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**Datasheet for the decision
of 15 January 2018**

Case Number: T 0217/13 - 3.2.02

Application Number: 04762945.6

Publication Number: 1682203

IPC: A61M5/142

Language of the proceedings: EN

Title of invention:

MEDICAL INJECTION DEVICE MOUNTABLE TO THE SKIN

Patent Proprietor:

Novo Nordisk A/S

Opponents:

Roche Diabetes Care AG
Sanofi-Aventis Deutschland GmbH

Headword:

Relevant legal provisions:

EPC Art. 54(3), 123(2)
RPBA Art. 12(4), 13(1)

Keyword:

Admissibility of requests - 1st to 5th and 11th to 14th
auxiliary requests (yes); 15th auxiliary request (no)
Novelty - 1st to 4th, 6th and 11th to 14th auxiliary requests
(no)
Added subject-matter - 5th auxiliary request (yes) -
unallowable disclaimer

Decisions cited:

G 0001/03

Catchword:



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Case Number: T 0217/13 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 15 January 2018

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Decision under appeal: **Interlocutory decision of the Opposition
Division of the European Patent Office posted on
3 December 2012 concerning maintenance of
European patent No. 1682203 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. Appeals were lodged by all parties against the interlocutory decision of the Opposition Division, posted on 3 December 2012, concerning maintenance of European patent No. 1 682 203 in amended form.
- II. In the decision under appeal, the Opposition Division held that the subject-matter of claim 1 of the patent as granted lacked novelty, *inter alia*, over the following earlier document from the proprietor, which was prior art under Article 54(3) EPC:

D2: WO-A-2005/002 649.

The first to fifth auxiliary requests underlying the impugned decision contained a plurality of different independent claims. Some of the requests contained a large number of independent claims. For example, in the first auxiliary request, claims 1 and 1a to 1p were all independent claims. The first to fifth auxiliary requests were found to contravene at least one of Articles 123(2), 54 and 56 EPC. The sixth auxiliary request underlying the decision was limited to one of the independent claims contained in preceding requests and was found to be allowable.

- III. The appellant/patent proprietor (hereinafter "patent proprietor") filed a notice of appeal on 23 January 2013, paying the appeal fee the same day. A statement setting out the grounds of appeal was received on 12 April 2013.

The appellant/opponent 1 (hereinafter "opponent 1") filed a notice of appeal on 4 February 2013, paying the

appeal fee the same day. A statement setting out the grounds of appeal was received on 15 April 2013.

The appellant/opponent 2 (hereinafter "opponent 2") filed a notice of appeal on 1 February 2013, paying the appeal fee the same day. A statement setting out the grounds of appeal was received on 12 April 2013.

IV. Oral proceedings were held on 15 January 2018.

The patent proprietor requested:

- that the decision under appeal be set aside and that the patent be maintained as granted or, in the alternative, on the basis of one of the first to fifth auxiliary requests, filed with letter dated 12 April 2013; or
- that the patent be maintained on the basis of the sixth auxiliary request, filed with letter dated 12 April 2013; or
- that the decision under appeal be set aside and that the patent be maintained on the basis of one of the eleventh to fourteenth auxiliary requests, filed with letter dated 15 December 2017, and the fifteenth auxiliary request, filed during the oral proceedings.

The seventh to tenth auxiliary requests, filed with letter dated 15 December 2017, were withdrawn.

The opponents requested that the decision under appeal be set aside and that the patent be revoked. The request for the patent proprietor's appeal to be held inadmissible, the request for remittal to the

department of first instance, as well as the request for the sixth auxiliary request to be held inadmissible were withdrawn.

V. Claim 1 of the **main request** (patent as granted) reads as follows:

"1. A medical device (1, 100, 500), comprising a first unit and a second unit adapted to be secured to each other in a situation of use, the first unit being in the form of a transcutaneous device unit (502) comprising:

- a transcutaneous device (530), and
- a mounting surface comprising adhesive means allowing the medical device to be attached to a skin surface of a subject, characterized in that the second unit is in the form of a reservoir unit (505) comprising:
 - a reservoir (760) adapted to contain a fluid drug, and
 - an expelling assembly (300, 580) adapted for cooperation with the reservoir to expel fluid drug out of the reservoir and through the skin of the subject via the transcutaneous device, the expelling assembly being in the form of a mechanical pump in combination with electronically controlled actuation means."

VI. Claim 1 of the **first auxiliary request** reads as claim 1 of the main request with the following expression added at the end:

"..., and wherein the expelling assembly is activated or allowed to be activated when the transcutaneous device unit and the reservoir unit are secured to each other and de-activated when the units are released from each other."

VII. Claim 1 of the **second auxiliary request** reads as claim 1 of the first auxiliary request, with the following additions as underlined by the Board:

"1. A medical device being a skin-mountable drug delivery device (1, 100, 500), comprising ...

...

- a mounting surface comprising adhesive means allowing the medical device to be skin-mounted by being attached to the skin surface of a subject, ... "

VIII. Claim 1 of the **third auxiliary request** reads as claim 1 of the second auxiliary request, with the following additions as underlined by the Board:

"- a mounting surface comprising adhesive means allowing the medical device as a whole to be skin-mounted by being attached by it to the skin surface of a subject, ... "

IX. Claim 1 of the **fourth auxiliary request** reads as claim 1 of the third auxiliary request, with the following additions as underlined by the Board:

"1. A medical device being a skin-mountable drug delivery device (1, 100, 500), comprising a first unit and a second unit adapted to be secured to each other with the second unit mounted to the first unit in a situation of use, ..."

X. Claim 1 of the **fifth auxiliary request** reads as claim 1 of the main request, with the following additions as underlined by the Board:

"1. A medical device being a skin-mountable drug delivery device (1, 100, 500), comprising ...

...

- a mounting surface comprising adhesive means allowing the medical device to be skin-mounted by being attached to the skin surface of a subject, ...

... and

wherein the medical device does not comprise:

- enclosure means encapsulating in a first configuration an inlet end and a skin-penetrating end of the transcutaneous device in an initial sterile state, the enclosure means being transformable from the first to a second configuration in which the inlet and skin-penetrating ends are allowed to communicate with the exterior of the enclosure means, the enclosure means not enclosing the mounting surface."

XI. Claim 1 of the **sixth auxiliary request** reads as claim 1 of the first auxiliary request.

XII. Claim 1c of the **eleventh auxiliary request** reads as claim 1 of the main request, incorporating the following amendments highlighted by the Board:

"1c. A medical device (~~1, 100, 500~~900), comprising ...

- a transcutaneous device (~~530~~930), ...

... in the form of a reservoir unit (~~505~~920) ...

...

- wherein the medical device further comprises a control unit (910) adapted to be mounted on the reservoir unit to control the expelling assembly through contacts (921)."

XIII. In claim 1c of the **twelfth auxiliary request** the same expressions were added to claim 1c of the eleventh auxiliary request as those mentioned under point VII above (regarding the second auxiliary request).

- XIV. In claim 1c of the **thirteenth auxiliary request** the same expressions were added to claim 1c of the twelfth auxiliary request as those mentioned under point VIII above (regarding the third auxiliary request).
- XV. In claim 1c of the **fourteenth auxiliary request** the same expressions were added to claim 1c of the thirteenth auxiliary request as those mentioned under point IX above (regarding the fourth auxiliary request).
- XVI. Claim 1 of the **fifteenth auxiliary request** reads as claim 1 of the patent as granted, with the following expression added at the end:
- "..., and
- wherein the transcutaneous device comprises a pointed end adapted to penetrate the skin of a subject, the pointed end being moveable between an initial position in which the pointed end is retracted relative to the mounting surface, and an extended position in which the pointed end projects relative to the mounting surface,
 - wherein the transcutaneous device unit comprises actuation means (540) for moving the pointed end of the transcutaneous device between the initial and the extended position when the actuation means is actuated, and
 - wherein the transcutaneous device unit comprises means for blocking the actuation means, the blocking means being released when the transcutaneous device unit and the reservoir unit are secured to each other, thereby allowing the actuation means to be actuated."
- XVII. The arguments of the patent proprietor relevant for the present decision are summarised as follows:

(i) Admissibility of the main request and the first to fifth auxiliary requests

The patent proprietor had no observations to make in respect of its previous document D2 as far as claim 1 of the granted patent was concerned. Likewise, there were no objections to the Board's preliminary opinion that the main request was inadmissible.

Since the Opposition Division had decided that the subject-matter of claim 1 of the patent lacked novelty, it was legitimate to file multiple independent claims in order to secure protection for all novel subject-matter contained in the patent. In particular, the seven independent claims of the first auxiliary request corresponded to claims 1, 1a, 1b, 1d, 1e, 1f and 1h respectively of the first auxiliary request underlying the decision. The independent claims of the second to fourth auxiliary requests defined additional features, responding to the objections raised concerning novelty and inventive step. The fifth auxiliary request contained a single independent claim, including a disclaimer which had also been presented before the Opposition Division (claim 1p of the second auxiliary request).

(ii) Admissibility of the eleventh to fourteenth auxiliary requests

The eleventh to fourteenth auxiliary requests corresponded to the first to fourth auxiliary requests, but with claims 1 and 1b deleted. The new requests were filed in reaction to the preliminary opinion of the Board, and the amendments in these requests were minor and raised no new substantive issues.

(iii) Admissibility of the fifteenth auxiliary request

The fifteenth auxiliary request should be admitted into the appeal proceedings since it had been filed in response to the Board not being persuaded by the arguments presented during oral proceedings in defence of the eleventh to fourteenth auxiliary requests. As it contained only one of the independent claims which was already present in the twelfth auxiliary request, its discussion should have been expected by the opponents and the Board.

(iv) Novelty

The device of claim 1 of the *first and sixth auxiliary requests* was novel since D2 did not disclose the feature of the expelling assembly being "de-activated when the units are released from each other". The notion of the expelling assembly being "de-activated" could not refer to the action of expelling fluid because this state would in any case be achieved when the units were separated. Paragraph [0034] of the impugned patent explained that in the de-activated state of the expelling assembly, only the actual pump action was de-activated while the control means remained active. This gave a definition of what claim 1 meant by defining the pump being "de-activated" when the units are released from each other. It was not inevitable that disconnection of the units of D2 de-activated the pump. Placing the pump unit on another platform unit, as disclosed on page 15, lines 19 to 20 of D2, could take place relatively swiftly, i.e. within a few minutes, so that it would be fully acceptable for the pump unit to remain active and allowed to expel one or two drops of insulin. By contrast, claim 1 of the *first and sixth auxiliary requests* was clearly to the

effect that the previously active mechanical pump of the expelling assembly ceased to be active, i.e. was de-activated.

Claim 1 of the *second to fourth auxiliary requests* contained further features defining the medical device to be skin-mountable as a whole to the skin surface of a subject, with the second unit mounted to the first unit. These features were intended to render the subject-matter claimed novel and inventive over cited documents other than D2.

Claim 1c of the *eleventh auxiliary request* defined the embodiment of Figure 26 of the patent, described in paragraph [0090], which was not disclosed in D2. The control means 1040 of D2 did not constitute a separate control unit as claimed. In the patent, the control unit 910 was releasably mountable on the reservoir unit 920 through mating coupling contacts 921. The claimed features allowed different control units to be used with different reservoir units.

Claim 1c of the *twelfth to fourteenth auxiliary requests* contained the same additional features as claim 1 of the second to fourth auxiliary requests, respectively.

(v) Disclaimer in the fifth auxiliary request

The disclaimer in claim 1 was introduced in order to restore novelty over D2. It was formulated on the basis of claim 1 of D2. However, in one of the embodiments disclosed in D2, the needle end was enclosed by a breakable paper sheet which was torn by a ramp (page 14, lines 23 to 26; page 15, lines 25 to 29). Therefore the needle could not communicate with the

exterior *through* the paper sheet. Consequently, claim 1 of D2 did not cover this embodiment, and it was thus necessary to draft the disclaimer with a wording different from that of claim 1 of D2 so as to exclude this embodiment too.

XVIII. The arguments of the opponents relevant for the present decision are summarised as follows:

(i) Admissibility of the main request and the first to fifth auxiliary requests

The main request should not be admitted, since the patent proprietor did not substantiate in its statement of grounds of appeal why it considered that the subject-matter of claim 1 of the granted patent was novel over D2.

Furthermore, the first to fifth auxiliary requests should not be admitted, since they contained several independent claims. Examination of such a large number of independent claims was considered to be an abuse of procedure, as the entire material contained in the opposed patent was presented for discussion, which concealed the focus of the patent proprietor's interest. The patent proprietor arbitrarily and randomly selected some of the inventions presented in the first-instance proceedings. The selected set of independent claims should have been presented in the latter proceedings. Moreover, the present large number of independent claims rendered the scope of the requests unclear.

(ii) Admissibility of the eleventh to fourteenth auxiliary requests

These requests should not be admitted, because they were filed late in the proceedings. The patent proprietor was selecting different sets of inventions as late as one month before the oral proceedings. Nothing justified this late filing; in particular, no new objections had been raised. Whilst the sixth auxiliary request narrowed down the appeal case to one independent claim, the late-filed requests went in several different, non-converging directions. This added even more complexity to the case as presented in the statement of grounds of appeal.

(iii) Admissibility of the fifteenth auxiliary request

This request was clearly inadmissible. No valid justification was given by the patent proprietor as to why it had waited until the end of the oral proceedings before filing yet another auxiliary request. All the novelty objections discussed during the oral proceedings had already been presented in the written proceedings.

(iv) Novelty; disclaimer

The arguments of the opponents relevant for the present decision regarding novelty over D2 and the disclaimer in the fifth auxiliary request are essentially those on which the reasons set out below are based.

Reasons for the Decision

1. The appeals are admissible.

2. *Admissibility of the main request*

2.1 In the decision under appeal, the Opposition Division held that the subject-matter of claim 1 of the patent as granted lacked novelty, inter alia over D2, an earlier application of the proprietor which is prior art under Article 54(3) EPC. In its statement of grounds of appeal, the patent proprietor said that it had no observations to make regarding novelty over D2 of the subject-matter of claim 1 of the granted patent.

The Board considers therefore that the patent proprietor's request to maintain the patent as granted is not substantiated, and is hence inadmissible. The patent proprietor indicated at the oral proceedings that it did not contest this finding.

3. *Admissibility of the first to fifth auxiliary requests*

3.1 Since in opposition proceedings the subject-matter of the independent claim of the granted patent was found to lack novelty under Article 54(1) and (3) EPC, the Board finds it legitimate for the patent proprietor to replace the granted independent claim by multiple independent claims in order to secure protection for all potentially novel subject-matter contained in the patent. This is in line with the established jurisprudence (as cited in Case Law of the Boards of Appeal, 8th edition 2016, IV.D.4.1.4 (b) and (c)). The formulation of these new independent claims is thus occasioned by the objection of lack of novelty against claim 1 of the granted patent, a deficiency confirmed by the Opposition Division in its decision and not contested by the patent proprietor (see point 2.1 above). The mere fact that the presence of several independent claims undeniably increases the complexity

of the proceedings is per se no reason to limit the number of independent claims. There is, moreover, no legal criterion to limit the number of independent claims of the present requests to a number which may be deemed to be permissible.

3.2 In the present case, the first auxiliary request filed with the statement of grounds of appeal contains seven independent claims. They were all contained in the first auxiliary request underlying the appealed decision. The independent claims which the Opposition Division held not to be allowable had been removed from the present first auxiliary request. The independent claims of the present second to fourth auxiliary requests incorporate additional features to the independent claims of the first auxiliary request. The fifth auxiliary request contains a single independent claim including a disclaimer which had likewise been presented in opposition proceedings (claim 1p of the second auxiliary request).

3.3 With its appeal the patent proprietor intends to obtain protection for more than just the subject-matter held allowable in the impugned decision (defined in claim 1 of the sixth auxiliary request). As indicated above, the Board does not find that the complexity resulting from the need to examine a number of independent claims timely filed with the statement of grounds of appeal is per se a valid reason for the patent proprietor to have to limit its appeal case to just one or a few of these independent claims. Moreover, the timely filing of the first to fifth auxiliary requests with the statement of grounds of appeal allowed the Board and the opponents sufficient time to adequately deal with them.

3.4 In view of the above, the Board decides that the first to fifth auxiliary requests are admitted into the proceedings in accordance with Article 12(4) RPBA.

4. *Novelty - first to fourth auxiliary requests*

4.1 It was not disputed by the patent proprietor that the subject-matter of claim 1 of the granted patent was known from its previous application, D2. This document discloses a skin-mountable medical device with two units adapted to be secured to each other: (i) a transcutaneous device unit (needle unit 110; page 14, lines 10 to 13) having a surface with adhesive means for attaching the medical device to the skin (page 14, lines 13 to 16), and (ii) a reservoir unit (pump unit 150; page 14, lines 10 to 13) comprising a reservoir for a fluid drug and an expelling assembly for expelling the fluid drug in the form of an electronically controlled mechanical pump (page 15, lines 7 to 15 and page 19, lines 16 to 25).

4.2 Claim 1 of the first auxiliary request adds to claim 1 of the granted patent the following expression:

"..., and wherein the expelling assembly is activated or allowed to be activated when the transcutaneous device unit and the reservoir unit are secured to each other and de-activated when the units are released from each other."

4.3 The first feature in this expression, i.e. that the expelling assembly is activated or allowed to be activated when the two units are secured to each other, is explicitly disclosed on page 15, lines 31 to 33 of D2. This has not been disputed either.

4.4 The second feature in the aforementioned expression, i.e. that the assembly is de-activated when the units are released from each other, is considered by the Board to be implicitly disclosed in D2. On page 15, lines 7 to 10, it is disclosed that the liquid drug containing reservoir comprises an outlet in the form of a septum 155 which is penetrated by a needle when the two units are secured to each other. D2 discloses the reservoir unit as a releasable multi-use pump unit which may be attached a number of times to a transcutaneous device unit (page 14, lines 16 to 17; page 15, lines 19 to 20). Upon connection of the two units the expelling assembly may start to automatically expel liquid (page 15, lines 31 to 33), and is thus "activated", as claim 1 recites. It is implicit from the notion of a "septum" that the same closes the reservoir outlet when the needle is retracted from the reservoir when the two units are released from each other. With a closed septum no liquid drug will be expelled from the pump unit, a state of the expelling assembly which the skilled person will consider to be a "de-activated" state, as recited in claim 1. Hence, in D2 "the expelling assembly is de-activated when the units are released from each other".

4.5 The patent proprietor argued that the notion of the expelling assembly being "de-activated" could not refer to the action of expelling fluid because this state would anyhow be achieved when the units were separated. Paragraph [0034] of the impugned patent explained that in the de-activated state of the expelling assembly only the actual pump action was de-activated, while the control means remained active.

The Board does not accept these arguments. Firstly, the skilled person would most naturally interpret an

"activated" fluid expelling assembly as one which expels fluid, and a "de-activated" fluid expelling assembly as one which does not. Furthermore, the specific features mentioned in paragraph [0034] of the description of the patent relate to a specific interplay of the constituents of the expelling assembly in the de-activated state, consisting in the actual pump action being de-activated while the control means remaining active. As these features are not included in claim 1, they do not limit the claimed device.

- 4.6 Claim 1 of the second to fourth auxiliary requests contains further features defining the medical device to be skin-mountable as a whole to the skin surface of a subject with the second unit mounted to the first unit. The patent proprietor explained that these features had been included in the claims with the sole purpose of rendering the subject-matter claimed novel and inventive over cited documents other than D2. It was not disputed that these features were clearly disclosed in D2 too (see also point 4.1 above).
- 4.7 As a consequence, the device of claim 1 of the first to fourth auxiliary requests lacks novelty within the meaning of Article 54(1) and (3) EPC.
5. *Allowability of a disclaimer - fifth auxiliary request*
- 5.1 According to the patent proprietor, the disclaimer in claim 1 of the fifth auxiliary request was introduced in order to restore novelty by delimiting the claim against D2, state of the art under Article 54(3) EPC. The patent proprietor considered that its formulation was based on the wording of claim 1 of D2.

5.2 The wording of the disclaimer is, however, different from the wording of claim 1 of D2.

Claim 1 of D2 reads "... a second configuration in which the inlet and skin-penetrating ends are allowed to communicate with the exterior **through** the enclosure means, ..." [emphasis added]. The disclaimer of claim 1, on the other hand, reads "... a second configuration in which the inlet and skin-penetrating ends are allowed to communicate with the exterior **of** the enclosure means, ..." [emphasis added].

5.3 The latter expression no longer requires the two ends (of for example needle 112 in Figure 1 of D2) to access the exterior of the enclosure means by going **through** the enclosure means (provided, for example, as a penetratable rubber membrane 121 and a breakable paper sheet 122 in Figure 1). The expression in the disclaimer merely requires the ends to access the exterior of the enclosure means. Therefore, the subject-matter disclaimed is broader than the one defined in claim 1 of D2.

The patent proprietor pointed to one of the embodiments disclosed in D2, in which the inlet needle end was enclosed by a breakable paper sheet which was torn by a ramp (page 14, lines 23 to 26; page 15, lines 25 to 29). Therefore, the needle could not communicate with the exterior **through** the paper sheet. Consequently, claim 1 of D2 did not cover this embodiment. It was thus necessary to properly amend its wording to disclaim this embodiment as well.

The Board cannot accept this argument, since in the embodiment of Figure 1 of D2 both needle ends, in particular the inlet needle end, communicate with the

exterior **through** the enclosure means (paper sheet 122 and rubber membrane 121), irrespective of ramp 156 tearing the paper sheet as mentioned by the patent proprietor. There is no convincing reason to infer that the embodiment of Figure 1 should not fall under the terms of claim 1 of D2. In any case, the wording of the disclaimer generalises the communication of the inlet needle end with the exterior of the paper sheet as disclosed on page 14, lines 23 to 26 and page 15, lines 25 to 29 of D2.

5.4 The Board therefore concludes that the disclaimed features are broader than those disclosed in D2. Therefore, claim 1 does not fulfill the condition for an allowable disclaimer established in decision G 1/03 that it should not remove more than is necessary to restore novelty (Reasons, point 3.).

5.5 Hence, the (undisclosed) disclaimer contravenes the requirements of Article 123(2) EPC.

6. *Novelty - sixth auxiliary request*

This request contains only one of the independent claims of the first auxiliary request, i.e. claim 1. Hence, for the reasons given above, this request too is not allowable for lack of novelty over D2.

7. *Admissibility of the eleventh to fourteenth auxiliary requests*

The patent proprietor filed the eleventh to fourteenth auxiliary requests one month before the oral proceedings. These requests correspond to the first to fourth auxiliary requests, respectively, wherein

independent claims 1 and 1b were deleted and the remaining independent claims renumbered.

As these requests were filed after the patent proprietor's statement of grounds of appeal and reply to the opponents' statements of grounds of appeal, they may be admitted and considered at the Board's discretion following Article 13(1) RPBA.

In these requests, a subgroup of the independent claims of the first to fourth auxiliary requests has been selected. On the one hand, the opponents are right in pointing out that no new objections were raised (in particular in the Board's preliminary opinion) which could have justified this late filing. On the other hand, however, this subgroup of independent claims was already contained in the requests filed with the statement of grounds of appeal. Moreover, since the eleventh to fourteenth requests were filed one month before the oral proceedings, there was sufficient time for the Board and the opponents to concentrate on this narrowed-down selection of independent claims, especially in view of the objections raised against these claims in the opponents' replies to the patent proprietor's statement of grounds of appeal.

Consequently, the Board decides to admit the eleventh to fourteenth auxiliary requests into the procedure under Article 13(1) RPBA.

8. *Novelty - eleventh to fourteenth auxiliary requests*

8.1 Claim 1c of the eleventh auxiliary request (the same as claim 1e of the first auxiliary request) adds the following feature to claim 1 of the main request:

"wherein the medical device further comprises a control unit (910) adapted to be mounted on the reservoir unit to control the expelling assembly through contacts (921)."

- 8.2 As indicated above, D2 discloses the pump to be an electronically controlled mechanical pump (page 15, lines 7 to 15 and page 19, lines 16 to 25). Specifically, page 15, lines 13 to 15 indicates that the reservoir and expelling means may be one of those disclosed with reference to Figures 7A-7D, described on page 19, lines 16 to 25. In particular, the expelling means of Figure 7A comprise an electric motor 1030 which is controlled by control means 1040.

The skilled person would understand such control means to be a "control unit", using the language of claim 1c. Since the control means is disclosed as a part of the expelling assembly, it must be fixed onto this assembly which is a constituent of the "reservoir unit". Thus, the control unit is "mounted on the reservoir unit" as claimed. For the electric motor to be controlled by the control unit, electric contacts need to be provided. It is therefore implicit that the control unit controls the expelling assembly "through contacts" as claimed.

- 8.3 The patent proprietor argued that the terms of claim 1c had to be understood in the light of what is disclosed in the embodiment of Figure 26 of the patent, described in paragraph [0090], which was not disclosed in D2. In the patent, the control unit (910) was releasably mountable on the reservoir unit (920) through mating coupling contacts (921). The claimed features allowed different control units to be used with different reservoir units. The control means 1040 in D2 was not a separate control unit in this sense.

The Board notes, however, that the wording of claim 1c does not include the aforementioned limitations of paragraph [0090]. As explained above, the claimed feature of the control unit being "mounted on the reservoir unit to control the expelling assembly through contacts" is broader, encompassing the embodiment of Figure 7A of D2 (page 19, lines 19 to 25) - an embodiment which is also included in the patent, as Figure 25A (column 23, lines 9 to 19).

8.4 Claim 1c of the twelfth to fourteenth auxiliary requests contains, undisputedly, the same additional features as those introduced into claim 1 of the second to fourth auxiliary requests, respectively. As indicated under point 4.6 above, these features (defining the medical device to be skin-mountable as a whole to the skin surface of a subject, with the second unit mounted to the first unit) are undisputedly disclosed in D2 too.

8.5 As a consequence, the device of claim 1c of the eleventh to fourteenth auxiliary requests lacks novelty within the meaning of Article 54(1) and (3) EPC.

9. *Admissibility of the fifteenth auxiliary request*

9.1 The patent proprietor filed the fifteenth auxiliary request at the very end of the oral proceedings, at 17.30 hrs, after the Board had announced its conclusion that the subject-matter of claim 1c of the eleventh to fourteenth auxiliary requests did not fulfil the requirement of novelty over D2. The fifteenth auxiliary request contains only one of the independent claims of the twelfth auxiliary request (its claim 1,

corresponding to claim 1a of the second auxiliary request).

- 9.2 It is the established jurisprudence of the boards of appeal that the appeal procedure is designed to ensure that the proceedings are as brief and concentrated as possible and ready for decision at the conclusion of the oral proceedings. Therefore, amendments to the claims must be filed at the earliest possible moment, and the Board has discretion under Article 13(1) RPBA to disregard amended claims if they are not filed at the earliest possible moment, and in particular if they are not filed in good time prior to oral proceedings (as mentioned in Case Law of the Boards of Appeal, 8th edition 2016, IV.E.4.2). The Board must exercise its discretion in view inter alia of the complexity of the new subject-matter submitted, the current state of the proceedings and the need for procedural economy.
- 9.3 In the present case, the Board sees no justifiable reason for the patent proprietor to have waited until the end of the oral proceedings to file the fifteenth auxiliary request.

The only justification given by the patent proprietor was that it was responding to the Board not having been persuaded by its arguments during the oral proceedings in defence of its previous requests.

The Board disagrees with the patent proprietor's view that an unfavourable outcome of its case during oral proceedings can in itself justify filing an amended set of claims at the end of those proceedings. The oral proceedings did not present any new, let alone any unforeseeable, developments. In particular, the novelty objection over D2 against claim 1c of the eleventh to

fourteenth auxiliary requests had been timely raised by the opponents in their replies to the statement of grounds of the patent proprietor, notably under point 4.6.2 of opponent 2's letter dated 13 August 2013. That the patent proprietor's arguments during the oral proceedings did not convince the Board is not an unforeseeable development.

Moreover, the Board's communication annexed to the summons to oral proceedings included an explicit caveat regarding late filings, citing the provisions of Article 114(2) EPC and Articles 12 and 13 RPBA. Given that the patent proprietor had filed one month before the oral proceedings the eleventh to fourteenth auxiliary requests in order to overcome the novelty objections regarding D2, which had been raised in good time, there was nothing to prevent it from filing the fifteenth auxiliary request too, at the same time, as an additional fall-back position. Although the fifteenth auxiliary request contains only one of the independent claims of the twelfth auxiliary request (its claim 1), the Board considered that it is inappropriate to admit and examine in substance for the first time this further independent claim at the end of the oral proceedings late in the afternoon.

9.4 Hence, the Board finds the fifteenth auxiliary request to be inadmissible under Article 13(1) RPBA.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.
2. The patent is revoked.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated