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**Datasheet for the decision  
of 11 May 2015**

**Case Number:** T 1592/11 - 3.2.02  
**Application Number:** 01272094.2  
**Publication Number:** 1349591  
**IPC:** A61M5/24, A61M5/315, A61M5/172,  
A61M5/145, A61M5/142  
**Language of the proceedings:** EN

**Title of invention:**  
PEN-TYPE INJECTOR HAVING AN ELECTRONIC CONTROL UNIT

**Patent Proprietor:**  
DCA Design International Limited

**Opponent:**  
Novo Nordisk A/S

**Headword:**

**Relevant legal provisions:**  
EPC Art. 54, 56, 111(1), 53(c), 84, 123(2)  
EPC R. 99(2), 115(2)  
RPBA Art. 13(1), 15(3)

**Keyword:**  
Admissibility of appeal - (yes)  
Admissibility of late-filed documents (yes); remittal (no)  
Method of treatment by therapy (yes)  
Support and clarity of disclaimer (no)  
Added subject-matter (no) - auxiliary request XIIIiii  
Novelty (yes) - auxiliary request XIIIiii

**Decisions cited:**

G 0001/07, T 0245/87

**Catchword:**



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Case Number: T 1592/11 - 3.2.02

**D E C I S I O N**  
**of Technical Board of Appeal 3.2.02**  
**of 11 May 2015**

**Appellant:** Novo Nordisk A/S  
(Opponent) Novo Allé  
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**Respondent:** DCA Design International Limited  
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**Decision under appeal:** Interlocutory decision of the Opposition  
Division of the European Patent Office posted on  
4 May 2011 concerning maintenance of the  
European patent No. 1349591 in amended form.

**Composition of the Board:**

**Chairman** E. Dufrasne  
**Members:** M. Stern  
C. Körber

## **Summary of Facts and Submissions**

- I. The opponent lodged an appeal against the interlocutory decision of the Opposition Division, dispatched on 4 May 2011, concerning maintenance of European patent No. 1 349 591 in amended form.
- II. Notice of appeal was filed by the opponent on 14 July 2011 and the fee for appeal was paid the same day. A statement setting out the grounds of appeal was received on 2 September 2011.
- III. Whilst during opposition proceedings the opponent based its novelty and inventive-step objections on documents D1 to D7, in the statement of grounds of appeal the objections were based on document D7 and newly introduced documents D8 to D11.
- IV. The Board summoned the parties to oral proceedings and set out its provisional opinion in a communication dated 6 February 2015.
- V. By letter dated 27 March 2015, the appellant-opponent announced that it would not appear at the oral proceedings. With said letter a new document D12 was introduced.
- VI. The following documents are cited in the present decision:

D7: WO-A-98/01 168  
D8: WO-A-99/52 575  
D9: US-A-4 812 724  
D10: US-A-4 345 483  
D11: US-A-5 551 850  
D12: EP-A-0 293 958.

VII. Oral proceedings were held on 11 May 2015 in the absence of the appellant-opponent. In accordance with Rule 115(2) EPC and Article 15(3) RPBA, the proceedings were continued without that party.

The appellant-opponent requested in writing that the decision under appeal be set aside and that the patent be revoked.

The respondent-patent proprietor requested that the appeal be dismissed or, in the alternative, that the decision under appeal be set aside and that the patent be maintained on the basis of one of the following auxiliary requests:

- auxiliary request I, filed with letter dated 17 January 2012,
- auxiliary request IA, filed during oral proceedings,
- auxiliary requests XIII and XIII*i*, filed with letter dated 2 April 2015 and
- auxiliary request XIII*ii*, filed during oral proceedings.

All other auxiliary requests were withdrawn.

VIII. Claim 1 of the request which the Opposition Division held to be allowable (hereinafter "**main request**") reads as follows:

"1. An injection device for injection of a medicament from a medicament cartridge, the medicament cartridge

(40) having a bung (48) displaceable within the medicament cartridge (40) to cause the medicament to be expelled from the medicament cartridge (40), the injection device comprising a drive mechanism (42) for selectively acting on the bung (48) to dispense the medicament from the medicament cartridge (40) and an electronic control unit for controlling operation of the drive mechanism (42) in which the drive mechanism (42) under the control of the electronic control unit initially acts at a first speed and at a second speed thereafter, characterized in that the second speed is slower than the first speed."

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

"1. An injection device for injection of a medicament from a medicament cartridge, the medicament cartridge (40) having a bung (48) displaceable within the medicament cartridge (40) to cause the medicament to be expelled from the medicament cartridge (40), the injection device comprising a drive mechanism (42) for selectively acting on the bung (48) to dispense the medicament from the medicament cartridge (40) and an electronic control unit for controlling operation of the drive mechanism (42) in which the drive mechanism (42) under the control of the electronic control unit initially acts at a first speed and at a second speed thereafter, ~~characterized in that~~ wherein the second speed is slower than the first speed, and wherein the injection device is a device used by users to administer a dose of medicament to themselves."

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

"1. An injection device for injection of a medicament from a medicament cartridge, the medicament cartridge (40) having a bung (48) displaceable within the medicament cartridge (40) to cause the medicament to be expelled from the medicament cartridge (40), the injection device comprising a drive mechanism (42) for selectively acting on the bung (48) to dispense the medicament from the medicament cartridge (40) and an electronic control unit for controlling operation of the drive mechanism (42) in which the drive mechanism (42) under the control of the electronic control unit initially acts at a first speed and at a second speed thereafter,  
~~characterized in that~~  
wherein the second speed is slower than the first speed,  
wherein the drive mechanism (42) is adapted to deliver more output force when operated at the second speed."

Claim 3 of **auxiliary request XIII** reads as follows:

"3. A method of dispensing a dose of medicament from a medicament cartridge within an injection device according to any of claims 1 or 2 comprising the steps of  
causing the drive mechanism (42) to act on the bung (48) at a first speed; and  
causing the drive mechanism (42) to act on the bung (48) at a second speed thereafter,  
wherein  
the first speed is faster than the second speed."

Claim 3 of **auxiliary request XIIIi** corresponds to claim 3 of auxiliary request XIII incorporating additionally a disclaimer specifying that "the medicament is not administered to a human or animal body".

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

"1. An injection device for injection of a medicament from a medicament cartridge, the medicament cartridge (40) having a bung (48) displaceable within the medicament cartridge (40) to cause the medicament to be expelled from the medicament cartridge (40), the injection device comprising a drive mechanism (42) for selectively acting on the bung (48) to dispense the medicament from the medicament cartridge (40) and an electronic control unit for controlling operation of the drive mechanism (42) in which the drive mechanism (42) under the control of the electronic control unit initially acts at a first speed and at a second speed thereafter,

~~characterized in that~~

wherein the second speed is slower than the first speed,

wherein

the device further comprises means to detect resistance to dispense, said means providing a resistance to dispense signal to the electronic control unit, in which the drive mechanism (42), following receipt of the resistance to dispense signal by the electronic control unit, under the control of the electronic control unit, acts at the second speed,



characterised in that the drive mechanism (42) is adapted to deliver more output force when operated at the second speed for overcoming the resistance to dispense."

Claim 2 of auxiliary request XIIIiii is a dependent claim.

IX. The arguments of the appellant-opponent relevant for the present decision are summarised as follows:

- *Admissibility of the appeal*

The appeal clearly fulfilled the requirements of Article 12(2) RPBA, and was clearly admissible. The appeal was not based on documents D1 to D6, but the statement of grounds of appeal substantiated why the invention claimed lacked novelty over any of documents D7 to D11 and why it lacked an inventive step over the combinations of D8 with any of D9, D10 and D11.

- *Admissibility of documents and remittal*

Documents D7 to D11 were prima facie relevant for novelty and inventive step of the claims held allowable in the impugned decision. D12 was moreover relevant for the auxiliary requests filed by the proprietor. If the Board considered any of the auxiliary requests to be novel, remittal to the Opposition Division was requested for further consideration of inventive step over the combination of D8 with D12.

- *Main request - Novelty over D8*

Claim 1 lacked novelty over D8, which disclosed an injection device (page 1, lines 10 to 17; claim 7)

comprising all the features of the preamble of claim 1 of the main request maintained by the Opposition Division. The HIGH and LOW speeds in Figure 15A were, respectively, the first and second speeds as claimed. The pressure of injection was constantly monitored. If the pressure was found to be excessive, the speed was reduced as depicted in Figure 16A. Consequently, claim 1 of the main request (held allowable by the Opposition Division) lacked novelty over D8.

- *Auxiliary request XIII - Article 53(c) EPC*

The method claims concerned a method of dispensing a dose of medicament from a medicament cartridge. As explained in the opposed patent, such methods included the step of administering an insulin or insulin-type drug to a human body. The methods obviously required invasive use of an injection needle on the human body and were therefore excluded from patentability under Article 53(c) EPC. Moreover, the method claimed having different speeds was not suitable for priming as described in paragraph [0025] of the patent.

- *Auxiliary request XIIIii - Allowability of the disclaimer*

The application as filed mentioned no other use than "to administer a dose of insulin or isulin-type medicine to themselves" (page 1, lines 7 to 8). Thus, disclaiming human and animal use made it unclear what the subject-matter claimed actually covered. The claimed subject-matter was furthermore not supported by the description as required by Article 84 EPC. The method of priming the device disclosed in paragraph [0025] of the patent did not relate to the claimed method because said paragraph referred to a

method including a tilt switch or an accelerometer together with a separate primer button, elements which were not part of the invention presently claimed. Moreover, the claim seemed to conflict with G 2/10 since it was not directly and unambiguously disclosed to the skilled person what the subject-matter of the method claims actually was.

- *Auxiliary request XIIIiii*

Claim 1 of auxiliary request XIIIiii was an intermediate generalisation conflicting with Article 123(2) EPC. There was nothing in the example of the originally filed description on page 10, lines 14 to 21 linking the disclosed higher output force of the drive mechanism to the slower second speed.

Moreover, claim 1 of auxiliary request XIIIiii lacked novelty over D8. On page 18, lines 8 to 15 it was disclosed that if a blockage persisted, i.e. if a persistent resistance to dispense was identified, the pressure, i.e. the output force, increased until the flow rate was lowered.

X. The arguments of the respondent-proprietor relevant for the present decision are summarised as follows:

- *Admissibility of the appeal*

The appellant had failed to substantiate the grounds for the appeal in a sufficient manner. Accordingly, the appeal was inadmissible under Rules 99(2) and 101(1) EPC. The appellant had also failed to sufficiently substantiate why documents D1 to D11 were relevant for the claims maintained by the Opposition Division.

- *Admissibility of documents and remittal*

Documents D7 to D11 had been filed late, and should therefore not be considered in the appeal proceedings. In addition, none of these documents was prima facie relevant for the maintained claims. The same applied all the more to D12, filed just several weeks before the oral proceedings and without any justification.

If the Board admitted these documents, it would be just and equitable to allow two instances to deal with the objections of novelty and inventive step regarding these documents, rather than having these objections considered only by the Board of Appeal. The requested remittal was consequently justified.

- *Main request - Novelty over D8*

The fact that in D8 a controller was available did not necessarily mean that the infusion pump operated under the control of a control system. In fact, in D8 the infusion pump was under the permanent control of the clinician for injecting an anaesthetic in periodontal treatments. Hence, the infusion pump in D8 was not operated under the control of an electronic control unit but under the control of a clinician. The clinician was expected to adapt the flow rate of infusion by releasing the pedal if the pressure was sensed to be too high (Figures 15A, 15B; page 17, lines 11 to 18). Furthermore, the infusion pump of D8 could not be considered to be an injection device as claimed. It was widely known that "infusion" and "injection" were different ways of administering a drug. Injection was used to administer rapidly absorbable drugs with the whole dose being brought quickly into the body. In contrast, infusion built the

drug concentration up to a steady level that was maintained as long as the infusion continued.

- *Auxiliary request I - Clarity*

Claim 1 clearly specified that the device was suitable for self-administration of the medicament. It was easy to ascertain whether a given device satisfied this requirement or not.

- *Auxiliary request IA - Admissibility*

This request had been filed to define the invention more clearly than in auxiliary request XIII. The definition was properly based on the example of paragraph [0049] of the patent.

- *Auxiliary request XIII - Article 53(c) EPC*

The claimed method did not necessarily encompass the step of administering a medicament to a human body. Instead, the claimed method could be used during a priming operation in which a small amount of a medicament is dispensed without administering any medicament to a human or animal body, as explained in paragraph [0025] of the patent. Moreover, the present method claims were only concerned with the operation of a device without any functional link between the claimed method and the effects produced by the device on the body (G 1/07, T 245/87). Hence, according to established case law, the claimed method did not qualify as a method for treatment within the meaning of Article 53(c) EPC.

- *Auxiliary request XIII i - Allowability of the disclaimer*

The claimed method of dispensing a medicament was presented in the description as also encompassing the priming of the device, wherein a small amount of medicament was dispensed without administering any medicament to a human or animal body (paragraph [0025] of the patent). Consequently, there was support for a method claim disclaiming the methods with therapeutic effects.

- *Auxiliary request XIIIiii*

Claim 1 of auxiliary request XIIIiii was properly based on originally filed claims 1, 4 and 9 and the example of originally filed page 10, lines 14 to 21 (paragraph [0049] of the patent). This embodiment was clearly described to overcome the detected resistance to dispense the medicament, similarly to what was described in paragraph [0048] of the patent, where the force to overcome the stiction of the bung in the cartridge was described.

The characterising feature of claim 1 of auxiliary request XIIIiii was not disclosed in D8 since this document did not provide any indication of the output force delivered by the drive mechanism. To increase the output force would even go against the purpose of reducing the flow rate of the drug in order to minimise subjective pain and potential tissue damage to the patient resulting from high pressure during the administration of the drug. This feature was absent also from D12, which did not even disclose the injection of a medicament with the two different speeds as claimed. In D12, when the counter-pressure in tissue was higher than normal, the delivery of insulin was prevented by stopping the electromotor altogether.

## **Reasons for the Decision**

### *1. Admissibility of the appeal*

- 1.1 In the impugned decision, the Opposition Division considered that the claims of the then filed auxiliary request satisfied the requirements of the EPC, in particular the requirements of novelty and inventive step in view of documents D1 to D6. The Opposition Division also indicated in the second paragraph of the minutes of oral proceedings that D7 was not admitted into the proceedings as it had been filed late and was not relevant.
- 1.2 In the statement of grounds of appeal the appellant-opponent challenged the position of the Opposition Division not to admit the late-filed document D7 and presented substantiated objections concerning novelty and inventive step of the claimed subject-matter on the basis of D7 and newly introduced documents D8 to D11.
- 1.3 The Board therefore finds that the appellant-opponent challenged at least one aspect of the impugned decision in a substantiated way. The statement of grounds of appeal thus contains at least one reason for setting aside the decision impugned, as required by Rule 99(2) EPC. Furthermore, according to established jurisprudence of the boards of appeal, an appeal is not to be considered inadmissible merely because it is based on evidence submitted for the first time with the statement of grounds of appeal (Case Law of the Boards of Appeal, 7th edition 2013, IV.E.2.6.5(a)). For the purpose of establishing the admissibility of the appeal it is moreover immaterial whether the arguments are,

upon subsequent examination as to its merits, found to be unconvincing.

1.4 The appeal is therefore considered to be admissible.

2. *Admissibility of late-filed documents and remittal*

2.1 Documents D7 to D12 were introduced into the opposition and appeal proceedings well after the nine-month opposition period (Article 99(1) EPC). D7 was introduced during the opposition proceedings, D8 to D11 with the statement of grounds of appeal, and D12 shortly before the oral proceedings before the Board.

2.2 The respondent-proprietor is in principle right to say that the appellant-opponent could have introduced these documents in time into the first-instance proceedings. However, this is not the only criterion to be considered when deciding on their admissibility. In particular, the Board considers (for reasons explained in greater detail under points 3 to 3.4 below) that document D8 is prima facie relevant regarding the novelty of the subject-matter of claim 1 which the Opposition Division held allowable. Also D12 appeared to be prima facie of relevance for some of the auxiliary requests which the respondent-proprietor filed in order to overcome the novelty objection regarding D8 (these requests were subsequently withdrawn during oral proceedings).

The Board considers therefore that these prima facie relevant documents D8 and D12 are to be taken into consideration for assessing the patentability of the claimed subject-matter and that it would not be appropriate to disregard these documents under Article 114(2) EPC. They involved moreover no



particular complexity and the time of their filing allowed a proper response from the respondent-proprietor. In fact, the respondent-proprietor filed a series of auxiliary requests responding both to the novelty objection regarding D8 and to the inventive-step objections involving D12.

2.3 The Board does not admit, however, documents D7 and D9 to D11 for the following reasons:

(i) D7 had not been admitted by the Opposition Division since it was found to be *prima facie* not relevant. Since the Board considers that the Opposition Division correctly exercised its discretion not to admit D7, the Board sees no reason to now decide otherwise. In fact, D7 is not relevant since it only discloses that the motor may be stopped (page 9, lines 18 to 19), i.e. its speed is then zero, which means that there is no longer any speed with which the drive mechanism acts.

(ii) D9 to D11 are also found, *prima facie*, to be of no relevance regarding novelty. D9 relates to an injection device for injecting contrast media from a syringe (abstract, first sentence), but not from a "medicament cartridge" as claimed. D10 relates to a metering apparatus with a pipette (column 1, first paragraph; column 2, second paragraph), rather than an injection apparatus for injecting a medicament. D11 relates to an infusion pump wherein the medicament is contained in a solution bag (64 in Figure 3; column 7, lines 27 to 34), whereby the pump of D11 lacks the claimed features of a medicament cartridge with a displaceable bung therein.

It is to be noted that documents D7 and D9 to D11 are in particular of no relevance for the present decision

on the maintenance of the patent on the basis of auxiliary request XIIIiii since no objection based on these documents was brought forward by the appellant-opponent against this request; see point IX above and point 8.1 below.

- 2.4 The respondent-proprietor considered that a remittal to the Opposition Division was just and equitable in order to have these documents considered by two instances. Also the appellant-opponent requested remittal if the Board considered any of the auxiliary requests to be novel, so as to allow inventive step to be considered regarding the combination of D8 with D12.

Article 111(1) EPC leaves it to the discretion of the Board whether to exercise any power within the competence of the department of first instance or to remit the case to that department. Hence, a party has no absolute right to have each individual issue considered by two instances (Case Law of the Boards of Appeal of the EPO, 7th edition 2013, IV.E.7.6.1). In the present case, the Board observes that the patent was granted in 2005, i.e. about ten years ago, and that remittal would prolong the already lengthy opposition proceedings. Moreover, as indicated above, the assessment of novelty over D8, and any possible consideration of inventive step involving also D12, were straight forward and the timing of the filing of the documents and of the amended claims allowed the other party and the Board enough time to prepare the case.

In view of the above circumstances and taking into consideration the imperative of procedural efficiency, the Board considers it appropriate to decide the case

itself rather than remit it to the department of first instance pursuant to Article 111(1) EPC.

3. *Main request*

3.1 Document D8 discloses a device for injecting a medicament from a medicament cartridge comprising, in essence, a drive mechanism (12) for displacing a bung within the cartridge to expel the medicament (page 1, lines 11 to 18; page 4, lines 1 to 2 and 7 to 8). In the embodiment of Figure 9, a cartridge holder (112) for holding a medicament cartridge (100) with a bung (104) therein is disclosed (page 9, lines 29 to 32). The injection device of D8 comprises, moreover, an electronic control unit controlling the drive mechanism (page 7, lines 21 to 26) at two successive different speeds, such as the HIGH and LOW fluid rates shown in Figure 15A (page 17, lines 11 to 18), wherein the second speed is slower than the first speed.

3.2 The respondent-proprietor argued that in D8 the system is operated by a clinician activating a foot pedal, whilst in the claimed device the drive mechanism is under the control of an electronic control unit.

The Board does not accept this argument. Although the drive mechanism speed is adjusted through activation of a foot pedal (176 in Figure 10), the latter operates on a "control unit" (microprocessor 154 in Figure 10; page 12, line 12; page 14, lines 21 to 32) which controls the motor (66) of the drive mechanism (12). D8 discloses, moreover, that when the system detects a persistent abnormally high fluid exit pressure the speed is gradually decreased as shown in Figure 16A (page 18, lines 11 to 15). This is clearly done automatically by the electronic control unit without

any intervention by the clinician, as summarised in D8 on page 5, lines 29 to 31.

3.3 The Board also dismisses the respondent-proprietor's contention that D8 disclosed an infusion pump, but not an injection device as claimed. Infusion and injection are certainly different ways to administer a drug, differing in the time used to deliver a dose. The device of D8 is capable of administering a drug over a "long" time interval (as in an "infusion") or over a "short" period of time (as in an "injection"). D8 in fact explicitly mentions that the infusion system is suitable for the "injection" of a drug (e.g. page 1, lines 11 to 17; page 4, lines 7 to 8).

3.4 It follows that the subject-matter of claim 1 of the main request (which the Opposition Division considered to be allowable) lacks novelty over document D8, contrary to Article 54(1) EPC.

#### 4. *Auxiliary request I*

Claim 1 additionally defines that "the injection device is a device used by users to administer a dose of medicament to themselves."

This expression defines a method step which makes reference to the users using the claimed device. It is therefore uncertain which structural features of the device this method step intends to define. The expression certainly differs from one stating that the device was suitable for self-administration of the medicament, as alleged by the respondent-proprietor.

As a consequence, claim 1 does not satisfy the requirement of clarity of Article 84 EPC.

5. *Auxiliary request IA*

5.1 The respondent-proprietor filed this request during the oral proceedings, asserting that it formulated the invention more clearly than in auxiliary request XIII.

The Board notes however that, compared with claim 1 of auxiliary request XIII, claim 1 of the present request leaves out, in particular, the feature of the injection device comprising means to detect resistance to dispense.

5.2 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 oral proceedings. Therefore, amendments to the claims must be filed at the earliest possible moment and the Board may disregard amended claims if they are not submitted in good time prior to oral proceedings (Case Law of the Boards of Appeal, 7th edition 2013, IV.E. 4.2.1). This practice corresponds to Article 13(1) RPBA, which gives a Board the discretion not to admit and consider amendments to the claims if they are not filed at the earliest possible moment, in particular if they are not filed in good time prior to oral proceedings. The Board must exercise that 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.

With regard to procedural economy, the factors to be examined in deciding whether a late-filed request is admissible include whether the subject-matter of the new claim is so clear and straightforward that it can

be understood and allowed without further discussion (Case Law of the Boards of Appeal, 7th edition 2013, IV.E.4.2.3(a)).

5.3 In the present case the Board is of the view that claim 1, far from addressing any (actually not objected to) clarity deficiencies of claim 1 of auxiliary request XIII, as alleged by the respondent-proprietor, appears to broaden its subject-matter. In fact, the Board considers that the amendments are prima facie not clearly compliant with Article 123(2) EPC. Whilst the respondent-proprietor indicated that the amendments were based on original page 10, lines 14 to 21 (paragraph [0049] of the patent), the Board finds that the presently retained definition of the increased output force of the drive mechanism seems to be originally disclosed in said passage in combination with detection means for detecting a resistance to dispense the medicament which are absent from the definition in claim 1.

5.4 The Board consequently decides that auxiliary request IA is not admissible under Article 13(1) RPBA.

## 6. *Auxiliary request XIII*

6.1 Independent claim 3 is directed to "a method of dispensing a dose of medicament from [...] an injection device". The Board questioned the allowability of such a method under Article 53(c) EPC in its communication attached to the summons to oral proceedings. An objection under this ground had already been examined during the oral proceedings before the Opposition Division (paragraphs 5 to 8 of the minutes of oral proceedings).

6.2 By definition, a medicament is a substance used in therapy. Paragraph [0002] of the patent makes it clear moreover that the claimed method encompasses the step of administering insulin or an insulin-type medicament to a human body. Consequently, the claimed method which comprises (or, at least, encompasses) such a step is deemed to be a method of treatment by therapy under Article 53(c) EPC (G 1/07, point 3.2.5 of the Reasons).

The respondent-proprietor's argument that the claimed method did not necessarily encompass the step of administering a medicament to a human body, but could instead be used during a priming operation of the device in which a small amount of a medicament is dispensed without administering it to a human or animal body (as explained in paragraph [0025] of the patent), is hence irrelevant.

6.3 Since the claim comprises (or encompasses) the therapeutic step of dispensing a dose of medicament to the human body, respondent-proprietor's further assertion that the present method claims were only concerned with the operation of a device without any functional link between the claimed method and the effects produced by the device on the body (G 1/07, Reasons 4.3.2; T 245/87, Reasons 5.2) is not accepted by the Board either. There is no room to question the existence of such a link when the therapeutic step is comprised (or encompassed) by the claim. The present claim is explicitly directed to "a method of dispensing a dose of a medicament", rather than to the operation of a device as in T 245/87.

6.4 Consequently, the method of claim 3 of auxiliary request XIII is a method for treatment by therapy

within the meaning of Article 53(c) EPC and therefore excepted from patentability.

7. *Auxiliary request XIII*

7.1 Independent claim 3 of this request defines "a method of dispensing a dose of medicament from [...] an injection device" including the disclaimer that "the medicament is not administered to a human or animal body".

7.2 Since a medicament is a substance used in therapy a method of dispensing a dose of medicament primarily implies that the medicament is administered to a human or animal body. To define that it is not appears to be an oxymoron. As such, the definition is unclear and not allowable under Article 84 EPC.

7.3 The respondent-proprietor argued that the patent specification included an example of a method of dispensing a medicament without any therapeutic effect. The disclosed example was a priming operation in which a small amount of medicament was ejected with the needle pointing upwards, without any medicament being administered to a human or animal body (paragraph [0025] of the patent).

The Board considers, however, that the disclosure of the priming operation of the device gives no support for defining it in other terms, particularly not in terms of the mentioned disclaimer. There is hence no support in the description for defining the priming of the device as a method of dispensing a dose of medicament from an injection device wherein "the medicament is not administered to a human or animal body".



7.4 For the above reasons, claim 3 of auxiliary request XIIIii is not considered to be allowable under Article 84 EPC.

8. *Auxiliary request XIIIiii*

8.1 The subject-matter of the claims of this request is the same as that of the device claims of auxiliary request XIII filed by the respondent-proprietor on 2 April 2015. It was objected to by the appellant-opponent in its letter dated 20 April 2015 under Article 123(2) EPC and as lacking novelty regarding D8.

The Board does not find these objections convincing for the following reasons.

8.2 The preamble of claim 1 is based on originally filed claims 1, 4 and 9. On page 10, lines 14 to 21 of the original application (corresponding to paragraph [0049] of the patent), an embodiment is described in which the drive mechanism acts with two different successive speeds, the second speed being slower than the first speed. The second and third sentences of that paragraph explicitly state that the drive mechanism is slowed to deliver more output force when a resistance to dispensing the medicament is detected. This unambiguously means that more output force is delivered at the slower, second speed (i.e. more than the output force delivered at the first speed) for overcoming the resistance to dispense.

Consequently, claim 1 of auxiliary request XIIIiii fulfils the requirements of Article 123(2) EPC.

8.3 Contrary to the the view of the appellant-opponent, the claimed device is also novel over D8 for the following reasons.

As indicated under point 3.2 above, the device of D8 comprises means for detecting resistance to dispense the medicament, and when an abnormally high fluid exit pressure persists, the speed is gradually decreased until it stops altogether, as shown in Figure 16A (page 18, lines 11 to 15). This is clearly done automatically by the electronic control unit without any intervention by the clinician, as summarised on page 5, lines 29 to 31. Consequently, the features of the last paragraph of the preamble of claim 1 of auxiliary request XIIIiii are also known from D8.

D8 is silent, however, as to the output force of the drive mechanism when the speed of the drive mechanism is slowed down.

Consequently, claim 1 differs from D8 in the feature of the characterising portion, i.e. that "the drive mechanism is adapted to deliver more output force when operated at the second speed for overcoming the resistance to dispense."

As a consequence, the device of claim 1 of auxiliary request XIIIiii satisfies the requirement of novelty in the sense of Article 54 EPC.

8.4 The appellant-opponent has not objected that the claimed subject-matter lacks an inventive step. The Board sees no objection under Article 56 EPC either.

8.4.1 The aforementioned differentiating feature solves the problem of allowing the medicament to be dispensed even

in the presence of a detected resistance to dispensing, for example if the medicament, such as insulin, is cold and therefore more viscous and difficult to expel (as explained in paragraph [0049] of the patent).

8.4.2 In contrast to this, D8 teaches that when a high pressure is detected the flow rate of the drug is to be reduced in order to minimise subjective pain and potential tissue damage to the patient resulting from the high pressures during administration of the drug (page 3, lines 29 to 31). Increasing the output force of the drive mechanism as in the claimed device would therefore go against the purpose of reducing the flow rate of the drug stated in D8.

8.4.3 D12 is even less relevant in this respect since the device disclosed does not even inject the medicament at two different speeds as claimed. In D12, when the counter-pressure in tissue is higher than normal, the further delivery of insulin is prevented by stopping the electromotor altogether (column 7, lines 29 to 44).

8.4.4 Consequently, the subject-matter of claim 1 of auxiliary request XIIIiii involves an inventive step in the sense of Article 56 EPC. This applies a fortiori to the preferred embodiment defined in dependent claim 2.

## 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 on the basis of:
  - claims 1 and 2 of auxiliary request XIIIiii filed during oral proceedings;
  - pages 2, 2a and 3 to 5 of the adapted description filed during oral proceedings; and
  - figures 1 to 3 and 3A of the patent as granted.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated