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Datasheet for the decision of 24 September 2015

Case Number: T 0570/12 - 3.3.07

Application Number: 04801711.5

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Language of the proceedings: EN

Title of invention:
PRE-METERED DRY POWDER INHALER FOR MOISTURE-SENSITIVE MEDICAMENTS

Patent Proprietor:
Boehringer Ingelheim International GmbH

Opponent:
Hörnchen, Ulrich, Dr.

Headword:
PRE-METERED DRY POWDER INHALER FOR MOISTURE-SENSITIVE MEDICAMENTS/Boehringer Ingelheim International GmbH

Relevant legal provisions:
EPC Art. 56
RPBA Art. 12(4), 13

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Keyword:
Inventive step - main request (no)
Inventive step - Auxiliary request 2 (no)
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Auxiliary requests 1, 3-5 (no)

Decisions cited:
T 0002/83

Catchword:

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Case Number: T 0570/12 - 3.3.07

D E C I S I O N
of Technical Board of Appeal 3.3.07
of 24 September 2015

Appellant: (Patent Proprietor)	Boehringer Ingelheim International GmbH Binger Strasse 173 55216 Ingelheim am Rhein (DE)
Representative:	Hoffmann Eitle Patent- und Rechtsanwälte PartmbB Arabellastraße 30 81925 München (DE)
Respondent: (Opponent 1)	Hörnchen, Ulrich, Dr. Steinenkreuz 28 53773 Hennef (DE)
Representative:	Vossius & Partner Patentanwälte Rechtsanwälte mbB Siebertstrasse 3 81675 München (DE)

Decision under appeal: **Decision of the Opposition Division of the European Patent Office posted on 12 January 2012 revoking European patent No. 1691783 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman D. Semino
Members: D. Boulois
S. Fernández de Córdoba

Summary of Facts and Submissions

I. European patent No. 1 691 783 based on application No. 04 801 711.5 was granted on the basis of a set of 18 claims.

Independent claims 1 and 18 as granted read as follows:

"1. A pre-metered dry powder inhaler, comprising a dry powder medicament dose and a container, characterized in that
the dry powder medicament dose is loaded into said container and comprises particles of tiotropium and particles of at least one dry excipient; the container constitutes a dry, high barrier seal, comprising aluminium whereby the high barrier seal of the container prevents ingress of moisture thereby preserving the dry powder medicament dose; and the dry powder medicament dose in the container has been formed by either volumetric or electric field dose forming methods."

"18. A dry powder medicament dose loaded into a container and formed by either volumetric or electric field dose forming methods, said dose comprising particles of tiotropium and particles of at least one dry excipient, characterized in that the container constitutes a dry, high barrier seal comprising aluminium preventing ingress of moisture and thereby preserving the dry powder medicament dose."

II. Two oppositions were filed against the granted patent on the grounds under Article 100 (a), (b) and (c) EPC that its subject-matter lacked novelty and inventive step, the patent was not sufficiently disclosed, and

its subject-matter extended beyond the content of the earlier application as filed.

III. The documents cited during the opposition proceedings included the following:
(1): WO 03/013633
(2): Spiriva® 18 Mikrogram, April 2010
(15): WO 03/084502
(21): Public Assessment Report
(22): US 5 590 645

IV. The present appeal by the patent proprietor lies from the decision of the opposition division to revoke the patent. The decision was based on 2 sets of claims filed as main request with letter of 14 April 2011, corresponding to the claims as granted with a correction in a dependent claim, and as auxiliary request 1 during oral proceedings.

Independent claims 1 and 18 of auxiliary request 1 read as follows, the difference(s) compared with the main request shown in bold:

"1. A pre-metered dry powder inhaler, comprising a dry powder medicament dose and a container, characterized in that
the dry powder medicament dose is loaded into said container **at a temperature below 25°C and a relative humidity below 15% Rh** and comprises particles of tiotropium and particles of at least one dry excipient; the container constitutes a dry, high barrier seal, comprising aluminium whereby the high barrier seal of the container prevents ingress of moisture thereby preserving the dry powder medicament dose; and the dry powder medicament dose in the container has been formed

by either volumetric or electric field dose forming methods."

"18. A dry powder medicament dose loaded into a container **at a temperature below 25°C and a relative humidity below 15% Rh** and formed by either volumetric or electric field dose forming methods, said dose comprising particles of tiotropium and particles of at least one dry excipient, characterized in that the container constitutes a dry, high barrier seal comprising aluminium preventing ingress of moisture and thereby preserving the dry powder medicament dose."

V. According to the decision under appeal, a basis for the feature "comprising aluminium" in claims 1 and 18 was found on page 9 of the application as originally filed, and a basis for the feature "10 µm" in claim 2 was in original claim 2, so that the requirements of Article 123(2) EPC were met. The feature "having a diameter of 10 µm or more" in claim 2 was not broader than the feature "having a diameter of 10 pm or more" in the granted claim, so that also the requirements of Article 123(3) EPC were met.

As regards disclosure, the opposition division considered that there was sufficient information in the patent about the excipients that could be used for the dry powder medicament.

As regards novelty, novelty over documents (1), (2), (15) and (21) was acknowledged for following reasons:
- Document (1) did not disclose clearly and unambiguously the subject-matter of claims 1 and 18, since tiotropium was disclosed in a list of suitable anticholinergic drugs and since the document related not only to pre-metered dry powder inhalers but also to

device-metered dry powder inhalers. This selection among several lists of possibilities already made the claimed subject-matter novel over document (1).
- The prior use (2), relating to the commercial product Spiriva® disclosed a device with a tiotropium formulation filled in capsules that were packed in blisters containing aluminium, thus not directly loaded into the container in accordance with the claimed subject-matter. Thus, the product Spiriva® or the kit Spiriva® and the HandiHaler® did not anticipate the subject-matter of claims 1 and 18.
- As there was no mention relating to the use of aluminium as material in document (15), this document alone did not anticipate the subject-matter of the claims. As to the question whether the teaching of document (22) could be incorporated in the teaching of document (15), which made reference to document (22) by the term "incorporated by reference", the opposition division considered that document (15) did not point out to the specific passage of document (22) which showed that the preferred materials for the medicament pack were plastics/aluminium laminates. Document (15), taking in account document (22) did not anticipate the subject-matter of the claims.
- Document (21) was outlined by document (2), vide supra.

As regards inventive step, document (15) referring to document (22) represented the closest prior art. This document disclosed the administration of an inhalable powder containing tiotropium in a mixture with a physiologically acceptable carrier by means of an exemplified inhaler according to document (22), "which is incorporated by reference" in document (15). The difference of the opposed patent in the light of document (15) was the presence of aluminium which acted

as a high barrier seal for the prevention of moisture ingress. The underlying problem was the improved protection of tiotropium form moisture. Document (22) disclosed hermetically sealed
pockets formed by sheets of plastics/aluminium laminates. The combination of the disclosure of document (15) and (22) was obvious for the skilled person. The main request was thus not inventive.

Though objected by the opponents under Article 123(2) EPC, auxiliary request 1 filed during the oral proceedings was found to be admissible and to meet the requirements of Articles 123(2) EPC. The problem solution approach as discussed for the main request applied mutatis mutandis for auxiliary request 1. The difference to the closest prior art (15) was the presence of aluminium acting as a high barrier seal for the prevention of moisture ingress, and the defined temperature and relative humidity conditions for the dose loading. The effect of these further differences to document (15) had not been shown, and was considered as a simple alternative to the teaching of document (15). The subject-matter of auxiliary request 1 was not inventive.

VI. The patent proprietor (appellant) filed an appeal against said decision. With the statement of grounds of appeal, the appellant submitted the following pieces of evidence:
(30): Ph.D. thesis entitled "Evaluierung und Quantifizierung von Einflussfaktore auf die aerodynamischen Eigenschaften inhalativer Pulvermischungen"
(31): decision T 2/83 of 15 March 1984
(32): Lab-Report

VII. With a letter dated 24 September 2012, opponent 02 submitted new documents:
(33): US 2003/0070679
(34): EP 978 276 B1

VIII. With a letter dated 10 June 2014, opponent 02 withdrew its opposition.

IX. With a letter dated 12 June 2015, the appellant submitted new auxiliary requests 1-3. Auxiliary request 2 corresponded to auxiliary request 1 discussed during the opposition procedure.

Claim 1 of auxiliary request 1 was amended by a single word, namely as follows, the difference(s) compared with the main request shown in bold:
"characterized in that the dry powder medicament dose is **directly** loaded into said container".

Claim 1 of auxiliary request 3 was amended by the following feature, the difference(s) compared with the main request shown in bold:
"characterized in that the dry powder medicament dose **is formed**, loaded **and sealed** into said container **at a temperature below 25°C and a relative humidity below 15%Rh**".

X. In a communication dated 28 July 2015 sent in preparation of oral proceedings, the board gave its preliminary opinion. In particular, it stated that the invention claimed in all requests appeared to be not inventive over document (15).
The Board also noted that the specific process steps claimed in claim 1 of auxiliary requests 2 and 3 did not appear to correspond to the experimental conditions described exhaustively in the experimental test (32).

XI. With a letter dated 28 August 2015, the respondent submitted auxiliary requests 4 and 5 and the experiments of document (35).

Claim 1 of auxiliary request 4 was amended by the following feature, the difference(s) compared with the main request shown in bold:
"characterized in that the dry powder medicament dose is **directly** loaded into said container **at a temperature below 25°C and a relative humidity below 15%Rh**".

Claim 1 of auxiliary request 5 was amended by the following feature, the difference(s) compared with the main request shown in bold:
"characterized in that the dry powder medicament dose **is formed, directly** loaded **and sealed** into said container **at a temperature below 25°C and a relative humidity below 15%Rh**".

XII. Oral proceedings took place on 24 September 2015.

XIII. The arguments of the appellant may be summarized as follows:

Admission of documents (32)-(35) into the proceedings

Document (32) and (35) should be admitted into the proceedings, since they were a response to the arguments of the decision of the opposition division and of the points raised by the Board in its preliminary opinion. Document (32) was filed with the statement of ground of appeal, and could not have been filed earlier; the opposing party had enough time to study the experiments comprised therein. Document (35)

comprised additional experiments, which did not change the case.

Document (33) and (34) should not be admitted, since they did not relate to the present case.

Main request - Inventive step

In the written proceedings, document (8) was seen as the closest prior art, since it was directed to the same purpose as the patent in suit. The aim of the invention disclosed in document (8) was the preparation of capsules being better adapted to the specific requirements of dry powder inhalers and which did not exhibit the problems associated with conventional capsules concerning storage stability of the contained powders.

The technical contribution of the patent in suit also resided in the identification of a new problem, which had not been recognized previously in the prior art, namely the need to exclude the ingress of even very small quantities of water in tiotropium containing dry powder formulations for inhalation in order to allow for a high and stable fine particle dose of such formulations over their shelf life. The present invention represented a problem invention in terms of decision T 2/83, according to which under certain circumstances a hitherto unrecognized problem may give rise to patentable subject-matter. These circumstances were given in the present case and inventive step had to be acknowledged for this reason.

During oral proceedings, a specific part of document (15) was seen as potential closest prior art. Document (15) disclosed several type of inhalers, among which

only the inhaler shown in Figure 1 was seen as relevant. This figure corresponded to the HandiHaler® of document (2), and was a marketed product. The other inhalers disclosed in document (15) were "paper inhalers" and "paper examples", and it was not realistic to take one of them as starting point for the assessment of inventive step. The closest technical technical part of document (15) was thus the HandiHaler® system, from which the claimed subject-matter differed in the direct loading of tiotropium bromide. The effect was the preservation of the fine particle dose (FPD) of tiptropium as shown by the description of the contested patent. The solution, namely the use of aluminium containing containers, was not obvious. There was no document dealing with a problem of stability linked with very small quantities of water, and the connection with very small quantities of water and FPD was not shown in any document. In particular, documents (15) and (22) were silent about this problem. The real contribution of the invention related to this specific small amount of water.

Admission of auxiliary request 1 into the proceedings

The amendment made to claim 1 was to prevent a possible objection on novelty or under Article 123(2) EPC already raised during the oral proceedings before the opposition division. The amendment had no impact on the assessment of inventive step in comparison to the subject-matter of the main request and all arguments regarding the inventive step of the main request also applied to this request. The amendment was also of simple nature. This request should therefore be admitted.

Auxiliary request 2 - Inventive step

A technical effect was specifically linked to the claimed loading step, and was demonstrated by the experiments of documents (32) and (35). A further difference with the teaching of document (15) was the controlled loading conditions, and the effect was an improvement with respect to the fine particle fraction of tiotropium obtainable under said loading conditions. Documents (32) and (35) showed that the fine particle fraction of a powder filled under the claimed conditions was higher than the fine particle fraction of a powder filled at higher temperature and residual humidity already after the filling process. Moreover, the fine particle fraction after storage under stress conditions remained almost the same, while it considerably dropped for the powder prepared under said higher temperature and residual humidity conditions. The problem was seen as the preservation of a higher and stable FPD of the tiotropium dry powder formulation. The solution was not obvious, since neither document (15), nor document (22) mentioned this problem. The solution was also not know from documents (21) or (33), which referred to filled capsule not to loading conditions under the same conditions of temperature and residual humidity. Document (33) could not be seen as a source of expectation of success.

Auxiliary request 3 - Admission into the proceedings

The amendment was made from paragraph [0057] of the description of the contested patent. This request was filed since auxiliary request 2 was challenged by the opposition division as regards inventive step and when considering the experiments of document (32). It was therefore justified to file this new request.

Auxiliary requests 4 and 5 - Admission into the proceedings

The amendments made to claim 1 of these requests correspond to the amendments made in auxiliary requests 1, 2, and 3. There were made for potential objections of novelty.

XIV. The arguments of the respondent (opponent 01) may be summarized as follows:

Admission of documents (32)-(35) into the proceedings

Document (32) and (35) should not be admitted into the proceedings, since they were not relevant for the assessment of inventive step. The temperature and humidity conditions of 25°C and 15% Rh used in these documents were indeed excluded by the claimed subject-matter and the conditions of temperature of 30°C and/or of 50% Rh used in the comparative situations were not realistic, since nobody would prepare a dry powder under one of these conditions. The equilibration step of 90 minutes as disclosed in the experiments of document (32) appeared also to be crucial and was not part of the claims.

Documents (33) and (34) should be admitted into the proceedings, since the former was mentioned in the description of the contested patent and the latter had been filed in response to the auxiliary request and document (32) filed by the appellant.

Main request - Inventive step

The subject-matter of the main request lacked inventive step in view of document (15) in combination with its

cross-reference document (22), wherein the inventive inhaler of the contested patent was disclosed. There was no indication that one inhaler disclosed in document (15) could have been seen as a preferred one.

The purported invention cold also not be seen as based on a prior unrecognised problem. As evidenced by the prior art, it was well established and commonplace that moisture ingress should have been avoided for a dry powder formulation.

The comparative data given in documents (32) and (35) could not be taken in consideration, and thus no effect had been shown. The temperature and humidity conditions of 25°C and 15% Rh used in these document were indeed excluded by the claimed subject-matter and the conditions of temperature of 30°C and of 50% Rh used in the comparative situations were not realistic, since nobody would prepare a dry powder under one of this condition.

Admission of auxiliary request 1 into the proceedings

This request could have been filed earlier and should not be admitted. Moreover, the amendments had no relevance on inventive step, and the arguments raised against the main request apply mutatis mutandis.

Auxiliary request 2 - Inventive step

The comparative data provided by document (32) were meaningless, since the loading conditions of documents (32) were excluded by the claimed subject-matter. The claimed step of "drug loading" could not comprise a step of equilibration as shown in document (32). Furthermore, the solution provided was obvious. It was

self-speaking for the skilled person to prepare a formulation which is hygroscopic and moisture sensitive such as one for a dry powder inhaler (DPI), at conditions of low humidity, in order to avoid aggregation and to ensure accurate dosing and dose conformity. It belonged to the good manufacturing procedure. Document (21) showed that the storage of inhalers comprising tiotropium had to be performed at 25°C and document (33) also showed the same temperature and humidity conditions as those claimed.

Auxiliary request 3 - Admission into the proceedings

The appellant had the possibility to file this request earlier in the proceedings, since objections under Article 123(2) were raised during the opposition proceedings. The filing of this request was not in conformity with the requirements of procedural economy.

Auxiliary requests 4 and 5 - Admission into the proceedings

There were no supplementary arguments.

XV. Requests

The appellant requested that the decision under appeal be set aside and that the patent be maintained according to the set of claims filed as main request with letter of 14 April 2011 or to one of the sets of claims filed as auxiliary requests 1-3 with letter dated 12 June 2015 or auxiliary requests 4-5 with letter dated 28 August 2015.

The respondent requested that the appeal be dismissed. The respondent further requested that documents (30)-

(32) and (35) and auxiliary requests 1, 3, 4 and 5 were not admitted into the proceedings.

Reasons for the Decision

1. Admission of documents and experimental data into the proceedings

1.1 Admission of documents (30)-(32) into the proceedings

Document (31) is the decision T 2/83 from the Boards of Appeal, and as such may be cited at any time during the appeal proceedings. There is thus no need to discuss its admission into the proceedings.

Documents (30) and (32) were filed by the appellant with the statement of grounds of appeal, thus at the earliest stage of the appeal proceedings:
- Document (30) is a general document relating to aerosol powders cited to show that several factors in addition to the moisture content of the powder affect its aerodynamic properties, and can be seen, for this reason, as a reaction to the decision under appeal.
- Document (32) is an experimental report cited to show the effect of the operating conditions of the loading step and can therefore also be considered as a reaction to the arguments of the decision of the opposition division.

Consequently, documents (30) and (32) are admitted into the proceedings (Article 12(4) RPBA).

1.2 Admission of documents (33) and (34)

The documents were filed by opponent 02, in response to the statement of grounds of appeal of the appellant, in

particular to the filing of the auxiliary request, which corresponds to the auxiliary request which was submitted for the first time during the oral proceedings before the opposition division. They can therefore be seen as a legitimate reaction to new submissions.

Consequently, documents (33) and (34) are admitted into the proceedings (Article 12(4) RPBA).

1.3 Admission of document (35)

This document constitutes an addendum to the experiments of document (32) in the form of supplementary experiments. These supplementary data are also a direct response to the points raised for the first time by the Board in its preliminary opinion. As such, they could not have been filed earlier. As the experimental data are a complement to the data given in document (32) and not a new document, their content does not change the case.

Consequently, document (35) is admitted into the proceedings (Article 13(1) RPBA).

2. Main request - Inventive step

2.1 The invention relates to the preservation and delivery of a high fine particle dose (FPD) of tiotropium by a dry powder inhaler (DPI) product comprising a metered dose of tiotropium medicament, adapted for inhalation, packaged in a dry and tight container, such that the FPD when delivered is unaffected for the shelf life of the medical product by normal variations in ambient conditions during handling, storage and delivery using

the DPI product (see the specification par. [0001] and [0015]).

2.2 The first step is the choice of the closest prior art.

2.2.1 Document (15) was considered by the opposition division to constitute the closest prior art. Not only the choice of this document was contested by the appellant, which considered in its written submission that document (8) was the only document directed to the same purpose as the patent in suit and as such should be the closest prior art, but also the relevant parts of said document (15) were contested by the appellant during oral proceedings.

2.2.2 Document (8) discloses capsules for inhalation made from hydrophobic plastics polymer and not from aluminium (see claims). This document does not relate to tiotropium.

2.2.3 Document (15) discloses an inhalation kit comprising an inhalable powder of tiotropium and a physiologically acceptable excipient (see page 2, lines 10-14 and 21-26). The examples show several powder compositions made from lactose and tiotropium bromide. As to the administration of said powder, document (15) proposes four alternative inhalers which can be used:

(a) A first alternative is represented by the inhaler described in Figure 1 of document (15) (see also the description pages 5, line 15 - page 7, line 18). This inhaler corresponds to the inhaler system used in the commercial product Spiriva®, wherein the medicament dose is usually loaded with a distinct hard gelatin capsule containing the tiotropium powder which has to be inserted within a capsule chamber before use of the inhaler (see

for instance document (2), first page). This specific embodiment does therefore not show an inhaler directly loaded with a container and the composition of the container is not given in document (15).

(b) Another alternative is represented by an inhaler comprising a medicament pack having a plurality of containers for containing a medicament in powder form wherein the containers are spaced along the length of and defined between two peelable sheets secured to each other, and said containers are engaged within the inhaler through an opening station, as in the claimed invention (see the description of document (15) on page 9, line 31 - page 11, line 21). This specific embodiment of document (15) shows thus a pre-metered inhaler device identical to the claimed pre-metered inhaler device, without the specification of the material composition of the barrier seal of the container. In relationship with the disclosure of this specific inhaler, a reference is made in the description of the contested patent to the type of inhaler devices disclosed in document (22), which disclosure is "incorporated by reference in its entirety" in the teaching of document (15) (see document (15), page 9, line 32). The teaching of said cross-reference document (22) shows several pre-metered inhalation devices in all of which is indeed mounted a flexible strip in the form of a lid sheet hermetically sealed to a base sheet and defining a plurality of pockets each of which containing a dose of medicament.

(c) Two other alternative inhalers were described in document (15) on page 7, line 20 - page 9, line

29 and on page 11, line 22-page 13, line 36, making reference to two further documents.

2.2.4 The argument of the appellant regarding the relevance of the different alternatives, namely that only the alternative corresponding to figure 1 of document (15) was a credible existing inhaler, and that the three other inhalers described in document (15) were "paper inhalers", cannot be followed.

First, in view of the disclosure of document (15), none of these alternatives can be distinguished as a preferred one, since they are all explicitly referred to as preferred embodiments.

Then, the disclosure of document (15) does not give any indication that one of the alternatives constituted by document (22) might constitute a theoretical or paper alternative, since all these alternatives are disclosed in the description of document (15) with explicit technical informations.

2.2.5 As to the choice of the closest prior art, document (15) thus not only relates to the claimed invention in the sense that it discloses subject-matter conceived for the same purpose or aiming at the same objective, corresponding to a similar use, or relating to the same or a similar technical problem or, at least to the same or a closely related technical field, but also, in comparison to the disclosure of document (8), discloses the greatest number of relevant technical features in common with the claimed invention, i.e. requiring the minimum of structural and functional modifications.

Document (15) does therefore explicitly refer to a pre-metered inhalation device comprising a dry powder

medicament dose loaded in a container , but without specific reference to the specific detailed material composition of the container. Hence, document (15), especially its embodiment described on pages page 9, line 31 - page 11, line 21, corresponding to document (22) is seen as the closest prior art.

2.3 According to the appellant, the problem is the provision of a pre-metered dry powder inhaler comprising a metered dose of tiotropium and a container allowing the delivery of a high fine particle dose (FPD) of tiotropium, which remains unaffected/preserved during the shelf life of the dry powder inhaler by normal variations in ambient conditions.

2.4 As a solution to this alleged problem, claim 1 of the main request proposes a pre-metered dry powder inhaler wherein in particular the container comprising the dry powder medicament dose made from tiotropium and particles of at least one dry excipient comprises aluminium.

2.5 It has to be investigated whether there is sufficient evidence supporting the problem as formulated.

The description of the contested patent provides a comparison made by using the Spiriva® inhaler system using the corresponding commercial gelatin capsule and a capsule made from aluminium foils. The test carried out shows that the moisture content of the gelatin capsule reduces the FDP with approximately 50% from the time of loading the dose into a capsule until the point in time when the product reaches the market, and shows a significant difference in favour of a container comprising aluminium since no changes in the FDP are detected even after long periods of time (See Table 1

and par. [0046]-[0047]). Although not using a inhaler with a container directly engaged therein, but a capsule system, this comparison of the contested patent show undoubtedly a satisfactory performance of a container comprising aluminium.

In view of the information found in the description of the contested patent, the board is convinced that the problem has been plausibly solved. In this respect, it is relevant to note that the problem refers to the achievement of satisfactory stability properties, but does not mention an improvement, as the comparative inhaler in the patent is not according to the closest prior art.

2.6 It remains to determine whether the solution was obvious to the person skilled in the art.

Document (15) proposes four explicit alternative inhalers which can be used, two of them being inhalers with a container system loaded within the inhaler device and one of the inhaler with a container system being an inhaler device as shown in document (22). While the reference to document (22) is given in document (15) only in relationship with the type of inhaler device to be used, said document (22) contains further information which could not be regarded as directly incorporated in document (15). Thus, the first inhaler embodiment shown in Figures 1 and 2 of document (22) gives the material composition of the strip, the further embodiments merely referring to said first embodiment (see Fig. 5-9, 10-12 13-16, 17-20, 32-34 and the corresponding texts in the description). In said first embodiment, the unique alternative given is that the strip is in the form of a lid sheet hermetically sealed to a base sheet, both sheet being preferably

formed of a plastics/aluminium laminate. By way of unique example, the lid material may be made from kraftpaper/PETP/aluminium and the base material may be a laminate of PVC/aluminium/poylamide (see col. 2, lines 46-66 and Figures 1 and 2). Thus, the use of containers comprising aluminium is disclosed as only possibility in document (22).

In view of the teaching in the prior art, the skilled person implementing the pre-metered inhaler device with the container system of document (15) would have consulted the supplementary technical information contained in document (22) and would have used the same kind of container. It follows that the skilled person would have used the container system disclosed in document (22) in the form of a lid sheet hermetically sealed to a base sheet comprising aluminium as explicitly taught in document (22).

The claimed solution results thus inevitably from a sequence of interconnected technical information originating from the main teaching of the closest prior art document (15) and a supplementary teaching originating from its cross-reference document (22). As a matter of fact, this interconnected technical information differs from a direct disclosure relevant for the question of novelty of the claimed invention only by the fact that document (15) did not contain a direct cross-reference to the materials used in the inhalers of document (22), but only on the type of pre-metered inhaler devices. Hence, the skilled person would have applied one of the possible solutions offered by document (15), which inevitably leads to the claimed solution. Applying this solution requires no particular skills and hence does not involve an inventive step.

As to the existence of the proven stability property which is not explicitly mentioned in document (15), this effect is considered as inevitable when following the alternative chosen as closest prior art and is regarded as a mere additional effect. An additional bonus effect cannot point towards an invention, if the skilled person would inevitably arrive at the invention by simply following the teaching of the prior art document.

2.7 Further arguments from the appellant

The appellant considered that the technical contribution of the patent in suit resides in identifying a problem, which was a hitherto unrecognized problem (cf decision T 2/83). The problem was dealing with the fact that the persistence of very small amounts of water was detrimental for the stability of the powder compositions and that this problem was connected with the influence on the reduction of the fine particle dose (FDP) of tiotropium delivered by the inhaler.

The Board could not follow this argument. The problem raised by the contested patent was indeed a known problem and therefore is not a hitherto unrecognized problem. As mentioned in paragraph [0029] of the description of the contested patent and in document (21) cited therein, tiotropium was known to be extremely sensitive to moisture and document (21) insists on the importance of mastering the water content of the capsules (see pages 6-7). The problem was also identified in document (33), which relates to capsules comprising tiotropium for inhalation having a reduced moisture content, to achieve a high degree of

stability and to ensure a high metering accuracy (see document (33), par. [0002], [0007] and [0008]).
As to the possible contribution of the contested patent as regards the influence of "very small quantities of water" over the prior art teaching, the description of the contested patent mentions indeed that the FPD of tiotropium becomes less over time when affected by "very small quantities of water" (see par. [0049]), but said "very small quantities" are not quantified anywhere in the description of the contested patent and therefore cannot be differentiated from the moisture level mentioned in documents (21) or (33). The identification of a smaller quantity of water than the moisture level of the prior cannot thus serve as the identification of a new technical problem.

2.7.1 The main request does not meet the requirements of Article 56 EPC.

3. Auxiliary request 1 - Admission into the proceedings

This request has been filed with the letter dated 12 June 2015 at a late stage in the proceedings. The subject-matter of claim 1 of auxiliary request 1 differs from the subject-matter of claim 1 of the main request by the addition of the feature “directly loaded”. According to the appellant, this amendment has no incidence on the discussion on inventive step and has been made to overcome possible objections against the main request on novelty over documents (2) and (21) and objections under Article 123(2) EPC.

Given that the only respondent's objections on the main request related to inventive step and that the amendment made has no incidence on said reasoning on inventive step and was not made to overcome a lack of

inventive step, the Board considers that it is appropriate to exercise its discretionary power by not admitting auxiliary request 1 into the procedure in accordance with Article 13(1) of the Rules of Procedure of the Boards of Appeal.

4. Auxiliary request 2 - Inventive step

The subject-matter of claim 1 of auxiliary request 2 differs from claim 1 of the main request by the addition of the feature "the dry powder medicament is loaded into said container at a temperature below 25°C and a relative humidity below 15% Rh".

As the added feature is a product-by-process feature, the first question to be answered is whether the conditions of loading defined therein imply a difference in the loaded powder, which can be acknowledged as a further feature of the claimed dry powder inhaler with respect to the one of the main request. In this respect, it is appropriate to analyse the experimental evidence filed by the appellant.

4.1 Document (32) studies the influence of different environmental conditions during packaging on the fine particle fraction of dry powder formulations of tiotropium packed in aluminium blisters. Two environmental conditions were tested, to be specific at a temperature T of 25°C and relative humidity Rh of 15% and a temperature T of 30°C and relative humidity Rh of 50%. The experimental procedure (part 4) consists in letting the blister strips and the powder blend to equilibrate for 90 minutes under the desired environmental conditions (at T=25°C/Rh=15% and T=30°C/ Rh=50%), limiting the time to blister cavity forming and filling to 90 minutes, and performing the filing in

rooms with adjusted and controlled room temperatures and relative humidity set again to T=25°C/Rh=15% and T=30°C/Rh=50% respectively. The results obtained were an initial fine particle fraction of 35,2% and 27,0% under the respective conditions of T=25°C/Rh=15% and T=30°C/Rh=50%, and a fine particle fraction after 4 weeks of storage of 33,4% and 12,4% under the respective conditions of T=25°C/Rh=15% and T=30°C/Rh=50%.
The results show clearly that a tiotropium dry powder formulation filled under the conditions of 25°C and Rh of 15% exhibits a higher initial and final fine particle fraction compared to the same formulation filled under the conditions of 30°C and Rh of 50%.

Document (35) provides an addendum to the study performed in document (32), that is at the packaging environmental conditions of 25°C and Rh of 50%. The initial fine particle fraction was 34,3%, very close to the result obtained at T=25°C/Rh=15%, while the fine particle fraction was 21,8% after a 4 week storage period, thus much less than the 33,4% obtained at under the respective conditions of T=25°C/Rh=15%.

4.2 The experiments of documents (32) and (35) are however irrelevant for establishing a difference in the product directly implied by the claimed conditions expressed by the feature that "the dry powder medicament is loaded into said container at a temperature below 25°C and a relative humidity below 15% Rh". The specific packaging environmental conditions used in the experiments (32) and (35) are indeed not representative of the claimed subject-matter and cannot be extrapolated thereto.

The claimed subject-matter refers only to a loading step, while the experimental procedure used in

documents (32) and (35) is more complex and includes an equilibration step, a limited filling time, a loading or filling step, and an immediate sealing step. None of those steps, apart from the filling step are part of the claimed subject-matter, nor of the corresponding part of the description where the feature "the dry powder medicament is loaded into said container at a temperature below 25°C and a relative humidity below 15% Rh" originates from paragraph [0057] of the specification. In particular, the blister strips and the powder were let to equilibrate for 90 minutes, an obviously crucial condition which does not appear to be part of the claimed feature or even of the description of the contested patent. The description indeed refers only to the steps of "dose forming, loading and container sealing" that should be closely controlled, with a temperature preferably below 25°C and relative humidity preferably below 15 % Rh.

The results of experiments (32) and (35) cannot therefore be extrapolated to the claimed subject-matter, and there is thus no evidence that a loading step into said container at a temperature below 25°C and a relative humidity below 15% Rh inevitably confers to the powder a different structure or property.
None of the further experiments (32) or (35) offer thus sufficient evidence to support the assumptions that the feature "the dry powder medicament is loaded into said container at a temperature below 25°C and a relative humidity below 15% Rh" provides a difference in the claimed subject-matter.

4.3 As there is no difference related to the added feature in the claimed dry powder inhaler, the analysis of inventive step remains the same as for the main request with the result that the subject-matter of claim 1 of

auxiliary request 2 does not involve an inventive step for the same reasons as outlined for the main request (see point 2 above).

Auxiliary request 2 does not meet the requirements of Article 56 EPC.

5. Auxiliary request 3-5 - Admission into the proceedings

5.1 Auxiliary request 3

This request has been filed with the letter dated 12 June 2015 at a late stage in the proceedings. The subject-matter of claim 1 of auxiliary request 3 differs from the subject-mater of claim 1 of the main request by the additional feature "the dry powder medicament dose is formed, loaded and sealed into said container at a temperature below 25°C and a relative humidity below 15% Rh". According to the appellant, this feature was introduced in order to overcome a possible objections under Article 123(2) EPC raised against the subject-matter of auxiliary request 2 during the oral proceedings before the opposition division.

The introduction of this feature, originating from the description, gives a considerable weight to the conditions under which the product is processed. Said processing conditions are however not exhaustively described in the description of the contested patent as regards their exact course and the control of "ambient conditions during dose forming, loading and container sealing" as mentioned in the description (par. [0057]) and do not correspond to the experimental procedure shown in documents (32) or (35). The introduction of this feature in claim 1 of auxiliary request 3 opens

thus a new discussion, is not of clear and simple nature, and does not seem likely to *prima facie* overcome the lack of inventive step observed for the subject-matter of auxiliary request 2 (see point 4.4.3 above).

Consequently, the Board fids it appropriate to exercise its discretion by not admitting auxiliary request 3 into the proceedings (Article 13(1) RPBA).

5.2 Auxiliary request 4

This auxiliary request has been filed with letter dated 28 August 2015, after the issue of the Board's preliminary opinion, at a late stage of the proceedings. The subject-matter of claim 1 of auxiliary requests 4 has been amended by the feature "characterized in that the dry powder medicament dose is **directly** loaded into said container **at a temperature below 25°C and a relative humidity below 15%Rh**". Since the term "directly loaded" has no incidence on the discussion on inventive step, the subject-matter of claim 1 as regards inventive step of this request corresponds to the subject-matter of claim 1 of auxiliary requests 2.

The Board sees thus no reason to admit this request into the proceedings (Article 13(1) RPBA).

5.3 Auxiliary request 5

This auxiliary request has been filed with letter dated 28 August 2015, at a late stage of the proceedings. The subject-matter of claim 1 of auxiliary request 5 has been amended by the feature "characterized in that the dry powder medicament dose **is formed**, **directly** loaded

and sealed into said container **at a temperature below 25°C and a relative humidity below 15%Rh".**
As for auxiliary request 3, the introduction of this feature in claim 1 of auxiliary request 5, is not of clear and simple nature, opens a new discussion and does not seem likely to *prima facie* overcome the lack of inventive step observed for the subject-matter of auxiliary request 2 (see point 4.4.3 above).

Accordingly, auxiliary request 5 is not admitted into the proceedings (Article 13(1) RPBA).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

S. Fabiani D. Semino

Decision electronically authenticated