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Datasheet for the decision of 6 February 2018

Case Number: T 2318/15 - 3.3.07

Application Number: 01947612.6

Publication Number: 1296651

IPC: A61K9/14, A61K47/26

Language of the proceedings: EN

Title of invention:
Method of making particles for use in a pharmaceutical composition.

Patent Proprietor:
Vectura Limited

Opponent:
NORTON HEALTHCARE LIMITED

Headword:
Method of making particles/VECTURA

Relevant legal provisions:
RPBA Art. 13(1)
EPC Art. 123(2), 84, 56

Keyword:

Late-filed documents - admitted (no)
Amendments - added subject-matter (no)
Claims - clarity - (yes)
Inventive step - (yes)

Decisions cited:

T 0244/11

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Case Number: T 2318/15 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 6 February 2018

Appellant: (Patent Proprietor)	Vectura Limited 1 Prospect West Chippenham, Wiltshire SN14 6FH (GB)
Representative:	Clarke, Christopher John Vectura Limited Intellectual Property Department One Prospect West Chippenham Wiltshire SN14 6FH (GB)
Respondent: (Opponent)	NORTON HEALTHCARE LIMITED Regent House 5-7 Broadhurst Gardens Swiss Cottage London NW6 3RZ (GB)
Representative:	Gillard, Richard Edward Elkington and Fife LLP Thavies Inn House 3-4 Holborn Circus London EC1N 2HA (GB)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 7 October 2015 revoking European patent No. 1296651 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	D. Boulois
Members:	A. Usuelli
	Y. Podbielski

Summary of Facts and Submissions

I. European patent No. 1 296 651 was opposed on the grounds that its subject-matter lacked novelty and inventive step.

The following documents, were among those cited during the first-instance proceedings:

D2: WO 96/23485
D7a: US 6,645,466

II. By decision issued on 1 December 2010 the opposition division revoked the patent.

The decision of the opposition division was appealed by the patent proprietor (case T 244/11). The competent board came to the conclusion that claim 1 of the patent was novel over example 3 of D2 and decided to set aside the decision of the opposition division and to remit the case to the department of first instance for further prosecution.

III. The present appeal of the patent proprietor (hereinafter: the appellant) lies from the 2nd decision of the opposition division to revoke the patent. The decision announced during the oral proceedings held on 15 September 2015 was based on a main request and on four auxiliary requests filed with letter of 15 July 2015.

Claim 1 of the main request read as follows:

"1. A method for making a pharmaceutical composition for inhalation comprising the steps of:

a) making composite excipient particles by milling particles of an excipient material in the presence of an additive material, wherein the milling step involves mechanofusion, ultracentrifugal milling, jet milling, high pressure homogenisation, ball milling, agitator bead milling, air jet milling, pin milling, hammer milling or knife milling; and
b) adding particles of active material;
wherein the composition consists essentially of the composite excipient particles and the particles of active material, and optionally a flavouring agent and wherein the mass median aerodynamic diameter of the composite excipient particles is not more than 50 µm".

IV. According to the decision under appeal:

(a) Document D2 was the closest prior art for the assessment of inventive step of the subject-matter of claim 1 of the main request. The distinguishing feature was represented by the requirement that the method of claim 1 resulted in the preparation of particles having a mass median aerodynamic diameter (MMAD) which was not more than 50 µm. In the absence of any technical effect associated with this feature the technical problem was the provision of an alternative method for preparing a pharmaceutical composition for inhalation. In the light of the teaching of D7a the skilled person would have selected carrier particles with a MMAD which was not more than 50 µm. The main request was therefore not inventive.

(b) Auxiliary requests 1 and 4 were not admissible under Rule 80 EPC.

(c) The subject-matter of claim 1 of auxiliary request 2 was obvious in view of the teaching of documents D2 and D7a.

(d) Claim 1 of auxiliary request 3 did not comply with Article 84 EPC.

V. With the statement setting out the grounds of appeal filed on 17 February 2016 the appellant submitted a main request and three auxiliary requests.

During the oral proceedings held on 6 February 2018 the appellant modified the order of its requests. By effect of this modification the request filed on 17 February 2016 as auxiliary request 1 became the new main request (hereinafter: main request).

Claim 1 of the main request differed from claim 1 of the main request pending before the opposition division (see point III above) in the wording of step a) which read as follows (amendments compared to claim 1 of the main request before the opposition division are in bold):

"...a) making composite excipient particles by milling particles of an excipient material in the presence of an additive material **to form a continuous coating on the surfaces of the particles of excipient material**, wherein the milling step involves mechanofusion, ultracentrifugal milling, jet milling, high pressure homogenisation, ball milling, agitator bead milling, air jet milling, pin milling, hammer milling or knife milling; and..."

VI. The opponent (hereinafter: the respondent) replied to the appeal of the patent proprietor by letter of

4 July 2016. By letter dated 4 January 2018 it submitted the following documents:

D35: WO 02/43701
D36: WO 00/53157

VII. The appellant's arguments can be summarised as follows:

(a) Admissibility of documents D35 and D36

The late-filing of D35 and D36 was not justified since the appellant had filed his requests already with the statement setting out the grounds of appeal. Moreover neither D35 nor D36 were *prima facie* relevant. These documents were therefore not admissible.

(b) Main request - Article 123(2) EPC and clarity

The feature "to form a continuous coating" was based on the passage of page 4 (lines 16 to 20) of the original description. The expression "continuous coating" was unambiguous and did not result in any problem of clarity.

(c) Main request - Inventive step

Document D2 was the closest prior art for the assessment of inventive step. This document described a process wherein the particles of the carrier were mixed with an additive and then treated by gentle milling. As a consequence of this process, the particles of the carrier were only partially covered by the additive. In contrast, the method of claim 1 resulted in a complete coating of the surface of the particles. This process was illustrated in methods 7 to 9 of the patent. The technical problem was the provision of a further method

for producing particles for inhalation. There was a clear teaching in D2 to avoid a complete coating of the carrier particles with the additive. Thus, the skilled person would have not arrived to the method of claim 1 in an obvious manner.

VIII. The respondent's arguments can be summarized as follows:

(a) Admissibility of documents D35 and D36

Documents D35 and D36 were filed in reply to the appellant's argument in relation to the feature "coating".

(b) Main request - Article 123(2) EPC and clarity

There was no reference in the original application to a "continuous coating". The introduction of this feature was against Article 123(2) EPC. Moreover, in the absence of any definition the expression "continuous coating" was unclear. Its meaning could not be derived from document D2 since this was not a document reflecting the general knowledge in the art.

(c) Main request - Inventive step

The method defined in claim 1 of the main request differed from the method of D2 in the size of the particles and in the requirement that the particles were continuously coated by the additive. However, there was no evidence in the patent that the particles were indeed coated by the additive. There was no improvement linked to the reduction of the size particles. This feature did not contribute to the inventiveness of claim 1. As to the fact that the

additive was coating the particle, this feature was not against the teaching of D2. In D2 it was merely explained that it was pointless to provide a continuous coating of the particles. Thus, the invention of the patent in suit was based on a characteristic of the coating that was regarded as superfluous in D2. This could not render inventive the subject-matter of claim 1 since there was no evidence of any improvement deriving from this characteristic. Thus, the subject-matter of the main request did not comply with the requirements of Article 56 EPC.

IX. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the main request, filed on 17 February 2016 as auxiliary request 1, or on the basis of auxiliary request 1, filed on 17 February 2016 as the main request, or on the basis of one of auxiliary requests 2 or 3, filed on the same date.

The appellant furthermore requested that documents D35 and D36 not be admitted into the proceedings.

X. The respondent requested that the appeal be dismissed.

Reasons for the Decision

1. Admissibility of D35 and D36:

1.1 The respondent submitted documents D35 and D36 on 4 January 2018, i.e. about one month before the oral proceedings. The documents have been presented by the respondent as a response to the introduction in claim 1 of a feature requiring the additive to form a coating on the surface of the excipient.

1.2 The board notes that the appellant had submitted all its requests with the statement setting out the grounds of appeal. Moreover, requests in which it was specified that the particles of the excipient are coated by the additive were submitted also during the first instance proceedings. Thus, the late-filing of documents D35 and D36 is not justified.

1.3 Concerning document D35, the respondent explains that this document shows that the term "coating" is used also to designate a discontinuous covering of the particles, contrary to the position expressed by the appellant. In this regard the board notes that when in document D35 the term "coating" is used in relation to a discontinuous covering (page 3, lines 12 to 15), it is qualified by the adjective "discontinuous". Thus, D35 does not appear to indicate that the term "coating", used alone, may indicate also a partial covering. Hence, D35 does not appear *prima facie* relevant.

Furthermore, the issue concerning the interpretation of the term "coating" is of no relevance in relation to the main request in which it is explicitly stated that the coating is "continuous".

1.4 D36 has been used by the respondent in combination with document D2 to attack inventive step. The board notes that D2 is a post-published document and that during appeal proceedings the respondent questioned the validity of the priority date for the first time with its submissions of 4 January 2018.

Furthermore, the passage of D36 cited by the respondent (page 5, line 10) suggests that it may be advantageous to attain a high degree of coating of the carrier.

However, it is not clear from this passage whether the coating is obtained by a milling process as in the method of claim 1. Thus, the short passage of D2 discussed by the respondent does not allow to conclude that this document is *prima facie* relevant.

1.5 On account of the above reasons the board decides not to admit documents D35 and D36 into the appeal proceedings (Article 13(1) RPBA).

Main request

2. Article 123(2) EPC

2.1 The respondent argues that the feature "to form a continuous coating" has no basis in the original application.

2.2 On page 4 (lines 16 to 18) of the original application it is stated that the additive material may be in the form of a coating on the surface of the excipient and that the coating may be a discontinuous coating.

The board concurs with the appellant that the indication on page 4 that the coating may be discontinuous also implies that it may not be discontinuous, i.e. that it may be continuous. Hence, the introduction of the feature "to form a continuous coating" complies in the board's view with the requirements of Article 123(2) EPC.

3. Clarity

3.1 The respondent remarks that no definition is given in the description for the expression "continuous coating". In its view, the introduction of this feature

in claim 1 would render the claim unclear (Article 84 EPC).

3.2 The board considers that the term "coating" is of common use and is clear *per se* even in the absence of a definition. In document D2, for instance, it is affirmed that the word "coating" is normally understood in the art to refer to a continuous envelop around the particle (page 16, lines 23 to 27). The board sees no reasons to consider that in the context of the patent in suit a different meaning could be given to this term.

The adjective "continuous", is in the board's view likewise clear. It would be interpreted by the skilled person as indicating that there is substantially no interruption of the coating on the surface of the particle.

The board concludes from the above, that the expression "continuous coating" does not render unclear the subject-matter of claim 1.

4. Inventive step

4.1 Closest prior art

4.1.1 It is not disputed by the parties that document D2 is the closest prior art.

4.1.2 In decision T 244/11 the board concluded that the requirement that the MMAD of the particles is not more than 50 µm (see step b)) represented a distinguishing feature over the disclosure of example 3 of D2.

4.1.3 In the board's view, a further distinguishing feature over D2 is represented by the requirement that the milling step of claim 1 results in the formation of particles in which the additive material forms a continuous coating on the surface of the excipient.

Indeed, the term "coating" indicates that the additive is continuously distributed over the whole surface of excipient. As discussed above (see point 3.2) such interpretation in line with the definition given in D2 for the term "coating" ("a continuous envelop around the particle" (page 16, lines 23 to 27)).

4.1.4 In example 3 of D2 it is explained that the carrier particles comprising lactose (excipient) and leucine (additive) are prepared as described in steps (a) and (b) of example 1. The particles prepared in this process are represented in Figure 1 of D2 (see reference to Fig. 1 on page 28, line 11). Figure 1 clearly shows that the additive material (4) covers only a limited portion of the surface of the carrier. Accordingly, it does not form a coating. This is in line with the general teaching of D2 which indicates that the additive covers only a limited portion of the carrier. Such teaching emerges in particular in the following sentence of D2 (paragraph bridging pages 16 and 17): "*inspection of the carrier particles under an electron microscope shows much of the surface of each lactose particle remaining exposed with leucine particles covering only limited portions of each lactose particle and forming a discontinuous covering on each lactose particle. It is believed that the presence of such a discontinuous covering, as opposed to a "coating" is an important and advantageous feature of the present invention*".

4.2 Technical problem

4.2.1 In the light of the closest prior art, the technical problem underlying the disputed patent may be formulated as the provision of an alternative method for making pharmaceutical compositions for inhalation.

4.2.2 This technical problem is solved by the process of claim 1 which comprises a step in which particles of excipient material are milled in the presence of an additive material. The milling process applies sufficient energy to ensure effective application of the additive material. The process is illustrated in Methods 7 to 9 of the description which relate to processes of wet milling. In paragraph [0086] it is stated that these processes allow the formation of a coating around the particles. The powder obtained by this process can be used directly in an inhaler ([0074]).

The board is therefore satisfied that the problem defined in point 4.2.1 above is effectively solved by the process of claim 1.

4.3 Obviousness

4.3.1 As explained above (see point 4.1.4), in the composite particles of D2 the additive material covers only a limited portion of the carrier. On page 17 of D2 (lines 4 to 7) it is stressed that this feature of the particles, i.e. the fact that the excipient forms a discontinuous covering, rather than coating the particles, is an important and advantageous feature of the invention.

Accordingly, the teaching of D2 would not lead the skilled person to the solution now claimed, namely to a process that results in the formation of a coating of additive material around the excipient particle. Quite to the contrary, in view of the teaching of D2 the skilled person would possibly regard the formation of a coating as a detrimental factor for the properties of the composition.

4.3.2 None of the other cited documents suggests the concept of providing a process that results in the formation of a layer of additive material coating the excipient particle.

Hence, the requirement that the milling step determines the formation of a continuous coating of additive material on the surface of the excipient particles, render the subject-matter of claim 1 inventive.

In view of this conclusion there is no need to consider whether the further distinguishing feature over D2, namely the size of the composite excipient particle, is suggested by the prior art.

4.4 Hence, the subject-matter of the main request fulfils the requirements of Article 56 EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the opposition division with the order to maintain the patent on the basis of the main request, filed on 17 February 2016 as auxiliary request 1, and a description to be adapted thereto.

The Registrar: The Chairman:

S. Fabiani D. Boulois

Decision electronically authenticated