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Datasheet for the decision of 13 July 2010

Case Number: T 0138/08 - 3.2.02

Application Number: 00950543.9

Publication Number: 1200143

IPC: A61M 5/145

Language of the proceedings: EN

Title of invention:
Syringe plunger driver system for engaging syringe plungers of different sizes and method

Patentee:
CareFusion 303, Inc.

Opponent:
Fresenius HemoCare GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 56
EPC R. 103
RPBA Art. 12(2), 13(1)

Relevant legal provisions (EPC 1973):
-

Keyword:
"Inventive step (yes, after amendments)"
"Reimbursement of the appeal fee (no)"

Decisions cited:
-

Catchword:
-

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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0138/08 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 13 July 2010

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 21 November 2007 rejecting the opposition filed against European patent No. 1200143 pursuant to Article 102(2) EPC 1973.

Composition of the Board:

Chairman: D. Valle
Members: C. Körber
M. J. Vogel

Summary of Facts and Submissions

I. The appellant (opponent) lodged an appeal on 17 January 2008 against the decision of the opposition division posted on 21 November 2007 to reject the opposition. The fee for the appeal was paid simultaneously and the statement setting out the grounds for appeal was received on 1 April 2008.

II. The following pieces of evidence are considered in the present decision:

D2 = EP - B1 - 916 353
D3 = JP - 09-122237 with translation
D4a = Rechnung MCM Medizintechnik GmbH
D4b = Technical manual MODULE DPS CE2
D4c = Memorandum zur Vorserie
D4d = Demande de création/changement produit et/ou de procédé N° 970283
D11a = Rechnung vom 16. Oktober 1998
D11b = Lieferschein vom 16. Oktober 1998
D11c = Stammdatenblatt HELIOS Klinikum Wuppertal GmbH
D11d = eidesstattliche Versicherung von Frau Doreen Lattner and, additionally, oral evidence to be given by the witness Mrs. Doreen Lattner
D11e = eidesstattliche Versicherung von Dr. Maximilian Brandt zum Originalgerät
D12a = Terufusion Instruction Manual
D12b = Veröffentlichung der Japan Medical Device Manufacturers, original version
D12c = German translation of D12b
D12d = Effect of Continuous Intravenous Infusion of Carteolol Chloride on Tissue Blood Flow in Rabbit Optic Nerve Head, by Tetsuya Sugiyama

et al, Japanese Journal of Ophthalmology, 43, 1999, pages 490-494

D12e = eidesstattliche Versicherung von Dr. Maximilian Brandt zur Funktionsweise der Spritzenpumpe Terufusion TE-311.

Furthermore the appellant offered a practical demonstration of the working of a syringe plunger system and to that end wanted to present a device at the oral proceedings.

III. In a communication annexed to the summons to oral proceedings, the Board indicated its preliminary opinion.

Oral proceedings took place on 13 July 2010.

The appellant (opponent) requested that the decision under appeal be set aside, that European patent No. 1 200 143 be revoked and, as an auxiliary request, that the case be remitted to the first instance for further consideration and the appeal fee be reimbursed.

The respondent (patentee) requested that the appeal be dismissed and that the patent be maintained on the basis of (sole extant request):

- Claims: 1 to 4 filed as third auxiliary request during the oral proceedings
- Description: columns 1 to 12 filed during the oral proceedings
- Drawings 1 to 29 as granted.

IV. Claim 1 of the respondent's sole request reads as follows:

"A syringe plunger driver system for engaging syringe plungers of different sizes, each plunger (22) having a plunger piston (26), a plunger flange (24), and a plunger stem (28) interconnecting the piston with the flange and each plunger forming a part of a syringe, each syringe having a barrel (16) into and out of which the plunger moves, each plunger flange (24) having an inner side facing the syringe barrel and an outer side, the plunger driver system having a drive head (30) adapted to move the syringe plunger (22) into the syringe barrel (16) in an operation mode, the driver system comprising:
a pushing surface (36) located on the drive head adapted to press against the outer side of the plunger flange to move the flange toward the barrel during the operation mode;
a plunger retainer located on the drive head configured to permit the location of the syringe plunger flange (24) in proximity to the pushing surface, the plunger retainer comprising a pair of pivotable arms (32) mounted in spaced-apart locations on the driver head, wherein said arms may move to engage the inner side of the plunger flange (24) and retain the flange in contact with the pushing surface (36), the pivoted arms further being spring-loaded towards the pushing surface to allow the plunger retainer to adjust itself to the thickness of the given plunger flange (24) and bias the plunger retainer towards the pushing surface (36), whereby siphoning is resisted, characterized in that:
the pivotal arms (32) are also spring-loaded inwardly to allow the plunger retainer to clamp the plunger stem

and to adjust itself to the diameter of the plunger stem, and further comprising an externally mounted activating lever (34) that an operator may touch and manipulate and that is interconnected with the first and second arms (32) such that, as the lever is moved into a first position, the lever pivotally moves the first and second arms outward and forward into a syringe plunger non-engagement position in opposition to the biasing forces on the first and second arms whereby easy loading of a syringe plunger is facilitated, and has a second position at which the lever does not apply force opposing the biasing devices on the first and second arms so that the arms may move toward each other and toward the pushing surface to capture a syringe plunger, and wherein the lever (34) is interconnected to the first and second arms such that when the lever is moved to said second position, the lever causes the arms to first move inward toward each other and then to move toward the pushing surface."

Claims 2 and 3 depend on claim 1 and independent claim 4 corresponds to claim 1 in terms of method steps.

V. The appellant argued as follows:

The set of documents D11 should be introduced into the proceedings as further support of the evidence for the prior use brought forward on the basis of the set of documents D4. Mrs Doreen Lattner was offered as witness concerning the content of document D11d. The syringe pump DPS 082220 with the serial number 16749133 should be introduced into the proceedings and a practical

demonstration of the working of the pump should be allowed. Said pump was part of the D4 prior use. The presentation of the pump would greatly facilitate the comprehension of the working of the pump itself. The offer to exhibit a pump relating to the prior use had already been made during the opposition proceedings, see opposition letter of 22 November 2006, page 11, second full paragraph, but not considered necessary by the opposition division (see decision under appeal, page 9, first paragraph), so it could not be regarded as late.

The set of documents D12 concerned the prior use of a pump Terufusion TE-311 corresponding to the pump described in D3. The submission of these documents was prompted by the objection raised by the opposition division that the arms of the device of D3 did not clamp the plunger stem.

The new request of the respondent for maintenance of the patent in amended form submitted during the oral proceedings before the Board should not be admitted because it was late filed and unjustified.

The expression in claim 1 that the lever had a second position at which the lever did not apply force was not clear if read in the light of the description, in particular paragraph 0032. The patent did not contain sufficient information in order to carry out the invention either.

The subject-matter of claim 1 did not involve an inventive step having regard to a combination of the teaching of D2 with D3 or/and D4. Also a combination of

the teaching of D3 with D4 or the teaching of D4 alone made the claim obvious.

D2 suggested that the lever was interconnected to the first and second arms such that when the lever was moved to said second position, the lever caused the arms first to move inward toward each other and then to move toward the pushing surface, see column 12, lines 28-30. The wording of point 0039 of the description of D2: "at the same time" meant that the shaft could be moved in the leftward direction and be rotated as well, and did not refer to the fact that the two movements were to be performed simultaneously.

The fact that D2 disclosed an externally mounted activating button connected to a lever instead of an externally mounted activating lever as the claimed invention was insignificant for the evaluation of the inventive step, being a result of a mere workshop activity.

D4 disclosed a syringe plunger driver system addressing the problem of anti-siphoning for syringes of different sizes, see D4b, pages 37, 58 and 79. The mechanical driving block unit of the system was illustrated in detail in the exploded drawing at page 78, where in particular the clamping arm 428 could be seen in the upper-left side. Such clamping arm was rotated and moved in the axial direction by means of a lever, see D4d, page 2, point 1.1.1.

The request for remittal to the first instance and for reimbursement of the appeal fee was justified because of a substantial procedural violation of the right to

be heard, since the appellant had not been given sufficient time for reply to the observations of the patentee in the opposition proceedings before the Opposition Division issued its decision.

On 9 August 2007 the opposition division communicated to the appellant that the patentee had filed observations, but it did not mention a time limit for a reply. Guidelines E VIII 1.2 - to be applied by analogy - stated that the length of the time period given for reply should be based on the amount of work which was likely to be required to perform the operation in question, i.e.:

– if simple acts were requested: two months;
– for communications from the opposition division raising matters of substance: four months.

The opposition division should have waited four months before issuing the decision, since the letter of the patentee raised matters of substance. That the letter raised matters of substance was proved by the letter of the appellant of 22 March 2010, in which a complex technical argumentation was necessary in order to reply to the arguments of the patentee.

VI. The respondent argued as follows:

Documents D11 and D12 should not be introduced into the proceedings because they were late filed and not particularly relevant. Nevertheless, if they were admitted, the case should be remitted to the first instance in order to have two levels of jurisdiction. For the same reasons, the Board should also not take up

the offer of a presentation of a syringe pump during the oral proceedings.

The new request for maintenance of the patent in amended form was justified as a direct reaction to the communication of the Board. The amendments brought forward were straightforward and did not represent an undue burden to the opposing party and for the procedure itself.

Claim 1 was clear and the patent contained sufficient information in order to carry out the invention. The subject-matter of claim 1 involved an inventive step against each combination of the opposed prior art.

The appellant's request for remittal for further consideration should be refused.

Reasons for the Decision

1. The appeal is admissible.

2. *Late filed evidence*

2.1 D11

The appellant filed with letter of 22 March 2010 (see point 3 from page 19) documents D11a to D11e in order to further support the prior use already asserted on the basis of the set of documents D4.

The set of documents D11 concerns in particular the evidence for the use of a syringe pump DPS 082220 with

the serial number 16749133 by the Klinikum Wuppertal GmbH, Heusnerstr. 40, Wuppertal. Mrs Doreen Lattner has been also offered as witness for such prior use. The appellant wanted to present the above cited pump at the oral proceedings and to make a practical demonstration of the working of the pump.

According to the Rules of Procedure of the Boards of Appeal of the European Patent Office, Article 12(2), the statement of grounds of appeal must contain a party's complete case and expressly specify all the facts, arguments and evidence relied on; all documents referred to must be attached as annexes. According to Article 13(1) RPBA, any amendment to a party's case after it has filed its grounds of appeal may be admitted and considered at the Board's discretion. That discretion must be exercised 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.

Taking into account the complexity of the new subject-matter submitted, the state of the proceedings and the need for procedural economy, the Board decides not to introduce the above evidence into the proceedings. The new evidence was filed on 22 March 2010, i.e. about 2 years after the filing of the statement of grounds of appeal (1 April 2008). Furthermore it is contested by the respondent. Lastly it is not particularly relevant since the set of documents D4 already in the proceedings contains a detailed description of the prior use.

Consequently, nor was it considered necessary to hear the witness Mrs Doreen Lattner.

The presentation of the syringe pump DPS 082220 with the serial number 16749133 and the practical demonstration of the working of the pump during the oral proceedings was not admitted by the Board since the offer of the pump was also made late and it was not particularly relevant for the case when compared with the set of documents D4 already in the proceedings.

The appellant argued that the offer to exhibit the pump DPS 082220 with the serial number 16749133 was not late, since already made during opposition proceedings. However, as recalled above, according to the Rules of Procedure of the Boards of Appeal of the European Patent Office, Article 12(2), the statement of grounds of appeal must contain a party's complete case and expressly specify all the facts, arguments and evidence relied on; all documents referred to must be attached as annexes. This has not been done for the offer to exhibit the pump and therefore, contrary to the statement of the appellant, the offer has to be considered as late filed.

2.2 D12

The set of documents D12 was also filed on 22 March 2010 and therefore late. These documents are considered by the Board to be prima facie not particularly relevant for the case when compared with document D3 already in the proceedings, and are not admitted into the proceedings.

3. *Admissibility of the late filed request for maintenance of the patent in amended form*

The only extant request on file was submitted during the oral proceedings as a reaction to the objections raised during the debate and includes amendments prompted by the observations contained in the communication of the Board attached to the summons to oral proceedings. The amendments brought forward in comparison to the version maintained by the decision of the opposition division are straightforward. They consist merely on some slight modifications in order to clarify the claim with respect to the previous request filed before the oral proceedings. The examination of the late submission did not represent an undue burden for the appellant or caused an excessive lengthening of the proceedings. For these reasons the request has been admitted into the proceedings.

4. Claim 1 consists essentially of the granted claims 1, 5, 7 and 8 and to that extent is not open to any objection of clarity, since the alleged discrepancy with the description is not a result of the amendment. Furthermore, the objection that the patent did not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art cannot be accepted by the Board since the description and the drawings contain sufficient information in that sense.

5. *Inventive step*

D2 (Figures 9 to 11) discloses a syringe plunger driver system for engaging syringe plungers of different

sizes, each plunger having a plunger piston, a plunger flange (15-1), and a plunger stem (15) interconnecting the piston with the flange and each plunger forming a part of a syringe (14), each syringe having a barrel into and out of which the plunger moves, each plunger flange having an inner side facing the syringe barrel and an outer side, the plunger driver system having a drive head (16) adapted to move the syringe plunger into the syringe barrel in an operation mode, the driver system comprising a pushing surface (16-1) located on the drive head adapted to press against the outer side of the plunger flange to move the flange toward the barrel during the operation mode; a plunger retainer located on the drive head configured to permit the location of the syringe plunger flange in proximity to the pushing surface, the plunger retainer comprising a pair of pivotable arms (27) mounted in spaced-apart locations on the driver head, wherein said arms may move to engage the inner side of the plunger flange and retain the flange in contact with the pushing surface, the pivoted arms further being spring-loaded towards the pushing surface (see reference number 29 in Figure 11A) to allow the plunger retainer to adjust itself to the thickness of the given plunger flange and bias the plunger retainer towards the pushing surface, whereby siphoning is resisted, and further comprising an externally mounted activating button (17-1) (connected to a lever (28)) that an operator may touch and manipulate and that is interconnected with the first and second arms such that, as the lever is moved into a first position, the lever pivotally moves the first and second arms outward and forward into a syringe plunger non-engagement position in opposition to the biasing forces on the first and second arms

whereby easy loading of a syringe plunger is facilitated, and has a second position at which the lever does not apply force opposing the biasing devices on the first and second arms so that the arms may move toward each other and toward the pushing surface to capture a syringe plunger.

However, D2 does not disclose: (a) that the pivotal arms are also spring-loaded inwardly to allow the plunger retainer to clamp the plunger stem and to adjust itself to the diameter of the plunger stem.

Furthermore, D2 does not disclose: (b) an externally mounted activating lever that an operator may touch and manipulate. Instead, an externally mounted activating button connected to a lever is provided.

Finally, D2 does not disclose: (c) that the lever is interconnected to the first and second arms such that when the lever is moved to said second position, the lever causes the arms first to move inward toward each other and then to move toward the pushing surface. In paragraph 0039 of D2, it is on the contrary emphasized that both movements occur at the same time.

The argument of the appellant that D2 suggested a sequential operation consisting of first moving the arms inwardly toward each other and then moving them toward the pushing surface (feature (c)) cannot be accepted. Point 0039 of D2 clearly states that the linear and the rotational movements of the shaft (causing the arms to move toward or away from the pushing surface and inwardly toward each other, respectively) occur at the same time. Furthermore,

Figures 11a to 11c of D2 clearly show an engaging pin 28-2 moving along the curved path of a screw-groove 27-2 causing the shaft 27-1 to move simultaneously axially and rotationally.

The purpose of the invention has therefore to be seen in simplifying the device known from D2 and in facilitating the loading of the syringe in the device itself.

Feature (b) contributes to the simplification of the device. Features (a) and (c) facilitate the correct loading of the syringe since the syringe is firstly held in a set position by the two arms clamping the plunger stem, and then the plunger is drawn toward the pushing surface of the driver until the plunger flange is pressed against it. In this way a precise alignment of the plunger (and of the syringe) with the axis of the device is assured even for plungers of different size and form; furthermore, the plunger is centred with respect to the two arms before coming into contact with the pushing surface (see also patent in suit, points 0025, 0026 and 0034).

Also D3 addresses the problem of reliably setting plungers of different diameters and shapes to the slide, see point 0006. D3 further discloses two inwardly spring-loaded arms grasping and pinching the plunger (feature (a)), see Figures 9-11 and description, points 0061, 0064, 0102, whereby the syringe is first fixed by means of the clamp (5), see Figures 1 and 5 and description, points 0100 - 0102. Furthermore, D3 discloses also feature (b) see reference number 52 in Figure 9. However, D3 fails to

disclose feature (c). Neither D2 nor D3 gives any hint towards the advantages achieved by features (c) as mentioned above. Accordingly, a combination of the teaching of D2 and D3 does not lead to the claimed invention.

D4 could not lead in an obvious way to the claimed invention in combination with D2 alone or in combination with D2 and D3, since it discloses a one-arm device, which implies a mechanical driving system quite different from that of the invention and of D2 and D3, consisting of two arms. There is no convincing reason why the skilled person in the field, starting from D2 or from a combination of D2 and D3, should ignore the one-arm mechanism of D4 and pick and choose from D4 the claimed features not known from D2 and D3. There is further no compelling reason for providing both arms disclosed in D2 and D3 with the mechanisms disclosed in D4 for the device having a single arm. These arguments are based on hindsight. The argument that feature (c) was disclosed in D4, as alleged by the appellant, can be left aside under these circumstances. For the same reason, also a combination of the features of D3 with those of D4 could not lead to the claimed invention in an obvious way.

Finally, the skilled person in the field would not choose D4 as a starting point in considering the inventive step of the claim, since the structure of a one-arm device is too different from that of the invention having two arms.

Accordingly, the subject-matter of claim 1 involves an inventive step within the meaning of Article 56 EPC.

The same applies mutatis mutandis to independent method claim 4.

6. *Reimbursement of the appeal fee and remittal to the first instance.*

The appellant complains that he was not given sufficient time to reply to the observations of the patentee filed in response to the opposition.

On the basis of the documents on file, the circumstances are the following:

- During opposition proceedings the patentee filed observations with letter dated 25 July 2007, received by the EPO on 26 July 2007;
- the letter was forwarded by the EPO for information to the opponent with communication of 6 August 2007 and received by him on 9 August 2007 (see letter of the appellant of 31 March 2008, page 3);
- the decision in opposition proceedings was signed on 1 November 2007, is dated 21 November 2007, was communicated to the opponent by fax on 19 November 2007, was sent to the opponent by post on 21 November 2007 and received on 27 November 2007.

Starting from the earlier date on which the decision was taken (1 November 2007), the above means that the opposition division waited 2 months and 21 days from the opponent's receipt of the observations of the patentee (9 August 2007) before it took its decision.

The question is whether the opponent had sufficient time to comment or, more specifically, whether 2 months and 21 days represent a sufficient time to do so.

The appellant referred to the Guidelines for examination in the EPO (December 2007) E-VIII 1.2 - to be applied by analogy - which stated that the length of the time period explicitly given for reply should be based in principle on the amount of work which is likely to be required to perform the operation in question. The uniform practice adopted by the Guidelines was as follows:

- if simple acts are requested: two months;
- for communications from the opposition division raising matters of substance: four months.

The appellant argued that in this case four months should have been given, since the communication raised matters of substance.

This view however cannot be shared. The communication of the observations of the patentee was made merely for information (see in the communication: "Please take note"). The opposition division did not raise any matter of substance in the communication. The opponent was free to decide whether to comment on it or to remain silent. Had he decided to remain silent no act would have been required; had he decided to react to the letter of the patentee, the simple act of sending a request for the time considered necessary for the reply would have sufficed. For that simple act a period of two months as indicated in the Guidelines is considered sufficient by the Board.

The objection of the appellant that the communication of the opposition division raised matters of substance, as proved by the complexity of the reply of the appellant himself of 22 March 2010, is not convincing since the proof cannot consist in an action lying within the freedom sphere of the appellant.

Accordingly, reimbursement of the appeal fee under Rule 103(1)(a) EPC is not justified. Remittal to the first instance is justified only in order to maintain the patent on the basis of the version established with the present decision.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the first instance with the order to maintain the patent on the basis of the following documents:

   – Claims: 1 to 4 filed as third auxiliary request during the oral proceedings
   – Description: columns 1 to 12 filed during the oral proceedings
   – Drawings 1 to 29 as granted.

3. The request for reimbursement of the appeal fee is rejected.

The Registrar: The Chairman:

D. Sauter D. Valle