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# Datasheet for the decision of 16 January 2018

**Case Number:** T 0126/15 - 3.3.07

**Application Number:** 04801709.9

**Publication Number:** 1691781

**IPC:** A61K9/14, A61K9/72, A61M15/00, A61J1/00, A61K31/46, A61P11/06, A61P11/08

**Language of the proceedings:** EN

**Title of invention:**
Inhalable tiotropium and container therefor

**Applicant:**
Boehringer Ingelheim International GmbH

**Headword:**
Tiotropium/BOEHERINGER

**Relevant legal provisions:**
EPC Art. 56, 111

**Keyword:**
Appeal decision - remittal to the department of first instance (yes)

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**Case Number: T 0126/15 - 3.3.07**

# D E C I S I O N
# of Technical Board of Appeal 3.3.07
# of 16 January 2018

| | |
|---|---|
| **Appellant:** (Applicant) | Boehringer Ingelheim International GmbH<br>Binger Strasse 173<br>55216 Ingelheim am Rhein (DE) |
| **Representative:** | Hoffmann Eitle<br>Patent- und Rechtsanwälte PartmbB<br>Arabellastraße 30<br>81925 München (DE) |
| **Decision under appeal:** | **Decision of the Examining Division of the European Patent Office posted on 18 June 2014 refusing European patent application No. 04801709.9 pursuant to Article 97(2) EPC.** |

**Composition of the Board:**

| | |
|---|---|
| **Chairman** | J. Riolo |
| **Members:** | A. Usuelli |
| | Y. Podbielski |

## Summary of Facts and Submissions

I. The appeal of the applicant (appellant) lies from the decision of the examining division to refuse European patent application No. 04801709.9, published as WO 2005/053646.

II. The decision was based on a main request and five auxiliary requests wherein the main request and auxiliary requests 1, 2 and 4 were filed on 25 February 2014 and auxiliary requests 3 and 5 were filed during the oral proceedings held on 25 March 2014.

The following documents were among those cited in the European Search Report:

D2: WO 00/74754
D3: US 2003/136405
D14: Pharmaceutical Technology, 2000, pages 68-77
D18: Public assessment report of Spiriva® 18 µg, inhalation powder in hard capsules, 2002.

III. In its decision the examining division came to the conclusion that the subject-matter of the main request was not novel over D18. The amendments introduced in claim 1 of auxiliary requests 1, 2 and 4 were considered to offend against Article 123(2) EPC. Auxiliary requests 3 and 5 were refused for lack of inventive step.

Claim 1 of auxiliary request 3 read as follows.

"1. A device comprising a dry powder inhaler and a medical product comprising a dry powder medicament dose loaded into a container for use in a dry powder

inhaler, in that the dry powder medicament dose comprises a fine particle dose of tiotropium and at least one dry excipient present in the form of finely divided particles; and wherein the container comprises a dry, high barrier seal, comprising aluminium foil characterized in that the container or the device further comprises a desiccant and wherein the ambient conditions during dose forming and loading and container sealing is below 15 % Rh at a temperature of below 25°C to limit the amount of water enclosed in the container."

The examining division considered that the wording of claim 1 of auxiliary request 3 covered also devices wherein the dry powder medicament was loaded in gelatin capsules contained in aluminium containers. Document D18 was the closest prior art for the assessment of inventive step of the subject-matter of auxiliary request 3. The device defined in claim 1 of auxiliary request 3 differed from the device of D18 at least on account of the requirement that it comprised a desiccant. The comparative experiments disclosed in the application were not suitable to show that the product claimed in the application in suit provided a higher fine particle fraction (FPD) of tiotropium compared to the product of D18, as argued by the appellant. The technical problem was therefore the provision of an alternative device for administering tiotropium in powder form. Document D18 showed that it was a standard measure to condition the atmosphere during the manufacturing process. Using desiccants for reducing the negative effects of moisture was disclosed for instance in D2 and D3. Other documents, such as D14 indicated that the use of containers comprising an aluminium barrier, such as blisters, was also a

standard measure. Accordingly, the subject-matter of auxiliary request 3 did not involve an inventive step.

Claim 1 of auxiliary request 5 differed from claim 1 of auxiliary request 3 in the indication that the container in which the powder was loaded was dry. The examining division considered that auxiliary request 5 was obvious substantially for the same reasons as that of auxiliary request 3.

IV. With the statement setting out the grounds of appeal, the appellant requested that the decision under appeal be set aside and a patent be granted on the basis of a main request or on the basis of one of four auxiliary requests.

V. On 15 December 2017 the appellant replaced the requests submitted with the statement of grounds of appeal by a new main request and three auxiliary requests.

During the oral proceedings held on 16 January 2018 the appellant withdrew all the requests on file with the exception of auxiliary request 3 which became its main and only request.

Claim of this request read as follows:

"1. A medical product comprising a dry powder medicament dose directly loaded and sealed into a dry container for use in a dry powder inhaler, characterized in that during dose forming, loading and container sealing the temperature is below 25°C and the relative humidity is below 15 %, in that the dry powder medicament dose comprises a fine particle dose of tiotropium and at least one dry excipient present in the form of finely divided particles; and wherein the

container comprises a desiccant and is made so as to act as a dry, high barrier seal made of aluminium foil, optionally laminated with polymers and the said at least one dry excipient is selected from the group consisting of lactose, lactose monohydrate, lactose anhydrous and mixtures thereof."

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

In the device according to claim 1 the dry powder medicament was sealed in an aluminium container whereas in D18 it was contained in a gelatin capsule which in turns was packed in a blister with a protective aluminium layer. Furthermore, D18 did not provide any information as to the conditions during the packaging of the dry powder. The experimental tests S1 and S2 disclosed in the application, showed that the particular conditions used for packaging the dry powder had a positive effect on the fine particle dose (FPD). The technical problem was to be formulated as the provision of an improved medical product containing tiotropium as active ingredient. Neither D18 nor any other document of the prior art suggested that packaging the tiotropium powder under the conditions defined in claim 1 resulted in an improvement of the FPD. The requirements of Article 56 EPC were therefore met.

VII. The appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the request submitted on 15 December 2017 as auxiliary request 3.

## Reasons for the Decision

1. Article 123(2) EPC

1.1 Claim 1 of the sole request before the board contains substantially the same features of claim 1 of auxiliary request 3 considered by the examining division. The conclusion drawn by the examining division as to the compliance of this claim with the requirements of Article 123(2) EPC (point 4.1 of the decision) applies in the board's view also to present claim 1. The features concerning the composition of the excipient (not included in claim 1 of auxiliary request 3 considered by the examining division) are based on original claim 9. Hence, claim 1 fulfils the requirements of Article 123(2) EPC.

2. Inventive step

2.1 The board agrees with the examining division that document D18 represents the closest prior art for the assessment of inventive step.

2.2 D18 is a public assessment report issued by the Dutch medicines evaluation board (College ter Beoordeling van Geneesmiddelen), concerning the pharmaceutical product Spiriva® 18 µg.

In the paragraph "Composition" (page 5), D18 explains that Spiriva® is an inhalation powder contained in hard gelatin capsules. The powder comprises tiotropium as active ingredient and lactose monohydrate as excipient. The gelatin capsules are packed in a blister made of polyvinylchloride and a protective aluminium layer.

2.3 In the decision under appeal the examining division took the view that claim 1 of auxiliary request 3 covered also devices wherein the dry powder medicament was loaded in gelatin capsules (see points 4.09 and 4.11 of the decision). This conclusion was apparently based on the consideration that the wording "*a dry powder medicament dose loaded into a container...wherein the container comprises a dry, high barrier seal, comprising aluminium foil*" does not exclude the case in which the dry power medicament is contained in a gelatin capsule which in its turn is contained in an aluminium container such as a blister. Accordingly, the examining division did not regard as a distinguishing feature over D18 the requirement that the powder is loaded in a container comprising a dry, high barrier seal, comprising aluminium foil whereas in the product of D18 the powder is contained in a gelatin capsule.

2.4 In the board's view, it is clear from the description that the application in suit does not intend to cover embodiments in which the powder is in a gelatin capsule. Indeed, starting form page 5, line 13, the description explains that the gelatin capsules contain 13-14% water and that dry powder formulations containing tiotropium as active ingredient are negatively affected by the presence of even very small quantities of water. The solution of this problem proposed by the present application "is not to use capsules at all, but rather to directly load doses into container made of dry packaging material..." (page 6, lines 1 to 6).

2.5 Claim 1 of the request before the board uses the language "*a dry powder medicament dose directly loaded and sealed into a dry container...wherein the container*

*comprises a desiccant and is made so as to act as a dry, high barrier seal made of aluminium foil*".

According to the description (page 9, lines 23 to 26), "directly loaded" means that the powder "*is loaded directly into the high barrier container, i.e. without first loading the dose into e.g. a gelatin capsule, and then enclosing one or more of the primary containers (capsules) in a secondary package made of a high barrier seal material*".

It is therefore unambiguous that claim 1 of the request before the board does not relate to products like Spiriva® in which the powder is contained in a gelatin capsule.

2.6 Claim 1 requires that during dose forming, loading and container sealing the temperature is below 25°C and the relative humidity is below 15%. The manufacturing process of Spiriva® is shortly described on page 6 of D18. This section does not provide any indication as to the conditions of temperature and humidity during dose forming, loading and container sealing. Hence, the indication that the packaging of the product of claim 1 is carried out at temperature below 25°C and relative humidity below 15% represents a further distinguishing feature over D18.

2.7 During the oral proceedings before the board the appellant explained that tests S1 and S2 of the application show that packaging the tiotropium powder under conditions of humidity below 15% has a beneficial effect on the fine particle dose (FPD) of the product, i.e. the respirable dose mass with an aerodynamic particle size below 5 µm.

2.7.1 Test S1 relates to the measurement of the FPD of a formulation prepared by loading in capsules of gelatin, at relative humidity below 10%, the bulk powder of Spiriva®. Test S2 relates to the measurement of the FPD of the commercial product Spiriva®. The results are reported in Figure 1 and are expressed as percentage of the FPD of the product of Test S2, i.e. the commercial product Spiriva® described in D18. The product of experiment S1, provides an FPD which is more than 150% of the FPD provided by the commercial product Spiriva®.

2.7.2 The products tested in S1 and S2 are based on the same formulation (the formulation of Spiriva®) loaded in the same type of capsules. The main difference of the two experiments is represented by the condition of relative humidity at which the formulations are loaded in the capsules. As observed above, D18 is silent as to the level of humidity during the process of loading the formulation into the capsules. In the absence of any indication that special measures have been adopted to work under dry conditions, the board assumes that in D18 (and in test S2) the powder loading is made under ambient conditions, i.e. at a level of relative humidity which is above 15%.

2.7.3 The application does not explain how long in tests S1 and S2 the formulations remained in the gelatin capsules before the FPD measurement. It is therefore possible that in the two experiments the formulations did not remain inside the gelatin capsules for the same time span. However, as pointed out by the appellant during the oral proceedings before the board, D18 explains that the Spiriva® capsules are stable when stored below 25°C and that the quality of the product remain acceptable (page 7, paragraph "Stability and shelf life of the finished product"). Thus, it can

reasonably be assumed that the length of the stay of the powder inside the gelatin capsules, is a factor that does not have a major impact on the FPD of the product.

2.7.4 Thus, the board agrees with the appellant that the results of tests S1 and S2 indicate that operating under conditions of low humidity during powder loading has a beneficial effect on the FPD of the product.

2.7.5 In the absence of the explanation provided by the appellant during the oral proceedings before the board in relation to tests S1 and S2, the examining division could not recognise the fact that working under conditions of low humidity during dose forming and loading increases the FPD of the product. This technical effect was therefore disregarded in the formulation of the technical problem and it was not considered whether it was obvious in the light of the available prior art. In this regard, it is observed that in paragraph 4.15 of the decision it is stated that "it was a standard measure...to condition the atmosphere during the manufacturing process (D18)". However, in D18 it is merely affirmed that before packaging, the water content of the filled capsules is conditioned. There is however no indication to work at relative humidity below 15% during dose forming, loading and container sealing.

2.7.6 Hence, since the examining division did not consider the technical effect demonstrated by tests S1 and S2 in the formulation of the technical problem, the decision under appeal does not hold good irrespective of the final conclusion.

3. Remittal

3.1 The primary function of an appeal is to consider whether the decision issued by the first-instance department is correct. Hence, a case is normally remitted if essential questions regarding the patentability of the claimed subject-matter have not yet been examined and decided by the department of first instance.

3.2 As explained above, the examining division did not consider that tests S1 and S2 of the application demonstrated that working under conditions of low humidity had a beneficial effect on the FPD of the product. Accordingly, it did not assess whether a skilled person seeking to improve the FPD of the product of D18 would have considered carrying out the operations of dose forming, loading and container sealing in conditions of relative humidity below 15%. Thus, in respect of this issue, which appears to be crucial for the examination of inventive step, the board cannot exercise its main function, namely to assess the correctness of the decision issued by the first-instance department. Hence, the board deems it appropriate to remit the case to the examining division for further prosecution.

**Order**

**For these reasons it is decided that:**

The decision under appeal is set aside. The case is remitted to the Examining Division for further prosecution.

The Registrar: The Chairman:

S. Fabiani J. Riolo

Decision electronically authenticated