

**Internal distribution code:**

- (A) [ - ] Publication in OJ  
(B) [ - ] To Chairmen and Members  
(C) [ - ] To Chairmen  
(D) [ X ] No distribution

**Datasheet for the decision  
of 23 September 2014**

**Case Number:** T 2289/10 - 3.2.02

**Application Number:** 04727338.8

**Publication Number:** 1613380

**IPC:** A61M15/00

**Language of the proceedings:** EN

**Title of invention:**

ANTISTATIC MEDICATION DELIVERY APPARATUS

**Applicant:**

Trudell Medical International

**Headword:**

**Relevant legal provisions:**

EPC Art. 56

**Keyword:**

Inventive step (no - all requests)

**Decisions cited:**

**Catchword:**



**Beschwerdekammern  
Boards of Appeal  
Chambres de recours**

European Patent Office  
D-80298 MUNICH  
GERMANY  
Tel. +49 (0) 89 2399-0  
Fax +49 (0) 89 2399-4465

Case Number: T 2289/10 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 23 September 2014**

**Appellant:** Trudell Medical International  
(Applicant) 725 Third Street  
London,  
Ontario N5V 5G4 (CA)

**Representative:** Grünecker, Kinkeldey,  
Stockmair & Schwanhäusser  
Leopoldstrasse 4  
80802 München (DE)

**Decision under appeal:** **Decision of the Examining Division of the  
European Patent Office posted on 28 June 2010  
refusing European patent application  
No. 04727338.8 pursuant to Article 97(2) EPC.**

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** M. Stern  
D. Ceccarelli

## Summary of Facts and Submissions

- I. The applicant lodged an appeal against the decision of the Examining Division refusing European application No. 04 727 338.8 on the ground of lack of inventive step.
- II. The Board presented its provisional opinion in a communication dated 16 May 2014, raising doubts about the inventiveness of the claimed subject-matter in view of the following documents:
- D1: Rupprecht L. et al.: "Conductive Plastics for Medical Applications", Medical Device & Diagnostic Industry, January 1999
- D2: WO-A-98/19 727
- D4: US-A-6 039 042.
- III. Oral proceedings took place on 23 September 2014.
- The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or, in the alternative, of one of auxiliary requests I to III, all filed with letter dated 8 November 2010.
- IV. Claim 1 of the different requests reads as follows (the differences to the main request are highlighted by the Board):
- Main request:*
- "1. A medication delivery apparatus (50) comprising an antistatic component made of a material having a surface resistivity of between about  $10E10$  and  $10E12$

ohm/sq, wherein at least a portion of said component is see-through."

*Auxiliary request I:*

"1. A medication delivery apparatus (50) comprising an antistatic component made of a material having a surface resistivity of between about 10E10 and 10E12 ohm/sq, wherein at least a portion of said component is see-through, **and wherein the antistatic property of the component is permanent.**"

*Auxiliary request II:*

"1. A medication delivery apparatus (50) comprising an antistatic component made of a material having a surface resistivity of between about 10E10 and 10E12 ohm/sq, wherein at least a portion of said component is see-through, **and wherein the material is one or more of polypropylene, polycarbonate, polystyrene, nylon, ABS, high density polyethylene (HDPE), acetal, PBT, or PETG.**"

*Auxiliary request III:*

"1. A medication delivery apparatus (50) comprising **a holding chamber (4), a mouthpiece (54) and a backpiece (22) wherein the holding chamber is** an antistatic component made of a material having a surface resistivity of between about 10E10 and 10E12 ohm/sq, wherein at least a portion of said component is see-through, **and wherein the material is one or more of polypropylene, polycarbonate, polystyrene, nylon, ABS, high density polyethylene (HDPE), acetal, PBT, or PETG.**"

V. The arguments of the appellant are summarised as follows:

- D2 was considered to be the closest prior art. In the spacer depicted in Figure 2, a transparent antistatic inner layer 24 of fluoropolymer was formed on a different outer layer 22. Hence, in this embodiment the antistatic component was not *made* of a material having the claimed surface resistivity. The spacer of Figure 1, instead, was made of an antistatic fluoropolymer, but page 5, lines 5 to 8 did not directly and unambiguously disclose that it was also transparent. The subject-matter claimed was inventive since the prior art did not motivate the person skilled in the art to modify the teaching of D2 so as to arrive at the present invention, in particular to use a fluoropolymer with the claimed surface resistivity range. D1 did not suggest the claimed surface resistivity range for a spacer with see-through properties and long-term stability.

- Claim 1 of auxiliary request I defined the long-term stability of the antistatic property. According to the description, page 2, lines 10 to 12, "permanent" had the meaning of about one year. D2 did not disclose the antistatic property to be permanent for that length of time.

- The materials recited in claim 1 of auxiliary request II were alternatives to the fluoropolymers disclosed in D2. The antistatic materials in Table I of D1 were not disclosed as being also transparent, in particular across the entire wall of the spacer of D2.

- The spacer 5 in D2 could not be considered as a holding chamber, in particular not a valved holding

chamber with inhalation and exhalation valves as disclosed in the application, e.g. on page 7, line 25 et seq. Therefore, the closest prior art for the apparatus claimed in auxiliary request III was not D2, but D4.

### **Reasons for the Decision**

1. The appeal is admissible.
2. *Main request*
  - 2.1 The description of the application indicates that inhalers are generally made of plastic materials which normally have a large surface resistivity (generally greater than  $10^{12}$   $\Omega$ /sq). Thus the interior of the holding chamber can become electrostatically charged, thereby causing some of the medication particles in the aerosol to be deposited on the walls of the holding chamber (paragraph bridging pages 1 and 2). In order to avoid this, the invention provides that the holding chamber of the inhaler is made of an antistatic material having a surface resistivity between  $10^{10}$  and  $10^{12}$   $\Omega$ /sq (page 2, lines 18 to 25). The material is moreover see-through, which has the additional advantage that the user can monitor and visualise the interior of the holding chamber (page 3, lines 15 to 17).
  - 2.2 Undisputedly, document D2 constitutes the closest prior art. As explained on page 1, lines 8 to 11 and page 2, lines 2 to 7, D2 is concerned with the design of a spacer for a metered dose inhaler in order to prevent or reduce the build-up of the drug on the walls of the spacer. The build-up is mainly caused by electrostatic activity (page 1, lines 26 to 27).

D2 discloses a medical delivery apparatus (a metered dose inhaler) comprising a component (spacer 5 in Figure 1; page 2, lines 2 to 7) which is see-through (page 5, lines 5 to 8) and made of a material which is antistatic (page 5, line 31 to page 6, line 7). In particular, on page 6, lines 3 to 7 of D2 it is explained that "the fluoropolymer forming the interior surface (of the spacer) can contain electrically conductive carbon particles sufficient to dissipate any opposite electrical charge while not destroying transparency."

In other words, according to D2, the fluoropolymer material of the spacer should be conductive enough to be antistatic, as well as transparent.

- 2.3 The appellant argued that whilst the spacer of Figure 1 was made of an antistatic fluoropolymer, page 5, lines 5 to 8 did not directly and unambiguously disclose that the spacer was also transparent.

This passage states that the antistatic fluoropolymer is "transparent in thick sections, e.g. the thickness of the cylinder wall forming the spacer ...". Contrary to the appellant's view, the Board interprets this sentence as clearly disclosing that the cylinder forming the spacer is transparent and made of an antistatic fluoropolymer.

- 2.4 Hence, the only feature of claim 1 which D2 does not explicitly disclose is that the surface resistivity of the antistatic material is between  $10^{10}$  and  $10^{12}$   $\Omega/\text{sq}$ . Insofar as the surface resistivity of a material which is designated as "antistatic" is not necessarily

comprised within the claimed range, the claimed apparatus is deemed to be novel over D2.

2.5 The objective technical problem underlying this feature is to determine a convenient value for the surface resistivity of the antistatic material of D2.

2.6 Document D1, which is concerned with conductive polymer materials for medical applications (title of D1 and page 1b, paragraph 4), mentions in particular antistatic inhalers (page 5, first bullet and the preceding paragraph). D1 discloses in Table I (bridging pages 2 and 3) that the surface resistivity for antistatic materials should be between  $10^{10}$  and  $10^{12}$   $\Omega/\text{sq}$  (the fourth column from the right is entitled "Antistatic **b**" and the bottom of Table I indicates that for this column "**b**" the surface resistivity is between  $10^{10}$  and  $10^{12}$   $\Omega/\text{sq}$ ).

Thus, faced with the aforementioned problem of finding a convenient value for the surface resistivity of the antistatic material of the spacer of D2, the skilled person would readily provide it with a value in the range of  $10^{10}$  and  $10^{12}$   $\Omega/\text{sq}$  disclosed in D1.

2.7 The appellant did not provide any evidence for its assertion that when devising the antistatic material of D2 with a surface resistivity in the claimed range the material would not be suitable for forming a spacer with see-through properties and long-term stability. The Board even regards that assertion as improbable, given the fact that D2 explicitly states (see point 2.2 above) that the filling of the fluoropolymer with conductive carbon particles in order to achieve the surface resistivity necessary for rendering the material antistatic does not destroy its transparency.



Similarly, D1 too mentions that "a number of conductivity thermoplastic compounds retain transparency while exhibiting static-control properties" (paragraph bridging pages 4 and 5). Furthermore, that the antistatic property should have "long-term stability", as argued by the appellant, is not reflected by any feature recited in claim 1.

2.8 As a consequence, the subject-matter of claim 1 of the main request lacks an inventive step within the meaning of Article 56 EPC.

3. *Auxiliary request I*

3.1 Claim 1 of auxiliary request I contains the additional feature that "the antistatic property of the component is permanent".

3.2 Firstly, this expression is indeterminate regarding the time scale on which the antistatic property is "permanent". The Board does not accept the appellant's view that "permanent" implies a period of about one year as indicated in the description of the application (page 2, lines 10 to 12).

Furthermore, metered dose inhalers, such as those of the application and D2, are generally disposable devices (page 1, lines 27 to 30 of D2), and as such, their functions and properties may be regarded as "permanent" only for the duration of their useful life.

Hence, on such a time scale, the antistatic property of the spacer of D2 may be said to be "permanent", even if D2 does not explicitly say so.

3.3 Consequently, the feature added to claim 1 of auxiliary request I is considered to be implicitly comprised in the disclosure of D2. It thus follows that the apparatus of claim 1 of auxiliary request I does not involve an inventive step either.

4. *Auxiliary request II*

4.1 Claim 1 of auxiliary request II recites in its last three lines different alternative antistatic materials, none of which is a fluoropolymer as disclosed in the closest prior art D2.

4.2 The objective technical problem to be solved by any of these different materials is to find an alternative material to the antistatic fluoropolymer of D2.

4.3 As indicated above, document D1 discloses in Table I a list of antistatic materials with a surface resistivity between  $10^{10}$  and  $10^{12}$   $\Omega/\text{sq}$ . Consequently, in search of an alternative antistatic material for the fluoropolymer spacer of D2, the skilled person would take into consideration document D1.

Since D1 explicitly mentions that a number of the materials retain transparency while exhibiting static-control properties (paragraph between pages 4 and 5), the skilled person would select from Table I of D1, by mere trial and error, those materials which also render the antistatic spacer transparent.

Table I of D1 discloses, inter alia, almost all the materials recited in claim 1 (polypropylene, polycarbonate, polystyrene, nylon, ABS, high-density polyethylene (HDPE), acetal and PBT). It is a fact confirmed by the present application that a spacer made

of any of these antistatic materials has both properties claimed, i.e. a surface resistivity between  $10^{10}$  and  $10^{12}$   $\Omega/\text{sq}$  and transparency.

Hence, in order to solve the aforementioned problem, the skilled person would readily choose from the aforementioned materials disclosed in D1 an appropriate alternative for the fluoropolymer material of D2, thereby arriving at the claimed apparatus.

4.4 Thus, the apparatus of claim 1 of auxiliary request II lacks an inventive step.

5. *Auxiliary request III*

5.1 Claim 1 of auxiliary request III adds to claim 1 of auxiliary request II the features that the apparatus comprises "a holding chamber (4), a mouthpiece (54) and a backpiece (22)" and that the antistatic component is the holding chamber.

5.2 The Board considers that the spacer 5 in D2 constitutes a "holding chamber" as claimed, and that the spout 12 in D2 is a "backpiece" as claimed (page 3, lines 10 to 12).

5.3 The appellant disputed that the spacer 5 in D2 could be considered to be a holding chamber, in particular a valved holding chamber with inhalation and exhalation valves, as disclosed in the application, e.g. on page 7, line 25 et seq.

The Board disagrees. The presence of valves on the holding chamber is clearly disclosed in the application as an optional feature (page 7, lines 25 to 26). Moreover, the holding chamber 4 in Figures 1 and 2 of

- the application is shown as an entirely analogous housing to the spacer 5 in Figure 1 of D2. The latter is described as a hollow cylinder of up to 300 mm in length which serves as an expansive interior volume for the drug, from which the dispensed drug can then be inhaled (page 3, lines 12 to 32). The Board therefore considers that the antistatic spacer 5 of D2 falls under the broadly claimed term of an antistatic "holding chamber", and that the closest prior art remains D2.
- 5.4 The subject-matter of claim 1 differs from D2 - apart from the differentiating features discussed above in relation to auxiliary request II - in that the apparatus comprises a mouthpiece.
- 5.5 The objective technical problem solved by this additional differentiating feature is the provision of an ergonomic attachment for the mouth of the patient using the apparatus. The effect of such an ergonomic device is entirely separate and different from the effect of the selection of antistatic materials discussed above. It is hence permissible to solve each of the respective objective technical problems separately.
- 5.6 The attachment of a mouthpiece to a holding chamber has been disclosed for another metered dose inhaler in D4 (mouthpiece 11 in Figure 1, attached to holding chamber 12; column 3, lines 32 to 34). Also in this case, the mouthpiece obviously serves the purpose of facilitating application of the patient's mouth.
- 5.7 Hence, for the purpose of improving the ergonomics of the apparatus of D2, the skilled person would readily

contemplate the attachment of a mouthpiece also to the holding chamber 5 in D2.

5.8 The Board therefore concludes that the subject-matter of claim 1 of auxiliary request III lacks an inventive step within the meaning of Article 56 EPC.

## Order

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

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated