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Datasheet for the decision of 5 June 2018

Case Number: T 0969/14 - 3.3.07

Application Number: 07110708.0

Publication Number: 1829533

A61K9/72, A61K9/14 IPC:

Language of the proceedings: EN

Title of invention:

Pharmaceutical formulations for dry powder inhalers

Patent Proprietor:

Vectura Limited

Opponent:

Norton Healthcare Ltd

Headword:

Pharmaceutical formulations for dry powder inhalers/Vectura Limited

Relevant legal provisions:

EPC Art. 87(1), 54(3)RPBA Art. 12(4)

Keyword:

Transfer of partial priority (yes)

Main request and auxiliary requests 1-3 - Validity of the priority (no)

Main request and auxiliary requests 1-3 - Novelty under Article 54(3) EPC (no)

Auxiliary request 4 - Admission into the proceedings (no)

Decisions cited:

G 0001/15, T 0015/01, T 0205/14

Catchword:

Cf. points 1.2 and 1.3



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 0969/14 - 3.3.07

DECISION
of Technical Board of Appeal 3.3.07
of 5 June 2018

Appellant: Vectura Limited

(Patent Proprietor) 1 Prospect West

(Patent Proprietor) 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: Norton Healthcare Ltd

(Opponent) 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 21 February 2014 revoking European patent No. 1829533

pursuant to Article 101(3)(b) EPC.

Composition of the Board:

Chairman J. Riolo
Members: D. Boulois
P. Schmitz

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Summary of Facts and Submissions

I. European patent No. 1 829 533 was granted on the basis of a set of 20 claims. The underlying patent application was filed on 17 April 2001 and claims priority from EP 00113608.4 filed on 27 June 2000 by Chiesi Farmaceutici S.p.A..

Independent claim 1 as granted read as follows:

- "1. A powder for use in a dry powder inhaler, the powder comprising:
- i) a fraction of fine particle size constituted of a mixture prepared by co-micronising a physiologically acceptable excipient and an additive, the mixture having a mean particle size of less than 35 μ m; ii) a fraction of coarse particles constituted of a physiologically acceptable carrier having a particle size of at least 100 μ m; and
- iii) at least one active ingredient having a particle size of less than 10 μm ;
- said mixture (i) being composed of up to 99% by weight of particles of the excipient and at least 1% by weight of additive and the ratio between the fine excipient particles and the coarse carrier particles being between 1:99 and 40:60% by weight, and wherein the additive partially coats the surface of both the excipients and the coarse particles."
- II. An opposition was filed against the granted patent under Article 100 (a), (b) and (c) EPC on the grounds that its subject-matter lacked novelty and inventive step, was not sufficiently disclosed and extended beyond the content of the application as filed.

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- III. The appeal by the patent proprietor lies from the decision of the opposition division to revoke the patent. The decision was based on 5 sets of claims, namely the claims as granted as main request, the claims filed as auxiliary requests 1-3 with letter dated 19 November 2012 and the claims filed as auxiliary request 4 with letter dated 16 December 2013.
- IV. The documents cited during the opposition proceedings included the following:

D14: WO 01/78693 filed by Chiesi on 17 April 2001 and published on 25 October 2001

D16: EP 00113608.4

D19: Assignment of EP 00113608.4 dated 12 April 2001 D20: Statement from Chiesi, dated 13 December 2013

V. According to the decision under appeal, the main request met the requirements of Article 123(2) EPC and the claimed invention was considered to be sufficiently disclosed.

Regarding the priority claim from D16, the assignment D19 could not validly demonstrate the transfer of the right of priority from Chiesi to the patentee Vectura. Chiesi also claimed priority from D16 for the application D14. This was an indication that the right of priority was not actually transferred with D19 or with the Supplemental Agreement mentioned therein. Given that the priority from D16 was not valid, document D14 became prior art under Article 54(3) EPC. The same process and composition was disclosed in D14 and it was concluded that claim 1 of the main request was not novel over D14.

Auxiliary requests 1 and 2 did not meet the requirements of Article 123(2) EPC.

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The subject-matter of claim 1 of auxiliary requests 3 and 4 was not novel over D14, for the same reasons as the main request.

VI. The patent proprietor (hereinafter called appellant) filed an appeal against said decision. With the statement setting out the grounds of appeal dated 2 July 2014, the appellant filed auxiliary requests 1-4 and submitted the following pieces of evidence:

D22: Redacted Supplemental Agreement dated 22nd January

2001 and signed on 30th January 2001

D23: Assignment dated 13th April 2001

D24: Declaration from Richard Summersell and Marco Poletti

The main request corresponded to the claims as granted.

Independent claim 1 of auxiliary requests 1-4 read as follows, difference(s) compared with claim 1 as granted shown in bold:

Auxiliary request 1

- "1. A powder for use in a dry powder inhaler, the powder comprising:
- i) a fraction of fine particle size constituted of a mixture prepared by co-micronising a physiologically acceptable excipient and an additive, the mixture having a mean particle size of less than 35 μ m; ii) a fraction of coarse particles constituted of a physiologically acceptable carrier having a particle

size of at least 100 µm; and

iii) at least one active ingredient having a particle size of less than 10 μm ;

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said mixture (i) being composed of up to 99% by weight of particles of the excipient and at least 1% by weight of additive and the ratio between the fine excipient particles and the coarse carrier particles being between 1:99 and 40:60% by weight, and wherein the additive partially coats the surface of both the excipients and the coarse particles,

wherein the additive is magnesium stearate."

Auxiliary request 2

1. A process for making a powder, comprising:

- i) a fraction of fine particle size constituted of a mixture prepared by co-micronising a physiologically acceptable excipient and an additive, the mixture having a mean particle size of less than 35 μm ;
- ii) a fraction of coarse particles constituted of a physiologically acceptable carrier having a particle size of at least 100 μm ; and
- iii) at least one active ingredient having a particle size of less than 10 μm ;
- said mixture (i) being composed of up to 99% by weight of particles of the excipient and at least 1% by weight of additive and the ratio between the fine excipient particles and the coarse carrier particles being between 1:99 and 40:60% by weight, and wherein the additive partially coats the surface of both the excipients and the coarse particles,

said process including the steps of:

- a) co-micronising the excipient particles and the additive particles so as to significantly reduce their particle size;
- b) spheronising by mixing the resulting mixture with the coarse carrier particles such that mixture particles adhere to the surface of the coarse carrier particles;

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c) adding by mixing the active particles to the spheronised particles.

Auxiliary request 3

- "1. A powder for use in a dry powder inhaler, the powder comprising:
- i) a fraction of fine particle size constituted of a mixture prepared by co-micronising a physiologically acceptable excipient and an additive, the mixture having a mean particle size of less than 35 μm ; ii) a fraction of coarse particles constituted of a
- physiologically acceptable carrier having a particle size of between 210 and 355 µm and
- iii) at least one active ingredient having a particle size of less than $6~\mu m;$

said mixture (i) being composed of up to 99% by weight of particles of the excipient and at least 1% by weight of additive and the ratio between the fine excipient particles and the coarse carrier particles being between 1:99 and 40:60% by weight, and wherein the additive partially coats the surface of both the excipients and the coarse particles."

Auxiliary request 4

- "1. A powder for use in a dry powder inhaler, the powder comprising:
- i) a fraction of fine particle size constituted of a mixture prepared by co-micronising a physiologically acceptable excipient and an additive, the mixture having a mean particle size of less than 35 μ m; ii) a fraction of coarse particles constituted of a physiologically acceptable carrier having a particle size of at least 100 μ m; and

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iii) at least one active ingredient having a particle size of less than 10 μm ; said mixture (i) being composed of up to 99% by weight of particles of the excipient and at least 1% by weight of additive and the ratio between the fine excipient

of additive and the ratio between the fine excipient particles and the coarse carrier particles being between 1:99 and 40:60% by weight, and wherein the additive partially coats the surface of both the excipients and the coarse particles,

wherein the additive is magnesium stearate and the active ingredient(s) is (are) not selected from budesonide and its epimers, formoterol, TA2005 and its stereoisomers, salts thereof, and combinations thereof."

- VII. A communication from the Board was sent to the parties. In this it was stated in particular that the patent proprietor did not have a priority right for some specific formulations which were claimed and that D14 was relevant for novelty for this reason.
- VIII. Oral proceedings took place on 5 May 2018.
- IX. The arguments of the appellant may be summarised as follows:

Validity of the priority

Between Vectura and Chiesi existed a joint venture. Within that context, it was agreed that Vectura could file patent applications, one of which is the one underlying the opposed patent, claiming general formulations of powders for use in dry powder inhalers. Chiesi could file its own application (D14), claiming formulations having the same general components as in the opposed patent, but in which the additive was

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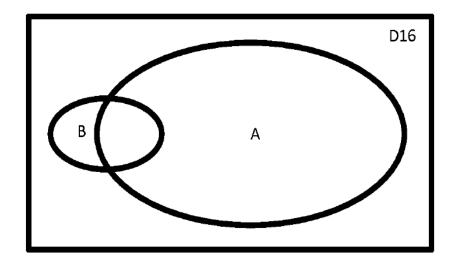
specified to be magnesium stearate and the active was selected from a specified list (so called Programme 2 formulations). Both patent applications were filed on the same date. Both applications claimed priority from D16. With the Supplemental Agreement (D22) which was executed on 30 January 2001, Chiesi assigned its rights to the ownership of application D16 to Vectura. In clause 4 of this assignment, it was agreed that Vectura would provide a formal assignment of the right to claim priority from D16 for the specific Programme 2 formulations. This re-assignment was executed on 13 April 2001 with the final assignment (D23). Thus, the effect was that Chiesi owned the right to claim priority from D16 for the specific formulations, for which they filed the application D14, whilst maintaining Vectura's right to claim priority from D16 for the opposed patent claiming the general formulations.

In the present case, there were actually two inventions:

- Invention A (claimed in the contested patent) related to the general formulations and specified co-micronised particular fine excipient and coarse carrier.
- Invention B (claimed in D14 and its resulting patent) related to the Programme 2 formulations in which the additive was magnesium stearate and the active was from a specified list.

According to the appellant, this was illustrated by the following diagram:

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The two inventions resulted in two patents, i.e. the contested patent and that granted from D14.

It was correct that Vectura did not have the priority right for invention B, it did however not follow that Vectura's priority claim for invention A was invalid. In each case, the "same invention" (invention A and invention B respectively) was specified in the priority document and the granted patent. D22, D19 and D23 allowed Vectura to retain the right to claim priority from D16 for invention A, and also to assign the priority right for invention B to Chiesi. The fact that there was some overlapping subject-matter between the inventions did not invalidate the priority claims. It has been established in T 015/01 that there was no exhaustion of priority rights, so that the same right of priority could be validly claimed by more than one European patent application.

Novelty over D14 under Article 54(3) EPC

Since the priority claim from D16 was valid, D14 was not part of the state of the art. Therefore the

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subject-matter of the main request and auxiliary requests 1-3 met the requirements of novelty.

Admission of auxiliary request 4 into the proceedings

The patentee could not file D22 and D23 during the opposition proceedings, in view of a confidentiality agreement with Chiesi. The fact that auxiliary request 4 had not been filed during the opposition proceedings was not resulting from a bad conduct of the patentee. The patentee also requested that the case not be remitted to the opposition division on the basis of this request to show its good will.

X. The arguments of the respondent may be summarised as follows

Validity of the priority

The opposed patent claimed priority from EP 00113608.4 (D16) which was filed in the name of Chiesi Farmaceutici S.p.A. and the application which became the opposed patent was filed in the name of Vectura Ltd. This issue was relevant because there was intervening prior art, D14, in the name of Chiesi, which also claimed priority from D16.

Agreements between Chiesi and Vectura on file which were relevant to the issue of the priority entitlement of the opposed patent were the following:

- i) D22 assigned "ownership of Application 3 (D16)" from Chiesi to Vectura. However, it did not mention the separate right to claim priority.
- ii) D19 was a so-called "confirmatory" assignment. Paragraph 1a referred to the assignment of "rights", but did not mention the right to claim priority.

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iii) D23 assigned the right to claim priority from Vectura to Chiesi for a certain limited subject-matter.

G 01/15 had set out that partial priorities were acceptable regardless of whether the subject-matter was explicitly divided in claims of the patent in question. Thus, in the present case, there existed a partial priority for the subject-matter of the Programme 2 formulations, and a separate partial priority for the remaining subject-matter. In the patentee's diagram, there existed separate partial priorities for (i) the subject-matter of area of overlap of A and B and (ii) the subject-matter of A minus B.

Given that claim 1 of the main request claimed the whole of the subject-matter of A, but was only entitled to the partial priority of (ii) the subject-matter of A minus B, it lacked novelty over (i) the subject matter of area of overlap of A and B, which was the subject-matter of D14.

Novelty over D14 under Article 54(3) EPC

The subject-matter of claim 1 of the opposed patent was not entitled to claim priority from D16. This made D14 a relevant prior art under Article 54(3) EPC.

Admission of Auxiliary request 4 into the proceedings

Auxiliary request 4 should have been presented during opposition proceedings. The opponent had challenged priority entitlement and had raised lack of novelty over D14 in the statement of opposition. The patentee had argued in reply that he was fully entitled to claim priority from D16. This was despite the fact that he

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knew (see D23) that priority rights in a key part of the invention had been assigned back to Chiesi in 2001. The opposition division took the preliminary opinion that D14 was prior art pursuant to Article 54(3) EPC. The patentee was therefore adequately warned by the opposition division that D14 was potentially relevant as prior art. At this point, the patentee was well aware that further assignments had been executed, and that there had even been an explicit reference to the transfer of priority rights in respect of certain subject-matter. It also turned out that he even had a pre-prepared disclaimer set out in claim 17 of the application as filed (see the WO specification) to address this very issue. However, the patentee chose not to file a request including this disclaimer, even not during oral proceedings before the opposition division, when said opposition division held that the patent as granted lacked novelty over D14 and the patentee was invited to respond. The patentee had stated that he did not want to file any further requests.

Only on appeal the patentee decided to file D22 and D23 and auxiliary request 4. It was clear from the dates of D22 and D23 that the patentee had these documents in his possession from the outset of the opposition proceedings. It was also clear from claim 17 of the application as filed (see the WO specification), that the patentee was aware that limitation to the subjectmatter of auxiliary request 4 was an option to establish novelty over D14.

XI. Requests

The appellant requested that the decision under appeal be set aside and that the patent be maintained as

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granted (main request) or on the basis of one of auxiliary requests 1 to 4 filed with letter dated 2 July 2014.

The respondent requested that the appeal be dismissed and that auxiliary request 4 not be admitted into the proceedings.

Reasons for the Decision

- 1. Validity of the priority
- 1.1 Pursuant to Article 87(1) EPC, a right of priority originates in the applicant of a first application. Therefore, in principle, the applicant has to be the same for the first application and for the subsequent application for which the right of priority is invoked. However, pursuant to Article 87(1) EPC, the right of priority may also be invoked by the "successor in title" of the person who has filed the first application. By reference to the "successor in title", it is recognised that the right of priority, being a legal right, may be transferred from the original applicant to a third person. It is generally accepted that the right of priority is transferable independently of the corresponding first application. The transfer must have occurred before the filing date of the subsequent application. This is well established jurisprudence of the Boards of Appeal (cf T 205/14 of 18 June 2015, with further references).
- 1.2 The application EP 00113608.4 (D16) was filed on 27 June 2000 in the name of Chiesi Farmaceutici SpA (in the following Chiesi), and the application which became the contested patent was filed in the name of Vectura Ltd (in the following Vectura) on 17 April 2001. Thus,

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it needs to be decided whether or not on the date of filing of the present application Vectura owned the priority right resulting from D16. As to this regard, the appellant has submitted documents D19, D20, D22, D23 and D24 to prove the transfer of the right of priority.

- 1.2.1 D19, the only assignment document filed before the opposition division, is a Confirmatory Assignment, confirming the transfer of the rights in application 3 (i.e. D16) effected by a Supplemental Agreement. From this it is not clear whether only the application or also the priority right had been transferred.
- 1.2.2 The Supplemental Agreement (D22) was only filed in appeal proceedings. In point 2 of it, Chiesi assigns to Vectura its rights to the ownership of application 3 (D16), but subject to the terms of this Supplemental Agreement. In point 4 it is specified that Chiesi agrees to file one or more applications taking priority from i.a. application 3 (D16) and relating to the specific Programme 2 formulations. For this purpose, Vectura will provide to Ciesi before 1 February 2001 a formal assignment of the right to claim priority for such applications from application 3 (D16). Point 5 contains that before 17 April 2001, Vectura will continue with a separate application based around the broader claims of application 3 (D16) but not including claims directed to the specific Programme 2 formulations.

In pursuance of this agreement, an assignment was executed on 13 April 2001 (D23), in which Vectura reassigned to Chiesi the right to claim priority from application 3 (D16) in worldwide patent applications insofar and only insofar as said worldwide patent applications shall claim the Programme 2 formulations.

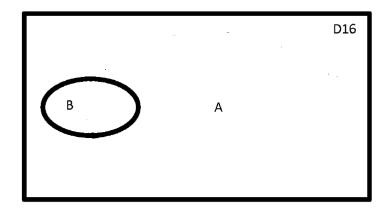
From this it is clear that Vectura owned, at the date of filing of their patent application, the priority right from D16, with the exception of the priority right for the Programme 2 formulations. In Schedule 2 attached to D23, the Programme 2 formulations are identified to be formulations comprising magnesium stearate in combination with specific active agents, namely "formoterol alone, or in combination with beclomethasone or budesonide, and budesonide alone". These formulations are the subject of application D14 which was filed by Chiesi, implementing the agreement with Vectura and for which Chiesi owned the priority right.

In decision G 1/15 (OJ EPO 2017, 82) the Enlarged Board 1.2.3 of Appeal has ruled that entitlement to partial priority may not be refused for a claim encompassing alternative subject-matter by virtue of one or more generic expressions or otherwise (generic "OR"-claim) provided that said alternative subject-matter has been disclosed for the first time, directly, or at least implicitly, unambiguously and in an enabling manner in the priority document. In the present case, the so called Programme 2 formulations are explicitly disclosed in D16 (e.g. in claims 8 and 12) and thus can form a basis for a partial priority right. Once it is acknowledged that partial priority rights exist, they must also be transferable separately. This, however, has consequences for the remaining priority right, because the assignor is left with a limited right. The appellant (patent proprietor) referred to decision T 15/01 (OJ EPO 2006, 153) which ruled that the same priority right may be validly claimed in more than one European patent application and that there was no exhaustion of priority rights. Therefore, he was entitled to claim priority from D16 for the whole

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subject matter of his broader claim. However, an applicant can only claim a right which he owns and this was not the case for the priority right concerning the Programme 2 formulations. An applicant cannot transfer a partial priority right and at the same time keep it for claiming it in a broader context.

1.2.4 Therefore, the priority situation in the present case can be illustrated as follows:



A is the priority right owned by Vectura and encompasses any formulations excluding the specific formulations B.

B is the priority right owned by Chiesi and relates to the specific "Programme 2 formulations" comprising magnesium stearate in combination with specific active agents, namely "formoterol alone, or in combination with beclomethasone or budesonide, and budesonide alone".

The agreements between Chiesi and Vectura on the priority rights give therefore a respective partial priority right to each company corresponding to two alternatives clearly distinct and precisely defined.

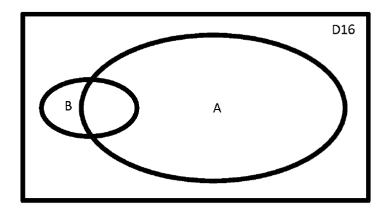
1.3 The subject-matter of the claims as granted, namely the main request is broader than the subject-matter covered

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by the priority right owned by Vectura, encompassing any formulations excluding the specific formulations B.

The subject-matter of the claims as granted relates indeed to formulations without any restriction as to the nature of the active agents or of the excipient and additive, with a unique restriction regarding the preparation of the fraction of fine particle size, namely "a fraction of fine particle size constituted of a mixture prepared by co-micronising a physiologically acceptable excipient and an additive".

Hence, said claimed subject-matter covers explicitly also the specific formulations defined as "Programme 2 formulations" with "a fraction of fine particle size constituted of a mixture prepared by co-micronising a physiologically acceptable excipient and an additive". The subject-matter of claim 1 of the claims as granted of the contested patent can thus be represented as follows:



Wherein:

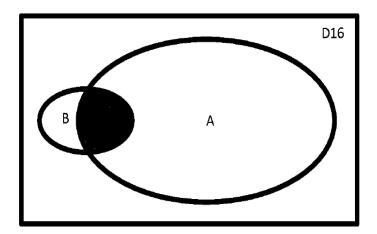
- A is the claimed subject-matter which encompasses any formulation comprising a co-micronised physiologically acceptable excipient and an additive, including specific formulations wherein magnesium stearate has

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been co-micronised with the excipient, and wherein the active agent may be "formoterol alone, or in combination with beclomethasone or budesonide, and budesonide alone".

- B is the priority right owned by Chiesi and the subject-matter of the application D14 relating to the specific "Programme 2 formulations" comprising magnesium stearate in combination with specific active agents, namely "formoterol alone, or in combination with beclomethasone or budesonide, and budesonide alone" and wherein magnesium stearate has been comicronised with the excipient or not.

It appears clear that the subject-matter of claim 1 encompasses formulations for which there is no valid priority right, shown in black:



This subject-matter relates to specific formulations of magnesium stearate with "formoterol alone, or in combination with beclomethasone or budesonide, and budesonide alone" wherein magnesium stearate has been co-micronised with the excipient.

Consequently, the subject-matter of claim 1 as granted encompasses embodiments for which the patent proprietor

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did not have the priority right and for which therefore the priority is not valid.

1.4 Hence, the priority of the contested patent is not valid as far as a combination of magnesium stearate with "formoterol alone, or in combination with beclomethasone or budesonide, and budesonide alone" as active ingredient is concerned (Article 87(1) EPC).

2. Main request - Novelty over D14

D14 claims a valid priority from application (D16), which is dated prior to the filing date of the contested patent, whose priority claim is not valid.

D14 discloses powder compositions comprising magnesium stearate as additive with an active ingredient selected from budesonise and its epimers, formoterol, TA 2005 and its stereoisomers, their salts and combinations; in D14, the excipient particles and magnesium stearate were also co-micronised to a size of less than 35 μm (see claims 1 and 10 and the examples).

Consequently, this document shows all features of claim 1 of the main request. This has not been contested by the appellant.

Consequently, the main request does not meet the requirements of Article 54(3) EPC.

3. <u>Auxiliary request 1 - Validity of the priority and novelty over D14</u>

The subject-matter of claim 1 of auxiliary request has been restricted by the feature "wherein the additive is magnesium stearate". This restriction has no incidence

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on the validity of the priority, since the claimed subject-matter still covers embodiments for which the priority is not valid, namely compositions comprising magnesium stearate and active ingredients selected from "formoterol alone, or in combination with beclomethasone or budesonide, and budesonide alone"; the restriction has also no incidence on the relevance of D14 since this document also discloses magnesium stearate as additive.

Hence, D14 is novelty destroying for auxiliary request 1 which therefore does not meet the requirements of Article 54(3) EPC.

4. Auxiliary request 2 - Validity of the priority and novelty over D14

The subject-matter of claim 1 of auxiliary request 2 corresponds to the subject-matter of the process claim 18 as granted with the product features of claim 1 as granted. As for the main request and auxiliary request 1 and for the same reasons, these amendments do not have any incidence as to the validity of the priority and the relevance of D14.

Hence, auxiliary request 2 does not meet the requirements of Article 54(3) EPC.

5. Auxiliary request 3 - Validity of the priority and novelty over D14

The subject-matter of claim 1 of auxiliary request has been restricted by the size of the carrier particles, which is the same than in D14 (see D14, page 12, 3rd par.). As for the main request and for auxiliary request 1 and for the same reasons, this amendment does

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not have any incidence as to the validity of the priority and the relevance of D14.

Hence, auxiliary request 3 does not meet the requirements of Article 54(3) EPC.

6. Auxiliary request 4 - Admission into the proceedings

6.1 The subject-matter of claim 1 of this request has been restricted by the disclaimer "wherein the additive is magnesium stearate and the active ingredient(s) is (are) not selected from budesonide and its epimers, formoterol, TA2005 and its stereoisomers, salts thereof, and combinations thereof", which was disclosed in claim 17 of the application as originally filed and in claim 16 of the patent as granted.

This request has not been submitted during the opposition proceedings, and has been filed for the first time with the statement of grounds of appeal.

The amendment brought to claim 1 of this request overcomes all issues as regards the validity of the priority and the relevance of D14 under Article 54(3) EPC.

According to Article 12(4) RPBA, the admission into the proceedings of a new request which could have been submitted by a party in the first instance proceedings is at the Board's discretion. When exercising its discretion the Board must take due account of the judicial nature of the appeal procedure and the interests of the parties concerned. Admission of a new request into the proceedings hinges on the question whether a party to appeal proceedings was in a position to make its submission earlier, and whether it could

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have been expected to do so under the circumstances (see e.g. T 301/11, T 23/10). In the present case the issue of validity of the priority and the resulting relevance of D14 was a point already raised in the notice of opposition by the opponent. In its summons to oral proceedings, the opposition division took the preliminary opinion that D14 was prior art pursuant to Article 54(3) EPC. The patentee was therefore fully aware of the relevance of this issue.

The patent proprietor could have filed a request disclaiming the formulations for which the priority was not valid. He even had an express basis for this in claim 17 as filed and in claim 16 as granted to address this very issue.

Even in the absence of documents D22 and D23 in the opposition proceedings, the introduction of the disclaimer would have de facto restored the priority right of the contested patent and would have excluded D14 from the relevant prior art; this introduction would have allowed the opposition division to take a complete decision on all grounds and points as regards the validity of the contested patent.

Moreover, the confidential status as such of D22 and D23 cannot be seen as a reason to not submit the subject-matter of auxiliary request 4 during the opposition proceedings since the patentee was aware of the partial priority right assigned to Chiesi.

6.3 The appeal procedure is a judicial procedure, separate from the preceding purely administrative opposition procedure, in which an administrative decision of an opposition division is reviewed by a judicial authority. Its function is mainly to give the losing

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party an opportunity to challenge the administrative decision against it and to obtain a judicial ruling on whether this decision is correct (G 10/91, OJ EPO 1993, 420, Reasons point 18). Since the appeal board, as a review instance, cannot be expected to deal with all the outstanding issues after the amendment of the appellant's case, admission of the auxiliary requests into the proceedings would give the appellant the opportunity to compel the board to remit the case. This would be contrary to a reliable and fair conduct of proceedings (T 301/11 of 3 February 2015). It follows from that that bringing an entirely fresh case is not in line with the purpose of the appeal proceedings.

6.4 Consequently, the Board exercises its discretionary power and decides to not admit auxiliary request 4 in the the appeal proceedings (Article 12(4) RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



S. Fabiani

J. Riolo

Decision electronically authenticated