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**Datasheet for the decision
of 25 April 2018**

Case Number: T 1598/12 - 3.2.02

Application Number: 07736288.7

Publication Number: 2015806

IPC: A61M5/145, A61M5/20

Language of the proceedings: EN

Title of invention:
DRUG DELIVERY DEVICE

Patent Proprietor:
Steadymed. Ltd.

Opponent:
Schmidt, Martin

Headword:

Relevant legal provisions:
EPC Art. 54(3)

Keyword:
Novelty - (no)

Decisions cited:

Catchword:



Beschwerdekammern
Boards of Appeal
Chambres de recours

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Case Number: T 1598/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 25 April 2018

Appellant: Steadymed. Ltd.
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Decision under appeal: **Decision of the Opposition Division of the
European Patent Office posted on 3 May 2012
revoking European patent No. 2015806 pursuant to
Article 101(3) (b) EPC.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. The patent proprietor has appealed against the Opposition Division's decision, dispatched on 3 May 2012, to revoke European patent No. 2 015 806.
- II. Notice of appeal was received on 12 July 2012. The appeal fee was paid on 13 July 2013. The statement setting out the grounds of appeal was received on 12 September 2012. With the statement of grounds the appellant filed a main request and first and second auxiliary requests.
- III. The Board summoned the parties to oral proceedings. In the communication accompanying the summons the Board explained why, in its preliminary opinion, the subject-matter of the independent claims of all requests was not novel over the following document considered by the Opposition Division in the impugned decision:

C7: WO-A-2007/010522.
- IV. With letter dated 4 April 2018 the respondent announced that it would not be attending the oral proceedings.
- V. Oral proceedings took place on 25 April 2018 in the respondent's absence.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the main request and the first and second auxiliary requests all filed with letter dated 12 September 2012. The third and fourth auxiliary requests filed with letter dated 12 April 2018 as well as the fifth and new fifth auxiliary requests filed during the oral proceedings were withdrawn during the

oral proceedings.

The respondent had submitted no requests.

VI. Claim 1 of the **main request** reads as follows:

"A drug-delivery device comprising a drug reservoir chamber (16) containing a substance to be delivered, in fluid connection with a drug administration means (18), and an electrically-controlled battery unit (10) comprising at least one displacement-generating battery cell (19) coupled to said drug reservoir chamber (16) by a coupling means (14), said battery cell (19) containing a displacement-generating electrode that undergoes a volume change during cell charge or discharge, the arrangement being such that the displacement derived from said battery unit (10) is conveyed by said coupling means (14) to said drug reservoir chamber (16) such that said substance is expelled from said drug reservoir chamber (16) towards said drug administration means (18),

provided that the electrochemical reaction system of said battery cell (19) is not the lead-acid reaction $Pb + PbO_2 + 2 H_2SO_4 = 2 PbSO_4 + 2 H_2O$ whereby one gm mole of reactants 642 gm (154 cc) contracts on discharge by 13%."

Claim 1 of the **first auxiliary request** reads as follows (amendments to the main request highlighted by the Board):

"A drug-delivery device comprising a drug reservoir chamber (16) containing a substance to be delivered, in fluid connection with a drug administration means (18), and an electrically-controlled battery unit (10) comprising at least one displacement-generating battery

cell (19) coupled to said drug reservoir chamber (16) by a coupling means (14), said battery cell (19) driving said drug delivery device and containing a displacement-generating electrode that expands due to ~~undergoes a volume change during cell charge or~~ discharge, the arrangement being such that the displacement derived from said battery unit (10) is conveyed by said coupling means (14) to said drug reservoir chamber (16) such that said substance is expelled from said drug reservoir chamber (16) towards said drug administration means (18),

provided that the electrochemical reaction system of said battery cell (19) is not the lead-acid reaction $\text{Pb} + \text{PbO}_2 + 2 \text{H}_2\text{SO}_4 = 2 \text{PbSO}_4 + 2 \text{H}_2\text{O}$ whereby one gm mole of reactants 642 gm (154 cc) contracts on discharge by 13%."

Claim 1 of the **second auxiliary request** reads as follows (amendments to the main request highlighted by the Board):

"A drug-delivery device comprising a drug reservoir chamber (16) containing a substance to be delivered, in fluid connection with a drug administration means (18), and an electrically-controlled battery unit (10) comprising at least one displacement-generating battery cell (19) coupled to said drug reservoir chamber (16) by a coupling means (14), said battery cell (19) containing a displacement-generating electrode that undergoes a volume change in excess of 20% of its initial volume during cell charge or discharge, the arrangement being such that the displacement derived from said battery unit (10) is conveyed by said coupling means (14) to said drug reservoir chamber (16) such that said substance is expelled from said drug reservoir chamber (16) towards said drug administration

means (18),

provided that the electrochemical reaction system of said battery cell (19) is not the lead-acid reaction $Pb + PbO_2 + 2 H_2SO_4 = 2 PbSO_4 + 2 H_2O$ whereby one gm mole of reactants 642 gm (154 cc) contracts on discharge by 13%."

VII. The appellant's arguments, as far as they are relevant to the present decision, may be summarised as follows:

In the impugned decision the Opposition Division had accepted that the disclaimer introduced in claim 1 of all requests established novelty over C7, in particular over the battery cell reaction explained in the table on page 13. The Board's objection was based on a less clear disclosure of another battery system of C7, which involved a different reaction that was neither clearly and unambiguously disclosed nor implemented in any specific example or embodiment. In the communication accompanying the summons to oral proceedings the Board provided calculations in relation to that different reaction, which were not present in C7.

VIII. The respondent has provided no arguments.

Reasons for the Decision

1. The appeal is admissible.
2. Despite having been duly summoned by communication dated 2 February 2018, the respondent was not present at the oral proceedings, as announced by letter dated 4 April 2018. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued

without the respondent.

3. The invention relates to a drug-delivery device comprising a reservoir chamber and drug administration means in which the administration is controlled by the means of a battery unit with a battery cell. An embodiment is depicted in figures 1a and 1b, reproduced below, according to which a control circuit (12) may activate and control a battery cell (10), such that an electrode (19) of the cell undergoes a volume change upon cell charge or discharge. This volume change can be used to generate a displacement of a wall (14) of the reservoir chamber (16), which causes the expulsion of the drug.

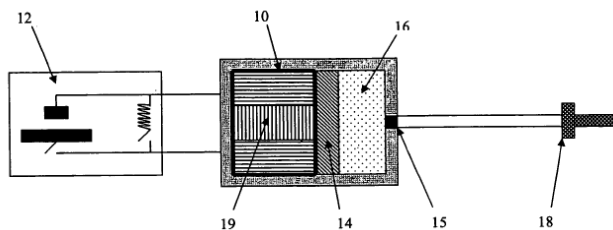


Fig. 1a

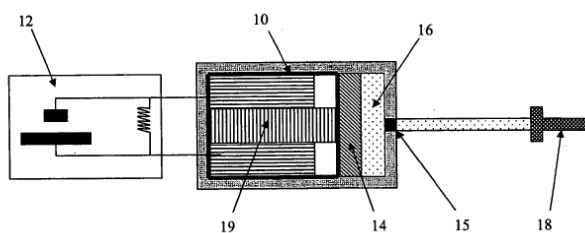


Fig. 1b

According to the patent the claimed provision of the battery unit as the means causing the drug to be expelled provides an inexpensive solution with which the drug expulsion can be very accurately controlled (paragraph [0003]).

4. Main request

It is undisputed that C7 is state of the art according to Article 54(3) EPC and concerns a drug-delivery device controlled by means of a battery unit. As shown in figure 1 reproduced below and described in the paragraph spanning pages 11 and 12, the drug-delivery device comprises a drug reservoir chamber (15) containing a substance to be delivered, in fluid connection (through conduit 17) with a drug administration means (cannula 18), and an electrically-controlled battery unit comprising a displacement-generating battery cell (the battery unit, controlled by control circuit 11, includes battery cell 10) coupled to said drug reservoir chamber by a coupling means (piston 14), said battery cell containing a displacement-generating electrode (one of its electrodes 12) that undergoes a volume change during cell discharge (for example in accordance with the reaction disclosed on page 9, third paragraph), the arrangement being such that the displacement derived from said battery cell unit is conveyed by said coupling means to said drug reservoir chamber such that said substance is expelled from said drug reservoir chamber towards said drug administration means.

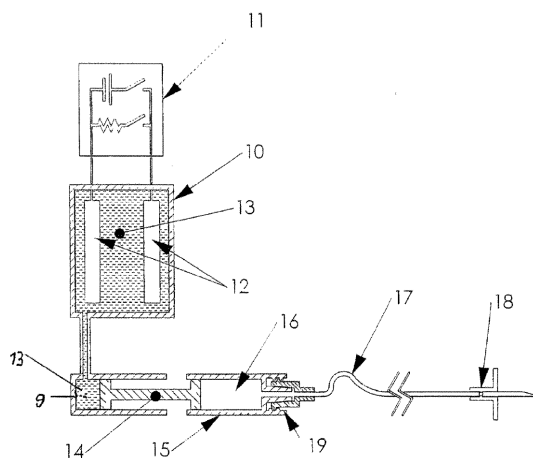
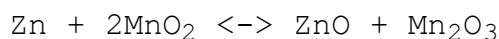


Figure 1

According to page 13, second paragraph of C7, a preferred embodiment of the drug-delivery device *"implements one of the battery or fuel systems such as those described above, including but not limited to nickel cadmium (NiCad), Formate/MnO2 fuel cell and dry cells. However, purely to demonstrate the volume change concept, the volume change associated with the well-known lead acid battery system is provided in [a] table"* on the same page.

As far as the dry cell reaction (page 9, third paragraph - referred to before) is concerned, a zinc electrode (anode) is gradually converted, on discharge, into zinc oxide according to the following reaction:



It is not disputed that the stoichiometry of this chemical reaction and the respective densities of the reactants are well known to the skilled person, as represented in the following table:

	Zn	2MnO ₂	ZnO	Mn ₂ O ₃
Mol wt (g)	65.38	173.87	81.41	157.87
Density (g/cm ³)	7.13	5.03	5.61	4.5
Volume (cm ³)	9.17	34.57	14.51	35.08

It is apparent that, on cell discharge, the zinc electrode, which is gradually converted into zinc oxide, undergoes a volume change.

Since the dry cell reaction disclosed in C7 is not disclaimed, an embodiment implementing this dry cell reaction anticipates the subject-matter of claim 1 of the main request.

In view of the disclosure on page 13 of C7 as quoted above, the appellant's argument that the dry cell reaction was not implemented in any example or embodiment of C7 cannot be accepted. Furthermore, since the stoichiometry and the respective densities of the reactants of the dry cell reaction are well known to the skilled person, the disclosure of such a reaction amounts to a direct and unambiguous, albeit implicit, disclosure of the claimed volume change during cell discharge.

It follows that the subject-matter of claim 1 of the main request lacks novelty (Article 54(3) EPC) over C7.

5. First auxiliary request

In claim 1 of the first auxiliary request it is specified that the displacement-generating electrode expands due to cell discharge. However, such an expansion also takes place in the device of C7 implementing the dry cell reaction. More specifically, it is derivable from the above table that, on cell discharge, the zinc electrode undergoes a volume increase, which would be 58% ($14.51 \text{ cm}^3 / 9.17 \text{ cm}^3 = 1.58$) if the conversion were complete.

It follows that the subject-matter of claim 1 of the first auxiliary request also lacks novelty (Article 54(3) EPC) over C7.

6. Second auxiliary request

In claim 1 of the second auxiliary request it is specified that the displacement-generating electrode undergoes a volume change in excess of 20% of its

initial volume during cell charge or discharge. However, such a volume change also takes place in the device of C7 implementing the dry cell reaction. More specifically, it is derivable from the above table that, on cell discharge, the zinc electrode has undergone a volume increase in excess of 20% already when a little more than one third of the zinc is converted.

It follows that the subject-matter of claim 1 of the second auxiliary request also lacks novelty (Article 54(3) EPC) over C7.

7. As a result, none of the appellant's requests is patentable in view of Article 52(1) EPC. Hence, the patent has to be revoked and the appeal dismissed.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated