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**Datasheet for the decision  
of 20 October 2011**

**Case Number:** T 1353/08 - 3.2.02

**Application Number:** 00935340.0

**Publication Number:** 1183061

**IPC:** A61M 15/00

**Language of the proceedings:** EN

**Title of invention:**  
Medicament delivery system

**Patent Proprietor:**  
Innovata Biomed Limited

**Opponent:**  
MEDA Pharma GmbH & Co. KG

**Headword:**

-

**Relevant legal provisions:**  
EPC Art. 54, 56, 123(2)

**Keyword:**  
"Extended subject-matter: no"  
"Novelty: - no (main request); - yes (auxiliary request)"  
"Inventive step: yes (auxiliary request)"

**Decisions cited:**

-

**Catchword:**

-



Case Number: T 1353/08 - 3.2.02

**DECISION**  
of the Technical Board of Appeal 3.2.02  
of 20 October 2011

**Appellant I:**  
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**Appellant II:**  
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**Decision under appeal:**                      Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
8 May 2008 concerning maintenance of European  
patent No. 1183061 in amended form.

**Composition of the Board:**

**Chairman:**                      C. Körber  
**Members:**                      D. Valle  
   M. J. Vogel

## Summary of Facts and Submissions

- I. On 8 May 2008 the Opposition Division posted its interlocutory decision concerning maintenance of European patent No. 1 183 061 in amended form.
- II. Appeals were lodged against this decision by both the patentee and the opponent, by notices received on 16 July 2008 and 18 July 2008, respectively, with the appeal fees being paid on the same respective days. The statements setting out the grounds of appeal were received on 17 September 2008 and 18 September 2008, respectively.
- III. By communication of 17 May 2011, the Board forwarded its provisional opinion to the parties.
- IV. Oral proceedings were held on 20 October 2011.

The final requests of the parties were as follows:

The patentee-appellant I requested that the impugned decision be set aside and that the patent be maintained on the basis of the main request filed on 5 June 2009, or on the basis of the auxiliary request filed during the oral proceedings before the Board.

The opponent-appellant II requested that the decision be set aside and that the patent be revoked.

- V. The following documents are of importance for the present decision:

E1: WO-A-93/03785

E9: WO-A-98/30262  
E11: EP-A-0 518 087  
E12: WO-A-92/04068.

VI. Claim 1 of the main request reads:

"1. A medicament delivery device (1) which is an inhaler and comprises a medicament reservoir (2), an inhalation passage (3) and a metering member (4) provided with at least one dispensing cup (13) adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage **characterised in that** the dispensing cup is provided with an air inlet in the form of an air duct (14) that allows air to be sucked through the metering member (4) upon inhalation by a patient."

Claim 1 of the auxiliary request reads as follows:

"1. A medicament delivery device (1) which is an inhaler and comprises a medicament reservoir (2), an inhalation passage (3) and a metering member (4) provided with at least one dispensing cup (13) adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage, the metering member (4) comprising a dispensing member (10) and a measuring member (9) associated therewith, said measuring member (9) being provided with at least one measuring chamber (12) for transferring medicament from the medicament reservoir (2) to the dispensing cup (13), the arrangement being such that the metering member (4) can be moved from a measuring position, in which medicament is transferred from the medicament reservoir (2) to the measuring chamber (12), to a

medicament transfer position, in which medicament is transferred from the measuring chamber (12) to the dispensing cup (13), and to a medicament delivery position, and the dispensing cup being provided with an air duct (14)."

Claim 2 is a dependent claim.

VII. The patentee-appellant's arguments are summarised as follows:

Claim 1 of the main request was based on original claim 19 in combination with page 5, line 30, to page 6, line 3, of the description as originally filed. The basis for the amendment introduced in claim 1 of the auxiliary request could be found at page 6, lines 15 to 20, and page 9, lines 3 to 7 of the description as originally filed and in original claim 17. The basis for claim 2 was at page 2, lines 26 to 30, and page 3, lines 5 to 6.

Claim 1 of the main request was novel over E11 since the device disclosed in E11 was an insufflator and not an inhaler. Furthermore, the coaxial base hole 66 of the dispensing cup had a much smaller diameter than the dispensing cup and did not allow air to be sucked through the metering member upon inhalation by a patient. Instead, the device of E11 included a manually operated pump 42 for generating an air stream that dispensed the medicament from the dispensing cup. Any reduction in pressure that the patient would be able to generate by inhalation would be sufficiently downstream of the coaxial hole 66 so that it would have no effect on the flow of air through the hole. Moreover, as

described between column 6, line 46 and column 7, line 9 of E11, the pump 42 was closed by a first non-return valve 44 at the air intake, as well as a second non-return valve 54 that communicated with the funnel-shaped vertical channel 51 and the coaxial hole 66. There was no indication in E11 that suction provided by the patient would be sufficient to open these non-return valves in order that air was sucked through the metering member.

Claim 1 of the auxiliary request was novel over all of the cited prior art documents since none of them disclosed a metering member of two-part construction, i.e. including both a measuring member and a dispensing member, distinct and separate from the measuring member. Moreover, there was no disclosure in any of these documents of an arrangement in which the dose of medicament was first measured by filling of a measuring chamber of the measuring member, before being transferred to a dispensing cup. The "medicament transfer position" as defined in claim 1, in which medicament was transferred from the measuring chamber to the dispensing cup, represented a functional feature of the claim and could not be disregarded when assessing novelty. None of the cited documents disclosed a thus defined "medicament transfer position".

Starting from document E1 as closest prior art, the technical effects achieved by the distinguishing features of claim 1 of the auxiliary request were that the transfer of medicament between the measuring chamber and the dispensing cup loosened the dose of the previously compacted medicament and hence facilitated

its dispensing from the dispensing cup. By virtue of the air duct provided therein, an improved emptying of the dispensing cup and a prolonged release of the medicament was achieved, without any loss in accuracy of the dose. The medicament could first be metered accurately into the measuring chamber formed in the measuring member, before it was subsequently transferred to the dispensing cup formed in the dispensing member for effective and complete delivery into the inhalation passage. The objective technical problem was therefore to provide an inhaler having improved air flow for emptying a dispensing cup of a dose of medicament without reducing the effectiveness of the medicament delivery, and without reducing the accuracy of the dose. None of the cited prior art documents disclosed or suggested anything akin to the two-part measuring member that characterised the invention. In all of those documents, a dosage member of some form was provided with a metering aperture, recess or cup that was filled with medicament and then moved to a location from which the medicament was inhaled directly from that aperture, recess or cup. Claim 1 of the auxiliary request therefore involved an inventive step.

VIII. The opponent-appellant's arguments are summarised as follows:

The feature of the dispensing cup being provided with an air duct that allows air to be sucked through the metering member upon inhalation by a patient in claim 1 of the main request was only disclosed in combination with a moisture resistant sleeve as an essential feature. The omission of the latter thus represented an

unallowable intermediate generalisation infringing Article 123(2) EPC.

The insufflator disclosed in E11 was a special type of inhalator with an additional air stream being generated by a pump, which, however, was not ruled out by the wording of claim 1 of the main request. E11 disclosed all structural features of the claim. The hole 66 in the dispensing cup 64 also allowed "air to be sucked" therethrough. The wording of the claim did not specify any quantity of air in this respect. The subject-matter of claim 1 was also anticipated by other cited documents of the prior art, in particular by E1, with the pressure outlet 23 being regarded as an "air duct", E9 (Figures 6 to 9) and E12 (Figures 1, 4 and 5).

The wording of claim 1 of the auxiliary request did not imply that the dispensing member and the measuring member had to be separate parts of the metering member. Furthermore, it was not required that the "medicament transfer position" had to be different from the "medicament delivery position", the respective functional definition of "the arrangement being such that ..." not representing a restriction of the claimed device.

E12 even explicitly disclosed a dispensing cup 23 which was distinct and separate from the measuring chamber 7. Since air could flow through the nozzle 23 representing the dispensing cup, it was also "provided with an air duct" as claimed. Figure 4 of E12 depicted the metering member in a "transfer position" from which it was subsequently moved to a "medicament delivery position" in which the dose of medicament was blown through the



nozzle into the inhalation passage. Accordingly, E12 was novelty-destroying for claim 1 of the auxiliary request.

Starting from E1 as closest prior art, the only difference compared to claim 1 of the auxiliary request was that in E1 the measuring chamber 32 also served as dispensing cup. The measuring chamber was moved from a measuring position as shown in Figure 3 to a medicament transfer position (Figure 4) and to a medicament delivery position (Figure 5). In the latter position it was provided with an air duct in the form of passageway 23. The measuring chamber 32 of E1 could thus already achieve the alleged advantages of better measurement accuracy and improved dispensing of the medicament simultaneously. Accordingly, the problem to be solved by a dispensing cup separate from the measuring chamber was to provide an alternative construction of the inhalator, which did not involve an inventive step. Moreover, such a separation was a disadvantage rather than an improvement compared to the integrated design of E1.

The subject-matter of claim 1 was further obvious from E1 or E11 when taking into account the teaching of E12, which disclosed a dispensing cup provided with an air duct as previously explained.

## Reasons for the Decision

1. The appeal is admissible.
2. Main request
  - 2.1 Amendments

Claim 1 is based on original claim 19 in combination with original claim 15 and page 6, line 1 of the description as originally filed, where reference is made to an "air inlet, e.g. an air duct", thus providing a basis for an air inlet in the form of an air duct as claimed. Contrary to the opponent-appellant's view, none of these parts of the original disclosure indicates that the additional presence of a moisture resistant sleeve is necessarily required.

- 2.2 Novelty

Document E11 discloses (in the wording of claim 1) a medicament delivery device (1) which is an inhaler and comprises a medicament reservoir (34), an inhalation passage (26) and a metering member (60) provided with at least one dispensing cup (64) adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage (see column 8, lines 2 to 24) wherein the dispensing cup is provided with an air inlet in the form of an air duct (66) that allows air to be sucked through the metering member (60) upon inhalation by a patient.

The Board is of the opinion that the term "inhaler" as claimed also covers an "insufflator" for nasal

administration of medicament as described in E11. Inhalation is the movement of air from the external environment through the patient's airways, which include the nose as well as the mouth. The claim is in no way restricted to oral inhalation.

Even though not explicitly described in E11, the air duct 66 "allows air to be sucked through the metering member upon inhalation by a patient", i.e. the duct is suitable for that purpose. The wording of the claim does not rule out that the inhalation of the medicament is further supported by an air stream generated by a pump as disclosed in E11. To what extent suction provided by the patient and pressure generated by the pump 42 contribute to the air flow depends on how strongly the patient inhales and how strongly the pump is squeezed. In any case, it cannot be said that inhalation would have "no effect" on the flow of air through the coaxial through hole 66, corresponding to the air duct of claim 1.

The fact that E11 states that the coaxial through hole 66 has a much smaller diameter than the cup 64 does not imply that it does not permit "air to be sucked" therethrough. Claim 1 does not specify any quantity of air in this context. Also, the presence of the two valves (44 and 54) in the device of E11 does not imply that it would be impossible for the patient to suck air through the air duct or hole 66. Regarding the non-return valve 54, it is explicitly stated in column 8, lines 19 to 24, that it allows an air stream to pass through the hole 66 into the tube 26, representing the inhalation passage. Valve 44 is only relevant with respect to the function of the pump 42.

Accordingly, the subject-matter of claim 1 of the main request is known from E11 and therefore not new (Article 54(1) and (2) EPC).

### 3. Auxiliary request

#### 3.1 Amendments

Claim 1 is based on original claims 15 and 17 in combination with Figure 2 and the respective part of the description, in particular page 6, lines 15 to 20, and page 9, lines 3 to 7, of the application as originally filed. The basis for claim 2 is found at page 2, lines 26 to 30, and page 3, lines 5 to 6.

#### 3.2 Novelty

##### 3.2.1 Document E11

The metering member 60 of the device disclosed in E11 does not comprise a dispensing member and a measuring member associated therewith, said measuring member being provided with at least one measuring chamber for transferring medicament from the medicament reservoir 34 to the dispensing cup 64. The medicament is filled directly into the dispensing cup 64 of the conveyor disc 60 (corresponding to the metering member), as shown in Figure 2. Contrary to the appellant-opponent's view, the cup 64 of E11 cannot be regarded as anticipating both the dispensing cup and a (distinct) measuring chamber simultaneously. The position shown in Figure 2 is denoted as "starting position". Upon rotation about axis 16, the cup 64 then reaches the

position corresponding to the lower end of tube 26, shown in dashed lines in Figure 2, which represents the "medicament delivery position". Between these positions, the metering member can also be said to be moved to some kind of "medicament transfer position", but in this position medicament is not transferred from a measuring chamber to the dispensing cup 64, as required by claim 1. The medicament simply remains in the dispensing cup.

### 3.2.2 Document E12

Document E12 discloses (in the wording of claim 1) a medicament delivery device which is an inhaler (cf. title of E12) and comprises a medicament reservoir (6), an inhalation passage (9) and a metering member (8, 12) adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage, the metering member (8, 12) comprising a dispensing member (12, 12a) and a measuring member (8) associated therewith, said measuring member (8) being provided with at least one measuring chamber (7), the arrangement being such that the metering member (8) can be moved from a measuring position, in which medicament is transferred from the medicament reservoir (6) to the measuring chamber (7), to a medicament delivery position.

The "measuring member" of claim 1 is to be equated to the dosage plunger 8 ("Dosierstempel") of E12, which is provided with a dose chamber 7 or "measuring chamber", as defined in claim 1. However, claim 1 further requires that the metering member is provided with at least one dispensing cup, i.e. an additional feature

distinct from the measuring chamber of the metering member. Such an additional dispensing cup forming part of the metering member is not present in E12. The Board does not accept that the dose chamber 7 of E12 may be seen as simultaneously anticipating both the measuring chamber and the dispensing cup.

The nozzle 23 of E12 is clearly fixed inside the air channel 9 of the mouthpiece 11, corresponding to the "inhalation passage" of claim 1. Accordingly, even if this nozzle 23 is regarded as a "dispensing cup", it is the mouthpiece 11 with its air channel 9 or "inhalation passage" that is provided with the dispensing cup in E12, and not the metering member, as required by claim 1.

Furthermore, the metering member 8, 12 can be moved from a measuring position, in which medicament is transferred from the medicament reservoir 6 to the measuring chamber 7 (Figure 1), to a medicament delivery position (Figures 4 and 5), but not to an - intermediate - medicament transfer position, in which medicament is transferred from the measuring chamber to the dispensing cup, as required by claim 1. It is to be noted that the position of the metering member 8, 12 is identical in Figures 4 and 5. Accordingly, it is not appropriate to associate Figure 4 with the "medicament transfer position" and Figure 5 with the "medicament delivery position", as attempted by the opponent-appellant. In the medicament transfer position according to claim 1, medicament is transferred from the measuring chamber to the dispensing cup. Since the metering member of E12 does not comprise a separate

dispensing cup, a thus defined medicament transfer position is not anticipated.

Accordingly, E12 fails to disclose that the metering member is provided with at least one dispensing cup being provided with an air duct, and that the metering member can be moved to a medicament transfer position, in which medicament is transferred from the measuring chamber to the dispensing cup.

### 3.2.3 Document E1

E1 discloses (in the wording of claim 1) a medicament delivery device which is an inhaler (page 1, lines 6 to 7) and comprises a medicament reservoir (11), an inhalation passage (16) and a metering member (22, 30) adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage, the metering member (22, 30) comprising a dispensing member (22) and a measuring member (30) associated therewith, said measuring member (30) being provided with at least one measuring chamber (32), the arrangement being such that the metering member (22, 30) can be moved from a measuring position (Figure 3), in which medicament is transferred from the medicament reservoir (11) to the measuring chamber (32), to a medicament delivery position (Figure 5).

E1, too, fails to disclose that the metering member 22, 30 is provided with at least one dispensing cup, which is provided with an air duct, the dispensing cup being distinct from the measuring chamber 32. Again, the Board does not accept that the dose chamber 32 of E1 may be seen as simultaneously anticipating both the

measuring chamber and the dispensing cup. Since a dispensing cup is not disclosed in E1, it can much less be provided with an air duct, as required by claim 1.

In the position shown in Figure 4, the medicament remains in the dosage chamber 32, corresponding to the measuring chamber of claim 1, while the movable dosage member 30, corresponding to the measuring member, is rotated until the dosage chamber is aligned with a pressure outlet passageway 23 from which the dose of medicament is blown by high pressure gas. In contrast, the medicament transfer position of claim 1 is defined for transferring medicament from the medicament reservoir to the dispensing cup, which is not anticipated by E1.

Accordingly, E1 fails to disclose that the metering member is provided with at least one dispensing cup provided with an air duct and that the metering member can be moved to a medicament transfer position in which medicament is transferred from the measuring chamber to the dispensing cup.

#### 3.2.4 Document E9

E9 discloses (in the wording of claim 1) a medicament delivery device which is an inhaler and comprises a medicament reservoir (56), an inhalation passage (57) and a metering member (53) adapted to transfer a measured dose of medicament from the medicament reservoir to the inhalation passage, the metering member (53) being provided with at least one measuring chamber (65). As described at page 11, line 18, to page 12, line 17, the metering member is rotated from a



measuring position, in which medicament is transferred from the medicament reservoir (56) to the measuring chamber (65), to a medicament delivery position.

However, the metering member (53) does not comprise a dispensing member and a measuring member associated therewith. Moreover, similarly to E1, E9 also fails to disclose that the metering member is provided with at least one dispensing cup provided with an air duct and that the metering member can be moved to a medicament transfer position, in which medicament is transferred from the measuring chamber to the dispensing cup.

3.2.5 From the above it follows that none of the cited documents discloses in combination the features of claim 1. The Board therefore considers that its subject-matter is new (Article 54(1) and (2) EPC).

3.3 Inventive step

3.3.1 Closest prior art

Document E1 is considered to represent the closest prior art, in accordance with the view of both parties.

3.3.2 Technical effects achieved by the distinguishing features

E1 includes a powder loading assembly that provides a packed, predetermined, agglomerated dose of the dry powder medicament in a dosage chamber 32 (see page 17, lines 29 to 31), in order to ensure accuracy of dose (see page 18, lines 14 to 18), and which is then dispensed directly from said dosage chamber using a

pressurised source of gas. By means of the provision of a dispensing cup separate from the measuring or dosage chamber and the transfer of medicament between the measuring chamber and the dispensing cup in the medicament transfer position, as defined in claim 1, the dose of medicament becomes loosened, thus facilitating its subsequent dispensing from the dispensing cup. The measurement accuracy is not compromised since the quantity of medicament is adjusted in the measuring position, in which medicament is transferred from the medicament reservoir to the measuring chamber, before it is transferred to the dispensing cup (provided with the air duct).

By virtue of the air duct provided in the cup, an improved emptying can be achieved, without any loss in accuracy of the measured dose. The displacement of medicament from the dispensing cup is not necessarily achieved solely by flow of air through the air duct. In the medicament delivery position, the dispensing member, with the filled dispensing cup, is exposed to the inhalation passage. Medicament may be drawn from the dispensing cup by flow of air through the inhalation passage, across the surface of the dispensing cup. The flow of air through the air duct then provides a supplementary flow of air that assists with emptying of the dispensing cup. Thus, a more prolonged release of medicament becomes possible in comparison with the device of E1, where the release of medicament from the dosage chamber by high pressure gas necessarily results in the medicament being inhaled as a bolus at high velocity.

### 3.3.3 Objective technical problem

The technical problem to be solved is therefore to provide an inhaler allowing a better controlled and more complete emptying of the medicament dose into the inhalation passage without compromising the accuracy of the dosage to be delivered. This problem is derivable from paragraph [0009] of the patent in suit. It is considerably more ambitious than the problem of providing an alternative design of the medicament delivery mechanism, as formulated by the opponent-appellant.

#### 3.3.4 Inventiveness

None of the above-mentioned documents E9, E11 and E12 discloses or suggests a metering member comprising a measuring member provided with a measuring chamber, said metering member being provided with a separate dispensing cup. They further fail to disclose transfer of medicament from the measuring chamber to the dosage cup in a medicament transfer position of the metering member. E9 and E12 disclose a measuring chamber ("recess 65" or "dosage chamber 7") into which the medicament is filled and which are then moved to a location from which the medicament is inhaled directly from said measuring chamber. The principle is thus analogous to that of E1. Accordingly, these documents give no hint towards deviating from the teaching of E1. When taking into account the teaching of these documents, the skilled person would not arrive at the solution according to claim 1.

E11, on the other hand, discloses a dispensing cup 64 with an air duct 66, but the medicament is directly

filled into this dispensing cup in the position shown in Figure 2, and the dispensing cup is then moved to the location shown in dashed lines from which the medicament is inhaled directly from the dispensing cup. Even when taking into account this teaching, the skilled person, starting from document E1, would not be led to the concept of providing the dispensing cup in addition to the measuring chamber of E1, and transferring the medicament from the latter to the former in a medicament transferring position.

When starting from document E11, the skilled person would be aware (see column 5, lines 8 to 12, and column 7, lines 19 to 34) of the fact that the air duct (coaxial through hole 66) in the dispensing cup may lead to a loss of medicament in the measuring position and thus compromise measurement accuracy. E11 therefore teaches keeping the diameter of the hole sufficiently small. However, when taking into account the teaching of E12, the skilled person would also not be led to the concept of providing the measuring chamber of E12 in addition to the dispensing cup of E11, and moving the metering member to a medicament transfer position as defined in claim 1, subsequent to the measuring position and before the delivery position.

3.3.5 Accordingly, the subject-matter of claim 1 of the auxiliary request is not rendered obvious in view of the above-mentioned documents. The Board considers that it is based on an inventive step within the meaning of Article 56 EPC.

## Order

### For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the department of first instance with the order to maintain the patent in the following version:

Claims: 1 and 2, filed as an auxiliary request during the oral proceedings before the Board;

Description: pages 2 and 2a, filed during the oral proceedings before the Board, and pages 3 and 4 of the patent specification;

Drawings: Figures 1 to 4c of the patent specification.

The Registrar:

The Chairman:

D. Hampe

C. Körber