Internal distribution code:

(A) [-] Publication in OJ
(B) [-] To Chairmen and Members
(C) [-] To Chairmen
(D) [X] No distribution

Datasheet for the decision of 9 January 2019

Case Number: T 0499/14 - 3.2.02

Application Number: 06003929.4

Publication Number: 1658872

IPC: A61M15/00

Language of the proceedings: EN

Title of invention:
Powder inhaler

Patent Proprietor:
CHIESI FARMACEUTICI S.p.A.

Opponent:
NORTON HEALTHCARE LIMITED

Headword:

Relevant legal provisions:
EPC Art. 123(2), 76(1), 83, 56

Keyword:
Added subject-matter - main request (yes); third auxiliary request (no)
Sufficiency of disclosure - third auxiliary request (yes)
Inventive step - third auxiliary request (yes)

Decisions cited:

Catchword:

Europäisches Patentamt
European Patent Office
Office européen des brevets

Beschwerdekammern

Boards of Appeal

Chambres de recours

Boards of Appeal of the
European Patent Office
Richard-Reitzner-Allee 8
85540 Haar
GERMANY
Tel. +49 (0)89 2399-0
Fax +49 (0)89 2399-4465

Case Number: T 0499/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 9 January 2019

Appellant: (Opponent)	NORTON HEALTHCARE LIMITED Regent House 5-7 Broadhurst Gardens Swiss Cottage London NW6 3RZ (GB)
Representative:	Elkington & Fife LLP Prospect House 8 Pembroke Road Sevenoaks, Kent TN13 1XR (GB)
Respondent: (Patent Proprietor)	CHIESI FARMACEUTICI S.p.A. Via Palermo, 26/A 43100 Parma (IT)
Representative:	Adam, Holger Kraus & Weisert Patentanwälte PartGmbB Thomas-Wimmer-Ring 15 80539 München (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 18 December 2013 rejecting the opposition filed against European patent No. 1658872 pursuant to Article 101(2) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	M. Stern
	D. Ceccarelli

Summary of Facts and Submissions

I. The opponent lodged an appeal against the decision of the Opposition Division, posted on 18 December 2013, rejecting the opposition against the European patent No. 1 658 872.

II. Notice of appeal was filed on 26 February 2014, and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 25 April 2014.

III. The Board issued a communication with the summons to oral proceedings dated 18 October 2018.

IV. By letter dated 7 December 2018, the respondent (patent proprietor) filed a test report.

V. Oral proceedings were held on 9 January 2019.

The appellant (opponent) requested that the decision under appeal be set aside and that the patent be revoked.

The respondent (patent proprietor) requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of the third to sixth auxiliary requests, all filed with letter dated 7 December 2018. The request for hearing of a witness and the first and second auxiliary requests filed with letter dated 7 December 2018 were withdrawn.

VI. The following documents are cited in the present decision:

D2: WO-A-01/097 889
D4: WO-A-90/15 635
D5: US-A-2003/0192532.

VII. Claim 1 of the patent (**main request**) reads as follows:

"1. Deagglomerator arrangement (16) for deagglomerating a powdered medicament, comprising:
a vortex chamber (73),
at least two air inlets (75) for directing air tangentially into the vortex chamber (73), and
an outlet (74) for outputting air with the deagglomerated powdered medicament, the outlet (74) being spaced from air inlets (75) in an axial direction of the deagglomerator arrangement (16),
characterized in that
the vortex chamber (73) has an opening for the supply of the powdered medicament,
an outer wall of each air inlet (75) is connected to the respective other air inlet (75) by a semicircular or arched wall portion (79) of the vortex chamber (73), each semicircular or arched wall portion (79) is positioned non-concentric to a base circle (77) defining a diameter d of the vortex chamber (73), and
the vortex chamber (73) has the diameter d of 6mm ≤ d ≤ 10mm."

VIII. Claim 1 of the **third auxiliary request** reads as follows (amendments to claim 1 of the main request highlighted by the Board):

"1. Deagglomerator arrangement (16) for deagglomerating a powdered medicament, comprising:

a vortex chamber (73), wherein the vortex chamber (73) has an opening for the supply of the powdered medicament,

~~at least~~ two diametrically opposed air inlets (75) for directing air tangentially into the vortex chamber (73), and

an outlet (74) for outputting air with the deagglomerated powdered medicament, the outlet (74) being spaced from the air inlets (75) in an axial direction of the deagglomerator arrangement (16),

characterized in that

~~the vortex chamber (73) has an opening for the supply of the powdered medicament,~~

an outer wall of each air inlet (75) is connected to the respective other air inlet (75) by a semicircular ~~or arched~~ wall portion (79) of the vortex chamber (73), each semicircular ~~or arched~~ wall portion (79) is positioned non-concentric to a base circle (77) defining a diameter d of the vortex chamber (73), the center of the respective semicircle of the wall portion (79) being positioned on the diameter connecting both air inlets (75) of the vortex chamber (73), and

the vortex chamber (73) has the diameter d of 6mm ≤ d ≤ 10mm."

Claims 2 to 15 of the third auxiliary request are dependent claims.

IX. The arguments of the appellant which are relevant for the present decision may be summarised as follows:

Main request - Article 100 (c) EPC in combination with Article 123(2) EPC

The arguments of the appellant regarding the third auxiliary request that are relevant for the present decision are essentially those on which the reasons set out below are based.

Third auxiliary request

- Claim 1 contravened Article 123(2) EPC since page 16 of the description included further features which were not included in claim 1. For example, on page 16, lines 2 to 4, the deagglomerator arrangement was disclosed as having an air outlet which was axially aligned with the vortex chamber such that airflow within the chamber lead to a strong velocity gradient. Therefore, the subject-matter of claim 1 extended beyond the content of the application as filed.

- Moreover, dependent claim 2 defined the placement of the air inlets along the circumference of the base circle as disclosed on page 37, lines 5 and 6, without defining the feature concerning a circular chamber outlet disclosed in combination for the same embodiment of Figure 27 (page 36, lines 22-23). The features of claim 12 (claim 13 of the patent as granted) were disclosed on page 38, lines 13 to 17, in combination with the feature of diametrically opposed air inlets, which were left out in claim 1 of the granted patent. There was, moreover, no basis for the powder inhaler of claim 15 (claim 16 of the patent as granted), because features disclosed on page 15, line 32 to page 16, line 16 had not been included in the definition of the powder inhaler. Hence, claims 2, 12 and 15 of the third auxiliary request contravened Article 123(2) EPC.

- Claims 12 and 15 (claims 13 and 16 of the patent as granted) contravened for analogous reasons Article 76(1) EPC.

- The invention was not sufficiently disclosed (Articles 100(b) and 83 EPC) because the skilled person would have been unable to provide, without undue burden, a vortex chamber having the required diameter with sufficient reliability. In particular, the vortex chamber as described on column 17, lines 39 to 41 had a generally "elliptical" cross section. Therefore, the diameter of the vortex chamber was a wholly ambiguous concept. Furthermore, although in connection with Figure 27 the patent explained how the diameter of the vortex chamber could be identified and measured, this was just one example of how the invention could be carried out. The disclosure of one such way would be sufficient only if it allowed the invention to be carried out across the whole range claimed. In the present case, however, there were alternative plausible constructions for measuring the diameter of the vortex chamber leading to different measured results.

- The closest prior art was document D2. The vortex chamber shown in Figure 5 of D2 contained circular wall portions which were connected to straight wall sections of each air inlet. The straight sections served to space the circular sections away from an imaginary "base circle" of the vortex chamber. Hence, in D2 the two circular sections of the wall of the vortex chamber were positioned non-concentric to a base circle defining a diameter d of the vortex chamber. The subject-matter of claim 1 differed from D2 in that the wall portions of the vortex chamber were *semi*circular and that the vortex chamber had a diameter of 6 mm to 10 mm. There was no evidence in the opposed patent or

even a plausible theoretical explanation as to how any technical benefit arose from the wall portions being semicircular and positioned non-concentric to the base circle of the vortex chamber. The technical problem was therefore to merely find an alternative construction to the chamber disclosed in D2. Hence, no inventiveness was required to devise the chamber with semicircular non-concentric wall portions as claimed. Moreover, non-concentric vanes were employed in D5 (Figure 2) for controlling the size of atomized particles. Furthermore, it would have been obvious to the skilled person to select a diameter for the vortex chamber in the range from 6 mm to 10 mm. D4 disclosed to vary the diameter of a vortex chamber to optimise the inhalation resistance and thus the flow rate, proposing an optimal diameter in the range of 10 mm to 20 mm (page 12, lines 11-12).

X. The arguments of the respondent which are relevant for the present decision may be summarised as follows:

Main request - Article 100 (c) EPC in combination with Article 123(2) EPC

The paragraph bridging pages 15 and 16 of the application as filed, especially page 16, lines 12-16, provided a basis for the definition of the geometry of the wall portions in the characterizing portion of claim 1, namely that "an outer wall of each air inlet is connected to the respective other air inlet by a semicircular or arched wall portion of the vortex chamber, each semicircular or arched wall portion is positioned non-concentric to a base circle defining a diameter d of the vortex chamber". This section of the description did not mention two diametrically opposed air inlets. Nor did it mention that the centres of the

semicircular or arched wall portions were located on the diameter of the vortex chamber. Dependent claim 13 as originally filed, whose features were incorporated into claim 1 during the examination procedure of the opposed patent, referred to "two diametrically opposed air inlets" and defined that the centre of the respective semicircle of the wall portion was positioned on the diameter of the vortex chamber. However, the aforesaid passages of the description provided a more general teaching. As explicitly stated on page 35, lines 16 to 20 of the description as filed, Figure 26 depicted only a schematic perspective view of the deagglomerator arrangement according to a preferred embodiment. Thus, it would have been clear to a skilled reader that the invention was not limited to what was shown in Figure 26. Finally, page 38, lines 18-33, and especially page 38, line 29, clearly disclosed that the wall portions of the vortex chamber were semicircular or arched, as defined in claim 1 as granted. Arched wall portions were considered to have at least partially a constant radius of curvature.

Third auxiliary request

The arguments of the respondent regarding the third auxiliary request that are relevant for the present decision are essentially those on which the reasons set out below are based.

Reasons for the Decision

1. The appeal is admissible

2. *The invention*

The invention relates to an arrangement for deagglomerating a powdered medicament (described in the patent from paragraph [0063] onwards in connection with Figures 26 and 27) constructed to have a particularly strong deagglomerating effect. Paragraph [0064] states that the purpose of the arrangement is to produce turbulences within the inhalation channel to pulverise agglomerations of the medicament.

The deagglomerator arrangement shown in Figures 26 and 27 comprises, in essence, two diametrically opposed air inlets (75) for directing air tangentially into a vortex chamber (73), an air outlet (74) for outputting air with the deagglomerated powdered medicament and an opening for the supply of the powdered medicament. An outer wall of each air inlet is connected to the respective other air inlet by a semicircular wall portion (79) of the swirl chamber, each of the semicircular wall portions being positioned non-concentric to a base circle defining a diameter d of the vortex chamber (Figures 27 and 28A to 28C), the centres of the semicircle of the wall portions being positioned on the diameter connecting both air inlets, and the diameter d having the dimensions 6 mm ≤ d ≤ 10 mm.

3. Main request - Article 100(c) EPC in combination with Article 123(2) EPC

3.1 Claim 1 of the main request (granted patent) defines the subject-matter of original claim 1 further limited by additional features. Firstly, it defines the expression of "at least *two* air inlets" which limits the original range "at least *one* air inlet" based on

the example with *two* air inlets disclosed on page 38, lines 8 to 33 (and depicted in Figure 27), in particular, page 38, lines 8 to 10. Furthermore, claim 1 contains further geometrical limitations of the vortex chamber, i.e. "an outer wall of each air inlet is connected to the respective other air inlet by a semicircular ... wall portion of the vortex chamber, each semicircular ... wall portion is positioned non-concentric to a base circle defining a diameter d of the vortex chamber", which are recited in original dependent claims 13 and 14. Finally, claim 1 defines a further alternative to the mentioned "semicircular" wall portions, which concerns "arched" wall portions, an alternative which is mentioned (just once) on page 38, lines 28 to 31.

3.2 The aforementioned limitations disclosed in original claims 13 and 14 do not refer, however, to *arched* wall portions. Contrary to the view of the respondent, the Board does not consider the paragraph bridging pages 15 and 16 of the application as filed as a direct and unambiguous basis for claiming *arched* wall portions in isolation from the specific context of page 38, lines 28 to 31 which refers to Figures 26 and 27. It is true that the paragraph bridging pages 15 and 16 refers to the non-concentric placement of circular outer wall portions (i.e. arcs) of the vortex chamber (page 16, lines 12 to 16) without mentioning that the centres of the circular wall portions are positioned on the diameter of the vortex chamber connecting two air inlets, as specified in original claim 13. However, this paragraph is entirely silent regarding the embodiment of *arched* wall portions included in claim 1 as well. This embodiment is mentioned just once in the entire application as filed, on page 38, lines 28 to 31. The notion of an *arched* wall portion is not to be

equated to a wall portion with the shape of an *arc*, as the respondent submitted. Whilst the term "arch" designates a generally curved structure, an "arc" denotes, more specifically, a segment of a circle.

3.3 As a consequence, the subject-matter of claim 1 of the granted patent extends beyond the content of the application as filed. It therefore contravenes the requirements of Article 123(2) EPC.

3.4 Hence, the grounds for opposition under Article 100(c) EPC prejudice the maintenance of the patent as granted.

4. Third auxiliary request

4.1 Articles 123(2) and 76(1) EPC

4.1.1 Claim 1 of the third auxiliary request includes the features of original claim 13 which were absent from claim 1 of the granted patent and no longer claims the alternative of arched wall portions. This remedies the aforementioned objection of added subject-matter. The feature of the centre of the respective semicircle of the wall portion being positioned on the diameter *connecting both air inlets* is disclosed on page 38, lines 18 to 24.

Hence, claim 1 satisfies the requirements of Article 123(2) EPC.

4.1.2 The feature of dependent claim 2 defining the placement of the air inlets along the circumference of the base circle is disclosed on page 37, lines 5 and 6. Nevertheless, the appellant objected that other features disclosed in combination for the same embodiment of Figure 27, notably the feature of a

circular chamber outlet (page 36, lines 22 and 23), had been omitted in claim 2, thereby leading to an unallowable intermediate generalisation. The Board, however, considers that the skilled person would recognise that the placement of the air inlets on the chamber and the form of the chamber outlet are two characteristics which are not directly and inextricably linked to each other. It is therefore permissible to define the former independently from the latter without unallowably generalising the content of the original application.

The features of claim 12 (corresponding to claim 13 of the patent as granted) are disclosed on page 38, lines 13 to 17, as acknowledged by the appellant. Moreover, since these features are defined in combination with the feature of diametrically opposed air inlets recited in claim 1, the appellant's objection in this respect is moot.

Claim 15 (corresponding to claim 16 of the patent as granted) defines a powder inhaler having the features of a deagglomeration arrangement according to any one of claims 1 to 14. Basis for this definition is found on page 8, lines 22 to 28, where the powder inhaler is disclosed as having the features defined in claim 1 and the dependent claims defining preferred and advantageous embodiments of the present invention.

Hence, dependent claims 2, 12 and 15 of the third auxiliary request satisfy the requirements of Article 123(2) EPC.

4.1.3 The above objections of added subject-matter of dependent claims 12 and 15 (claims 13 and 16 of the

granted patent) were also raised under Article 76(1) EPC.

The parent application 02 016 908.2 as filed is entirely equivalent to the present application as filed in that it particularly includes:

- an independent claim 59 which is identical to original claim 1 of the present application as filed
- dependent claims 64 and 71 which in combination correspond to original claim 13 of the present application as filed
- a dependent claim 72 which is identical to original claim 14 of the present application as filed
- a description which is identical to that of the present application as filed.

Thus, claims 12 and 15 of the third auxiliary request satisfy the requirements of Article 76(1) EPC.

4.2 Article 83 EPC

4.2.1 The appellant argued that the disclosure of the granted patent was insufficient within the meaning of Article 83 EPC because the skilled person would have been unable to provide, without undue burden, a vortex chamber having the diameter specified in claim 1 with sufficient reliability.

4.2.2 The Board does not share this view for the following reasons.

An example explaining how the diameter (d) of the vortex chamber (73) may be identified is disclosed in the patent with reference to the embodiment depicted in Figure 27. Hence, the teaching of the patent enables

the skilled person to carry out the invention as claimed. It may be plausible that other ways for measuring the diameter of the vortex chamber are conceivable, thus leading to different measured results, as asserted by the appellant. Such a variance of results may introduce uncertainty regarding the scope of the claim. This is, however, a question related to Article 84 EPC rather than Article 83 EPC.

The reference in column 17, lines 39 to 41 to a vortex chamber with a generally "elliptical" cross section, which was mentioned by the appellant, may be seen as not being consistent with the definition in claim 1 of the granted patent of a circular cross section. Such an inconsistent statement in the description (which could probably have been objected to and remedied in first-instance proceedings) does not, however, detract from the aforementioned fact that the patent contains an example enabling the skilled person to carry out the invention as claimed.

4.2.3 The Board therefore concludes that the patent discloses the subject-matter of claim 1 of the third auxiliary request in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, in accordance with Article 83 EPC.

4.3 *Inventive step*

4.3.1 Document D2 is undisputedly the closest prior art. It discloses a deagglomerator arrangement for deagglomerating a powdered medicament (Figure 1) comprising a vortex chamber (swirl chamber 14) with an opening (22) for the supply of the powdered medicament and two diametrically opposed air inlets (24, 25) for directing air tangentially into the vortex chamber

(page 5, line 28 to page 6, line 2), and an outlet (20) for outputting air with the deagglomerated powdered medicament which is spaced from the air inlets (24, 25) in an axial direction of the deagglomerator arrangement. As shown in Figures 1 and 5, an outer wall of each air inlet (24, 25) has a straight section which connects to a circular wall portion (12) of the vortex chamber (page 5, lines 9 to 14) which is connected to the respective other air inlet.

4.3.2 The features of the characterising portion of claim 1 are not disclosed in D2.

As shown in Figures 1 and 5, the extension of the straight sections of the outer wall of each air inlet is such that the circular wall portions of the vortex chamber span an angle well below 180°, so that the wall portions of the vortex chamber are not **semi**circular, as claim 1 defines.

The Board does not agree with the appellant that Figure 5 of D2 is conducive to concluding that the straight sections of the outer wall of the air inlets serve to space the circular sections of the chamber wall away from an imaginary base circle. If anything, the passage on page 5, lines 11 to 14 stating that the vortex chamber includes circular cross-sectional areas arranged transverse to the axis A appears to imply that the chamber is axially symmetric. For certain, this passage, or any other in D2, does not directly and unambiguously disclose that the two circular sections of the wall of the vortex chamber are positioned **non-concentric** to a base circle defining a diameter d of the vortex chamber, as recited in claim 1.

The claimed diameter range of the vortex chamber of **6mm ≤ d ≤ 10mm** is not disclosed in D2 either.

4.3.3 The patent states that the overall technical problem underlying the invention was to provide a deagglomerator arrangement allowing an improved pulverisation of agglomerations of a powdered medicament (paragraph [0017]). The purpose of the deagglomerator arrangement was to produce turbulences to pulverise agglomerations of the medicament (paragraph [0064]). The patent explains in further detail that the semicircular wall portions of the vortex chamber which are non-concentric relative to the interior of the wall chamber, i.e. the "base circle", contributed to a very effective deagglomeration within the vortex chamber (paragraph [0076], last sentence). Paragraphs [0071] to [0074] refer to studies which had been performed showing that the diameter d of the base circle of the vortex chamber had an important influence on the deagglomerator effect, a diameter d between 6 mm and 10 mm providing a very good efficiency.

4.3.4 In view of the effects described in the patent, the Board dismisses the appellant's claim that there was no evidence in the opposed patent or even a plausible theoretical explanation as to how any technical benefit arose from the wall portions being semicircular and positioned non-concentric to the base circle of the vortex chamber. The Board consequently agrees with the respondent that the objective technical problem may be formulated as providing a deagglomerator arrangement which allows an improved pulverisation of agglomerations of a powdered medicament, as mentioned in paragraph [0017] of the patent.

4.3.5 The Board therefore disagrees with the appellant that the objective technical problem may be formulated as merely finding an alternative construction to the chamber disclosed in D2. Moreover, even if one were to assume, for the sake of argument, that it was permissible to formulate the technical problem along these lines, the skilled person would have not readily modified the vortex chamber of D2 the way claim 1 prescribes. As indicated under point 4.3.2 above, in the vortex chamber depicted in Figures 1 and 5 of D2, due to the extension of the straight sections of the outer wall of each air inlet, the circular wall portions of the vortex chamber span an angle well below 180°. It would hence be technically unfeasible to replace these circular wall portions of D2 by considerably extended ones spanning full semicircles while at the same time having the air inlets directing air tangentially into the vortex chamber, as required by the claim. When queried in this respect by the Board during oral proceedings, the appellant did not actually explain how this could be done. The Board therefore concludes that D2 is not prior art which the skilled person would have readily modified so as to arrive at a vortex chamber with non-concentric semicircular wall portions as defined in claim 1.

The appellant's reference to D5 in this respect is not relevant either. D5 discloses a swirling chamber (30) of considerably different construction to that of D2 having walls or vanes (26, 27) with a generally curved shape (Figure 3) for generating fluid swirl and effectively directing fluid flow of particles of atomized medication (paragraphs [0038] and [0042]). The vanes of D5 are certainly not non-concentric semicircular walls as claimed.

4.3.6 In view of the non-obviousness of the aforementioned features, there is no need for the Board to establish whether the skilled person, considering the teaching of D4, would have readily devised the diameter of the vortex chamber of D2 in the claimed range of 6 to 10 mm, even if the diameter has an important influence on the deagglomerator effect of the chamber too, as explained in paragraph [0071] of the patent.

4.3.7 It follows that the subject-matter of claim 1 of the third auxiliary request is not obvious to a person skilled in the art and therefore meets the requirement of Article 56 EPC.

4.4 The Board concludes that the objections raised do not prejudice the maintenance of the patent on the basis of the third auxiliary request.

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 with the order to maintain the patent on the basis of:

   - claims 1 to 15 of the third auxiliary request filed with letter dated 7 December 2018;

   - description: columns 1 to 4, 7 to 16, 19 and 20 of the patent as granted and columns 5, 6, 17 and 18 filed during the oral proceedings; and

   - Figures 1 to 28C of the patent as granted.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated