. Oral proceedings took place on 20 January 2011 in the absence of the parties.

VII. The opponent's submissions, as far as relevant for the decision, can be summarised as follows:

There was no description in the application as originally filed that combined a specific Kurtosis of 5 or 6 with a specific particle size distribution.

VIII. The patentee contested the arguments of the opponent:

The opponent's arguments in relation to Article 123(2) EPC presented in its grounds of appeal had no relevance whatsoever to the claims of the pending requests. For the reasons given in its grounds of appeal these claims were fully supported by the application as filed.

IX. The opponent requested that the decision under appeal be set aside and that the European patent be revoked.

X. The patentee requested that the patent be maintained on the basis of the main request or the first to sixth auxiliary requests, all filed with letter of 9 August 2007.

Reasons for the Decision

1. The appeals are admissible.

2. *Requirements of Article 123(2) EPC; main request*

Claim 16 of the main request concerns a composition comprising therapeutically active particles comprising a therapeutically active substance and having a median diameter of not more than 50µm and a normalised Kurtosis of at least 5 or 6.

Claims 22, 23, 24 and 25 as originally filed (see WO 2001/074332) read:

"22. A composition comprising active particles comprising an active substance, the composition being obtainable by the method of any of claims 1 to 21.

23. A composition comprising active particles comprising an active substance and having a median diameter of less than 100µm and a normalised Kurtosis of at least 5.

24. A composition as claimed in claim 22 or claim 23 comprising active particles having a median diameter of not more than 50µm.

25. A composition as claimed in any of claims 22 to 24 comprising active particles having a Kurtosis of at least 6."

The reference in claim 25 to claims 22, 23 and 24 leaves it open whether a Kurtosis of at least 6 is meant to relate to not more than 50µm or less than 100µm with respect to the median diameter and at the same time whether it was meant to relate to a composition according to claim 22 or to claim 23 or even to a combination of claims 24 and 22.

Thus, the specific combination of features forming the subject-matter of claim 16 of the main request is not individualised in the claims as originally filed and is in breach of the provisions of Article 123(2) EPC in this respect.

The same problem, however, arises *mutatis mutandis* with respect to the description as originally filed.

On page 25 of the description as originally filed (here considered in the form of the published WO 2001/74332) a composition comprising active particles comprising an active substance and having a median diameter of less than 100µm is disclosed in connection with a preferable Kurtosis of at least 5, 6, 8, 10 or 20 (lines 18 to 24 on this page).

In the next paragraph, the active particles are defined as having preferably a mass median diameter of not more than 100µm, alternatively, not more than 50µm, such that a particular combination of a Kurtosis of 6 and a median diameter of not more than 50µm is not individualised.

Consequently, claim 16 of the main request contains subject-matter which extends beyond the content of the application as originally filed and thus fails to comply with Article 123(2) EPC.

3. *Requirements of Article 123(2) EPC; first to sixth auxiliary requests*

3.1 Claims 16 of all the auxiliary requests refer to a definition of the particle size in terms of a mass median **aerodynamic** diameter.

3.2 The only place in the description of the application as originally filed where particle size is defined in terms of mass median **aerodynamic** diameter, is in the text beginning on page 25, line 29 and ending on page 26, line 1. After the words "Where the active particles are intended to be inhaled", the mass median **aerodynamic** diameter is said to be less than 10µm or more preferably less than 5µm.

3.3 However, as regards the feature mass median **aerodynamic** diameter, no indication of any value for Kurtosis is to be found. In lines 18 to 24 of page 25 of the description as originally filed, it is implied that the Kurtosis value refers exclusively to particles having a **mass** median diameter of less than 100µm. This

implication is derived from lines 23 and 24 on page 9 of the description, where it is stated that "unless indicated otherwise, the word diameter as used herein" is defined to "be taken to mean mass median diameter".

Therefore, any claim directed to compositions comprising therapeutically active particles comprising a therapeutically active substance and having a mass median **aerodynamic** diameter of less than 10µm or 5µm and any normalised Kurtosis value, contains subject-matter which extends beyond the content of the application as originally filed and thus does not comply with Article 123(2) EPC.

4. Consequently, the subject-matter of the main request and that of the first to sixth auxiliary requests does not comply with Article 123(2) EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The patent is revoked.

The Registrar: The Chairman:

N. Maslin U. Oswald