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**Datasheet for the decision  
of 24 July 2007**

**Case Number:** T 1077/05 - 3.2.02

**Application Number:** 99905106.3

**Publication Number:** 1066073

**IPC:** A61M 15/00

**Language of the proceedings:** EN

**Title of invention:**  
Pressurised dispensing containers

**Patentee:**  
GLAXO GROUP LIMITED

**Opponents:**  
THE SECRETARY OF STATE FOR DEFENCE  
3MM Innovative Properties Company

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 54, 56

**Keyword:**  
"Novelty and inventive step - yes (after amendments)"

**Decisions cited:**  
G 0002/98

**Catchword:**  
-



Case Number: T 1077/05 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 24 July 2007

**Appellants:**  
(Opponent I)

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**Decision under appeal:**

Interlocutory decision of the Opposition  
Division of the European Patent Office posted  
28 June 2005 concerning maintenance of the  
European No. 1066073 in amended form.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** D. Valle  
M. J. Vogel

## Summary of Facts and Submissions

- I. The appellant I (opponent I) lodged an appeal on 7 September 2005 against the decision of the opposition division posted on 28 June 2005 maintaining the European patent 1 066 073 in amended form. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 4 November 2005.
- II. The appellant II (opponent II) lodged a further appeal on 25 August 2005 against the above cited decision. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 20 October 2005.
- III. The following documents are relevant for the present decision:
- D1a: WO - A - 96/32151
- D2: EP - A - 642 992
- D13a: WO - A - 99/47195
- D14a: GB 9 803 780 (priority document of the patent in suit)
- D20: Banker G.S. and Rhodes C.T. Modern Pharmaceuticals, 2nd edition, 1989, pages 605 and 622 to 624.
- IV. Oral proceedings took place on 24 July 2007.

The appellant I was not represented at the oral proceedings (as announced with letter of 10 June 2007). In the written proceedings he requested that the decision under appeal be set aside and that the patent be revoked.

The appellant II requested also that the patent be revoked.

The respondent (patentee) requested that the patent be maintained in amended form according to the main or one of the auxiliary requests 1 to 3, all filed during the oral proceedings.

- V. Claim 3 of the main request is directed to a metering valve. This is the broadest claim of the main request, since the further claim 1 is directed to a container having a metering valve as in claim 3. Claim 3 reads as follows:

"Metering valve for dispensing a medicament for use with a pressurized dispensing container, the valve comprising a valve stem co-axially slidable within a valve member, said valve member and valve stem defining an annular metering chamber, and outer and inner annular seals operative between the respective outer and inner ends of the valve member and the valve stem to seal the annular metering chamber therebetween, characterized in that at least a portion of an internal surface of the metering chamber has a layer of one or more cold plasma polymerised monomers bonded thereto, wherein the layer is of a cold plasma polymerized fluorinated hydrocarbon, and wherein said internal surface is a surface of the valve member."

Claim 3 of the first auxiliary request, which is again the broadest claim, reads as follows (the additions with respect to the main request are underscored):

"Metering valve for dispensing a medicament for use with a pressurized dispensing container, the valve comprising a valve stem co-axially slidable within a valve member, said valve member and valve stem defining an annular metering chamber, and outer and inner annular seals operative between the respective outer and inner ends of the valve member and the valve stem to seal the annular metering chamber therebetween, characterized in that at least a portion of an internal surface of the metering chamber has a layer of one or more cold plasma polymerised monomers bonded thereto, wherein the layer is of a cold plasma polymerized fluorinated hydrocarbon, wherein said internal surface is a surface of the valve member and wherein the surface of the valve member is made from a plastic polymer."

Claim 3 of the second auxiliary request, which is again the broadest claim, reads as follows (the additions with respect to the main request are underscored):

"Metering valve for dispensing a medicament for use with a pressurized dispensing container, the valve comprising a valve stem co-axially slidable within a valve member, said valve member and valve stem defining an annular metering chamber, and outer and inner annular seals operative between the respective outer and inner ends of the valve member and the valve stem to seal the annular metering chamber therebetween,

characterized in that at least a portion of an internal surface of the metering chamber has a layer of one or more cold plasma polymerised monomers bonded thereto, wherein the layer is of a cold plasma polymerized fluorinated hydrocarbon, wherein said internal surface is a surface of the valve member and wherein the layer has a thickness in the range of 0.005 to 0.5 microns."

Claim 2 of the third auxiliary request, which is the broadest claim, reads as follows (the additions with respect to the main request are underscored):

"Metering valve for dispensing a medicament for use with a pressurized dispensing container, the valve comprising a valve stem co-axially slidable within a valve member, said valve member and valve stem defining an annular metering chamber, and outer and inner annular seals operative between the respective outer and inner ends of the valve member and the valve stem to seal the annular metering chamber therebetween, characterized in that at least a portion of an internal surface of the metering chamber has a layer of one or more cold plasma polymerised monomers bonded thereto, wherein the layer is of a cold plasma polymerized fluorinated hydrocarbon, wherein said internal surface is a surface of the valve member and wherein the layer is of cold plasma polymerised perfluoro-hexane."

VI. The appellant II argued as follows:

The patent in suit was not entitled to the priority of D14a as far as fluorinate hydrocarbons other than tetrafluorethylene (Teflon) were claimed. Consequently D13a had to be considered as state of the art for the

assessment of novelty according to Article 54(3) EPC. The subject-matter of claim 3 according to the main and the first auxiliary requests was not novel over the disclosure of D13a.

Since the range of values for the thickness of the plasma coating according to claim 3 of the second auxiliary request was also known from D13a, the subject-matter of this claim was also not novel over the disclosure of D13a. D13a disclosed that the coating formed a thin layer. The claimed values represented the typical range of thicknesses obtained with a cold plasma process. In the field of plasma coating high tolerances were usual and the claimed range was very broad. Furthermore the subject-matter of this claim did not involve an inventive step having regard to the disclosure of D1a and, if necessary, D2. The only difference of the claimed metering valve with regard to D1a was the coating thickness. However, this feature did not have any technical effect and did not contribute to the claimed invention. Moreover, D2 suggested values for the thickness of a plasma coating overlapping with the claimed values.

Auxiliary request three was not objectionable.

- VII. The respondent disagreed with the arguments of the appellant II and stated in particular that D14a described on page 5, lines 1 to 4 a layer of plasma polymerised tetrafluorethylene (Teflon). Since Teflon was the most representative element of the class of plasma fluorinate hydrocarbon polymers, D14a disclosed at least implicitly this complete class. Hence the priority of D14a was validly claimed and D13a did not



form part of the state of the art according to Article 54(3),(4) EPC.

D13a did not disclose clearly and unambiguously the precise range of values for the thickness of the coating claimed in the second auxiliary request. The thickness depended *inter alia* on the length of time of the coating process and the concentration of material employed. The values disclosed in D2 were not typical. For example D1a disclosed on page 7 values of thickness which all lay outside the claimed range (100 to 1 micron).

D1a taught away from coating the internal surfaces of the valve member, since it suggested to provide a coating exclusively on a can surface and not on the surface of a valve member. D2 disclosed applying the coating to the surface of a can as well. Therefore the skilled person had no reason to provide a coating on the surface of a valve member, in particular since the desired purpose was already achieved by coating the can walls. Therefore, the subject-matter of all present requests also involved an inventive step. It was however conceded that the range of thickness of the coating according to claim 3 of the second auxiliary request did not have a special technical effect "per se".

## **Reasons for the Decision**

1. The appeal is admissible.

2. *Validity of the priority with respect to D14a*

D14a does not form a valid priority for the subject-matter claimed in the patent in suit as far as it refers to fluorinate hydrocarbons other than tetrafluoroethylene.

According to G 2/98 (OJ EPO 2001, 413) the priority of a previous application is to be acknowledged only if the person skilled in the art can derive a claimed subject-matter directly and unambiguously, using common general knowledge, from the previous application as a whole.

In the present case the previous application D14a discloses in the paragraph bridging pages 4 and 5 that valve members and valve stems are subjected to a cold plasma polymerisation treatment which creates a very thin layer of a plasma polymer, such as a plasma polymerised tetrafluorethylene. In other words D14a teaches to use for the cold plasma polymerisation treatment a material from the group of "polymers", for example "tetrafluorethylene". However, there is no disclosure in D14a that any "fluorinated hydrocarbon" could be used for the plasma treatment. Therefore the use of any fluorinated hydrocarbon for the cold plasma polymerisation either requires a selection out of all polymers or a generalisation starting from tetrafluorethylene.

The argument that tetrafluorethylene, being the most representative substance of the group of fluorinated hydrocarbons, and being only exemplarily cited as the material to be used for the plasma treatment led the

skilled person, using his general knowledge, to conclude that the whole group of fluorinated hydrocarbons were disclosed in D14a is not convincing.

Although it is well known that tetrafluorethylene belongs to the group of fluorinate hydrocarbons, the only group referred to in D14a is the group of polymers. Hence the generalisation from tetrafluorethylene to the group of fluorinate hydrocarbons cannot be directly and unambiguously derived from D14a. The selection of fluorinated hydrocarbons out of all polymers can also not be done in a direct and unambiguous way, since there are a lot of sub-groups of polymers which might be used for plasma polymerisation (for example siloxanes, see WO-A-9942154, page 7, lines 24 to 26).

With respect to the above findings D13a - having a priority date of 19 March 1998 which lies before the priority date of 24 March 1998 of the patent in suit - has to be considered for the assessment of novelty according to Article 54(3),(4) EPC.

### 3. *Novelty*

D13a discloses a metering valve for dispensing a medicament for use with a pressurized dispensing container, the valve comprising a valve stem (7) co-axially slidable within a valve member (14), said valve member and valve stem defining an annular metering chamber (4), and outer (9) and inner (12) annular seals operative between the respective outer and inner ends of the valve member and the valve stem to seal the annular metering chamber therebetween,

wherein at least a portion of an internal surface of the metering chamber has a layer of one or more cold plasma polymerised monomers bonded thereto (see page 4, lines 4 to 6), wherein the layer is of a cold plasma polymerised fluorinated hydrocarbon (for example: PVDF, PVF, FEP, see page 4, first full paragraph) and wherein said internal surface is a surface of the valve member (see page 3, third paragraph).

Furthermore D13a discloses that the valve member is made from a plastic polymer (see page 11, last paragraph).

Accordingly the subject-matter of claim 3 of the main request and of the first auxiliary request is not novel.

4. *Auxiliary request 2, novelty*

Claim 3 of the auxiliary request 2 contains the additional feature that the layer has a thickness in the range of 0.005 to 0.5 microns. This feature is not clearly and directly derivable from D13a. D13a discloses merely a "thin" layer of plasma polymer (page 4, line 4). However, this does not mean that the plasma polymerisation according to D13a necessarily results in a layer of the claimed range.

The subject-matter of claim 3 is therefore novel over D13a.

5. *Auxiliary request 2, inventive step*

D1a which undisputedly represents the most relevant pre-published state of the art discloses a metering valve for dispensing a medicament for use with a pressurized dispensing container (see page 1, lines 12, 13), wherein at least a portion of an internal surface of the metering chamber has a layer of one or more cold plasma polymerised monomers bonded thereto, wherein the layer is of a cold plasma polymerized fluorinated hydrocarbon (see claim 1 and page 9, lines 16 to 25, where a temperature of 20°C is cited which corresponds to the "ambient temperature" used in the cold plasma treatment as mentioned in the patent in suit, see WO - 99/42154, page 7, lines 27 o 29) and wherein said internal surface is a surface of the valve member (see claim 1).

The respondent's contention, that D1a discloses only a coating layer applied to the can and not to the valve member can not be followed. D1a clearly states that all internal surfaces of a metered dose inhaler (MDI) can be coated (see claim 1). This is provided to avoid that the drug to be administered deposits on the internal walls with which it is in contact. It is clear that the internal surface of the valve member is one of these surfaces, being it in contact with the drug (see page 2, line 2). Certainly the examples given in D1a all refer to the coating of a MDI can. However, in the wording of D1a, a MDI comprises - *inter alia* - a can and a valve (see page 2, lines 24 to 26).

However, D1a does not disclose:

- (a) that the valve comprises a valve stem co-axially slidable within a valve member, said valve member and valve stem defining an annular metering chamber, and outer and inner annular seals operative between the respective outer and inner ends of the valve member and the valve stem to seal the annular metering chamber therebetween, and
  
- (b) that the layer has a thickness in the range of 0,005 to 0,5 microns.

Feature (a) merely describes the typical constructive elements of a metering valve suitable for a MDI. D20 for example discloses that a metering valve "typically" (see page 623, first line) comprises a valve stem co-axially slidable within a valve member, said valve member and valve stem defining an annular metering chamber, and outer and inner annular seals operative between the respective outer and inner ends of the valve member and the valve stem to seal the annular metering chamber therebetween (see Figures 3 and 4). Hence the use of the elements described in D20 in the valve according to D1a is obvious.

Although the range of thicknesses defined in feature (b) does not appear to have a special technical effect "per se", the object to be achieved by this feature may be regarded as to provide a very thin layer of plasma polymer which is sufficient for significantly reducing the deposition of drugs, and which does not

require new tooling and moulds (see patent in suit, column 4, paragraph 24).

It is obvious that the skilled person - in the light of this object - would select the thinnest possible layer as long as it is still thick enough to avoid the deposition of drugs. In doing so he would inevitably select a thickness of the claimed range, in particular since D2 shows that a layer of plasma polymerised monomers (see column 5, lines 7 to 16) of the claimed range (see column 2, lines 38, 39; and column 5, lines 22, 23) is suitable to avoid the deposition of drugs (see column 2, lines 25 to 27).

Accordingly, claim 3 of the second auxiliary request does not involve an inventive step.

6. Auxiliary request 3

The third auxiliary request was not objected by the appellant. Since the Board found that the documents of this request meet the requirements of the EPC, they are suitable to form the basis for the maintenance of the patent in amended form, in particular since the additional feature of claims 1 and 2 according to which the fluorinated hydrocarbon is perfluoro-hexane, is not suggested by the available state of the art.

**Order**

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

1. The decision under appeal is set aside.
2. The case is remitted to the first instance with the order to maintain the patent on the basis of:

**Claims:** 1 to 2 filed as third auxiliary request during the oral proceedings;

**Description:** columns 1 to 5 filed during the oral proceedings, and

**Drawings:** Figures 1 to 4 as granted.

The Registrar:

The Chairman:

V. Commare

T. Kriner