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Datasheet for the decision of 11 January 2017

Case Number: T 0044/12 - 3.2.02

Application Number: 04256588.7

Publication Number: 1529546

IPC: A61M5/168

Language of the proceedings: EN

Title of invention:
Syringe pump rapid occlusion detection system

Patent Proprietor:
Smiths Medical ASD, Inc.

Opponents:
B. Braun Melsungen AG
Fresenius Vial S.A.S.

Headword:

Relevant legal provisions:
RPBA Art. 13
EPC Art. 53(c), 123(2), 54, 111(1)

Keyword:
Late filed request - admitted (yes)
Exceptions to patentability - (no)
Added subject-matter (no)
Novelty - (yes)
Remittal to the department of first instance - (yes)

Decisions cited:
G 0001/07, T 0245/87

Catchword:

Europäisches Patentamt
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Case Number: T 0044/12 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 11 January 2017

Appellant: (Patent Proprietor)	Smiths Medical ASD, Inc. 160 Weymouth Street Rockland, MA 02370-1136 (US)
Representative:	Findlay, Alice Rosemary Reddie & Grose LLP 16 Theobalds Road London WC1X 8PL (GB)
Respondent: (Opponent 1)	B. Braun Melsungen AG Carl-Braun-Str.1 34212 Melsungen (DE)
Representative:	Winter, Brandl, Fürniss, Hübner, Röss, Kaiser, Polte - Partnerschaft mbB Patent- und Rechtsanwaltskanzlei Alois-Steinecker-Strasse 22 85354 Freising (DE)
Respondent: (Opponent 2)	Fresenius Vial S.A.S. Le Grand Chemin 38590 Brézins (FR)
Representative:	Maikowski & Ninnemann Patentanwälte Partnerschaft mbB Postfach 15 09 20 10671 Berlin (DE)
Decision under appeal:	**Decision of the Opposition Division of the European Patent Office posted on 3 November 2011 revoking European patent No. 1529546 pursuant to Article 101(3)(b) EPC.**

Composition of the Board:

Chairman	E. Dufrasne
Members:	P. L. P. Weber
	M. Stern

Summary of Facts and Submissions

I. The appeal of the patent proprietor is against the decision of the Opposition Division posted on 3 November 2011 to revoke the patent. The Opposition Division considered that the subject-matter of claim 2 of the main request was a method for treatment of the human body by therapy and therefore fell under the exception to patentability pursuant to Article 53(c) EPC. Moreover, it considered that claim 1 lacked novelty in view of D1.

II. Notice of appeal was filed on 10 January 2012 (fax), and the fee was paid on 13 January 2012. The statement setting out the grounds of appeal was filed on 13 March 2012 (fax). A main request and first and second auxiliary requests were filed with the statement setting out the grounds of appeal.

Claim 1 of the main request as filed with the statement setting out the grounds of appeal read as follows (amendments over claim 1 of the patent as granted underlined):

"A method of automatically detecting an occlusion in a downstream fluid line (22) of a medical pumping system (10), the downstream fluid line (22) being configured to carry fluid under pressure between a fluid source (13) and a patient (24), the method comprising:
during a pumping sequence, determining a first force value indicative of force in the downstream fluid line (22) at time T1;
during the pumping sequence, determining a second force value indicative of force in the downstream fluid line (22) at time T2;

providing an indication of an occlusion in the downstream fluid line, characterised in that an indication of an occlusion is provided if a relationship between the first and second force values departs from an expected relationship."

Claim 1 of the first auxiliary request as filed with the statement setting out the grounds of appeal read as follows (amendments over claim 1 of the patent as granted underlined):

"A method of automatically detecting an occlusion in a downstream fluid line (22) of a medical pumping system (10), the downstream fluid line (22) being configured to carry fluid under pressure between a fluid source (13) and a patient (24), the method comprising:
during a pumping sequence, determining a first force value indicative of force in the downstream fluid line (22) at time T1;
during the pumping sequence, determining a second force value indicative of force in the downstream fluid line (22) at time T2;
providing an indication of an occlusion in the downstream fluid line, characterised in that an indication of an occlusion is provided if a slope relationship between the first and second force values departs from an expected slope relationship."

III. The following documents are cited in the present decision:

D1: US-A-5501665
D2: WO-A-01/72357
D6: US-A-4882575
D7: WO-A-02/38204.

IV. Oral proceedings were held on 11 January 2017.

The appellant requested that the decision under appeal be set aside and that the patent be maintained on the basis of one of the main, first and second auxiliary requests, filed with letter dated 8 August 2016, and the third and fourth auxiliary requests, filed with letter dated 19 September 2016.

Respondent 01 requested that the appeal be dismissed.
Respondent 02 requested that the appeal be dismissed.

Subsidiarily, the appellant requested that the case be remitted to the department of first-instance for further prosecution if the subject-matter of claim 1 were found not to fall under the exceptions pursuant to Article 53(c) EPC and to be novel in view of D1.

Subsidiary respondent 01 and respondent 02 declared that they were not opposed to a remittal to the first-instance department for further prosecution if the subject-matter of claim 1 were found not to fall under the exceptions pursuant to Article 53(c) EPC and to be novel in view of D1, and in any case requested remittal for further prosecution if the subject-matter of claim 1 were found to be novel.

V. Claims 1, 2, 21 and 40 of the main request as filed on 8 August 2016 read as follows (additions over version as granted underlined):

"1. A method of automatically detecting an occlusion in a downstream fluid line (22) of a medical pumping system (10), the downstream fluid line (22) being configured to carry fluid under pressure between a

fluid source (13) and a patient (24), the method comprising:
during a pumping sequence, determining a first force value indicative of force in the downstream fluid line (22) at time T1;
during the pumping sequence, determining a second force value indicative of force in the downstream fluid line (22) at time T2; and
providing an indication of the occlusion in the downstream fluid line,
characterised in that the step of providing an indication of an occlusion includes:
determining a slope relationship between the first and second force values by dividing a difference between the second force value and the first force value by a difference between time T2 and time T1; and
determining if the slope relationship departs from an expected slope relationship by comparing the slope relationship to the expected slope relationship,
wherein an indication of an occlusion is provided if the slope relationship between the first and second force values departs from the expected relationship."

"2. The method of automatically detecting an occlusion of claim 1, wherein the fluid source (13) is a syringe (13), and the medical pumping system (10) is a syringe pump (10) having a housing (14) adapted to support the syringe (13) containing a plunger (16) moveable inside the syringe (13) by pushing an end of a plunger (16) with a pusher (17) to expel fluid from an outlet of the syringe into the fluid line (22) connected to the outlet so as to carry fluid under pressure to a patient (24), the method further comprising:
mounting the syringe (13) onto the housing (14) with the plunger end extended;

coupling the pusher (17) to the end of the plunger (16); and
initiating the pumping sequence to cause the fluid to flow into the fluid line (22).”

“21. A pumping system, comprising
a fluid source (13),
a fluid line (22) having a downstream fluid line (22) configured to carry fluid under pressure between the fluid source (13) and a patient (24),
a sensor (33) for determining first and second force values indicative of the force between the fluid source (13) and the patient (24) in the downstream fluid line (22) taken at times T1 and T2 during a pumping sequence, respectively,
a pump (10) configured to generate a force between the fluid source and the patient in the downstream fluid line (22),
a processor (31) in communication with the pump (10), and
a memory (32) bearing program code, the program code for initiating providing an indication of an occlusion, the processor (31) being configured to execute the program, code characterised in that
the program code when executed on the processor (31) enables the processor (31) to:
determine ~~if~~ a slope relationship between first and second force values in the downstream fluid line (22) taken, respectively, at time T1 and T2 by dividing a difference between the second force value and the first force value by a difference between time T2 and time T1;
determine if the slope relationship departs from an expected slope relationship by comparing the slope relationship to the expected slope relationship; and

to initiate providing an indication of an occlusion in the downstream fluid line (22) if the slope relationship departs from the expected slope relationship."

"40. A program product comprising a program code for initiating an indication of an occlusion and a signal bearing medium bearing the program code, characterised in that the program code is configured to:
determine ~~if~~ a slope relationship between first and second force values indicative of the force in the downstream fluid line taken, respectively, at time T1 and T2 during a pumping sequence by dividing a difference between the second force value and the first force value by a difference between time T2 and time T1; and
determine if the slope relationship departs from an expected slope relationship by comparing the slope relationship to the expected slope relationship, the program code providing an indication of an occlusion in the downstream fluid line if the slope relationship departs from the expected slope relationship."

VI. The arguments of the respondents/opponents may be summarised as follows:

Main request – admissibility

This request should not be admitted into the proceedings because it was filed late, without reason for doing so, and although the Rules of Procedure of the Boards of Appeal required the whole case to be filed early. Furthermore, it contained features from the description.

Main request - exception to patentability pursuant to Article 53(c) EPC

The methods of claim 1 and claim 2 had to be considered methods for treatment by therapy, even by surgery. They not only required the patient to be connected to the pumping system by puncturing, i.e. a functional link, but they also required the therapeutic substance to be injected while the method was carried out since the method was executed during such a pumping sequence. Claim 2 was even clearer in this respect because it required the initiation of the therapeutic injection. The situation was different from that decided on in T 245/87, because in the present case the patient was mentioned in the claim.

Main request – added subject-matter

The amendment introducing the "downstream" fluid line into the wording of the claim was not supported by the application as filed because the indicated paragraph [0028] was more precise. The same was true of the amendment introducing the "slope relationship", which was not supported by paragraphs [0011] and [0046]. Hence, both amendments were unallowable intermediate generalisations. Further objections as to added subject-matter were not maintained during the oral proceedings.

Main request – novelty in view of D1

Nothing in the claim wording indicated that the force values had to be instantaneous force values, and in any case this was not relevant since D1 also disclosed such instantaneous values.

The calculations and comparisons explained in the first paragraphs of column 5 of D1 anticipated those in the claimed method since they were mathematically equivalent.

The other features also being known from D1, the subject-matter of claim 1 was not novel.

Remittal

The respondents/opponents agreed with a remittal.

VII. The arguments of the appellant/patent proprietor are essentially those underlying the reasons for this decision as set out below.

Reasons for the Decision

1. The appeal is admissible.

2. The invention relates to the detection of an occlusion in a fluid line of a medical pumping system. In the prior art there are devices in which an alarm is triggered when the pressure becomes too high. The present invention proposes determining the pressure (or force) at least at two points in time, which allows a slope to be determined and therefore helps to determine whether an occlusion will appear before it actually occurs.

3. Main request – admissibility

According to the respondents/opponents, this request filed in August 2016 was late-filed and was not to be admitted into the proceedings. The Rules of Procedure

of the Boards of Appeal required that the parties filed their complete case at the start of the appeal proceedings. In the whole of the present appeal proceedings, no reason for filing new requests was present; in particular, the annex to the summons did not raise any new issue. Moreover, some of the features added to the independent claims came from the description, which was an additional reason not to admit the requests.

The Board does not share this opinion. Present claim 1 contains a more precise definition of the meaning of the "slope relationship" already present in the first auxiliary request filed with the statement setting out the grounds of appeal. In other words, claim 1 of the main request filed with the statement setting out the grounds of appeal, claim 1 of the first auxiliary request filed with the statement setting out the grounds of appeal and present claim 1 are convergent, as the step of comparing a measured relationship with an expected relationship is defined more and more precisely. Since the Opposition Division revoked the patent because of lack of novelty, such a more precise definition of a claimed feature is a priori also in the interests of procedural efficiency, given that the raised objection of lack of novelty seems more likely to have been overcome. The parties and the Board can also be expected to be able to deal with the amendments because the more precise definition (taken from the description) of the "slope relationship" had reasonably to be taken into consideration when analysing the significance of this expression in claim 1 of the first auxiliary request filed with the statement setting out the grounds of appeal.

For the above reasons, the Board decided to admit the main request pursuant to Article 13 RPBA.

4. Main request - method for treatment of the human body by therapy - Article 53(c) EPC

4.1 The Opposition Division and the respondents/opponents considered that the step "initiating the pumping sequence to cause the fluid to flow into the fluid line" of claim 2 was a therapeutic step because it changed the patient's status through the injection of medicine. Even claim 1 fell under the exception of Article 53(c) EPC, because it encompassed the surgical step of placing the infusion needle and the therapeutic step of pumping medicine into the patient during the execution of the claimed method. The method decided on in T 245/87 was different from the present one in that it did not mention the patient in its wording.

4.2 The parties cited T 245/87. The object of that decision was to determine whether a flow measuring method applicable to an insulin pump implanted in a patient according to EP-A-0141965 fell under the exclusion of Article 52(4) EPC 1973 (equivalent to Article 53(c) EPC). More precisely, the method described there was entitled "*A method for measuring the flow of small quantities of liquid passing through a tubular element*" and was intended for measuring the flow of small liquid quantities in tubing of small diameter and with small flow speeds (page 4, lines 9 to 20), in particular for application to implanted medicine delivery devices (page 1, lines 20 to 25), for which it was important to be able to detect any disturbances in the functioning, such as occlusion of the narrow tubing (page 1, lines 25 to 35). The invention described there consists in measuring an electrical resistance between two

electrodes placed in the electrically conductive fluid flowing in the tubing, once without a small gas bubble in the tubing and once with a small gas bubble in the tubing, and then deducing a flow time from the difference between the measured electrical resistances. In that decision the board considered that such a flow measuring method was not a method of treatment of the human body by therapy, because there was no functional link between the method claimed and the dosing of the drug administered by means of the device.

The decision includes the following passages:

"3.2 (...)
The subject-matter of Claim 1 does not include any steps constituting a functional link between the timing of the variation in resistance and the pump conveying the liquid in the example. Thus, the steps described in Claim 1, even when the method is applied to an implanted device for controlled drug administration, only involve measuring the volume of the drug solution flowing into the body per unit of time and the flow itself is not affected. These steps may therefore be performed without any medical knowledge and they have no therapeutic effect whatsoever in themselves.
(...)
3.2.2 (...)The operating parameters measured according to the method claimed allow the doctor complete liberty to plan the operating timetable of the pump - and thus the drug intake required for treatment - with medical discretion.
(...)
3.2.3 A method therefore does not fall within the scope of the first sentence of Article 52(4) EPC if there is no functional link and hence no physical causality between its constituent steps carried out in relation to a therapy device and the therapeutic effect produced on the body by that device."

4.3 The Enlarged Board of Appeal endorsed the approach of T 245/87 and similar decisions in G 1/07. Although this decision deals more specifically with the question of what is a surgical step and when does a claimed method fall under the exception to patentability for methods for treatment of the human body by surgery, in point 4.3.2 the Enlarged Board of Appeal addressed the methods only concerning the operation of a device and stated the following:

"The approach adopted in that jurisprudence has not been put into question in these proceedings and the Enlarged Board also sees no reasons for doing so. Methods which are merely directed to the operating of a device without themselves providing any functional interaction with the effects produced by the device on the body are teachings in which the performance of a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy is not required in order for the teaching of the claimed invention to be complete. Hence, even if in such a case the use of the device itself requires the application of a surgical step to the body or is for therapeutic treatment the same does not apply to the claimed method for operating the device. It appears therefore to be correct to say that such inventions are not methods for treatment of the human or animal body within the meaning of Article 53(c) EPC and that the distinction made in the jurisprudence of the technical boards properly delimits patentable methods of a merely technical nature from such inventions as fall within the exclusion under Article 53(c) EPC. Whether or not a claimed invention only concerns the operation of a device without any functional link to the effects of the device on the body, is not an issue of law but requires an evaluation of the overall technical circumstances of the case and is therefore a matter to be determined by the first instance and the technical boards of appeal in the individual cases under consideration."

4.4 In the Board's opinion in the present case the subject-matter of claims 1 and 2 falls within this definition of methods only concerning the operation of a device. Indeed, the method according to claim 1 not only is entitled "*A method of automatically detecting an occlusion in a downstream fluid line of a medical pumping system*", which as such already points towards an occlusion detecting method only, but also basically only includes determining two force values at two different times, determining a slope relationship between the first and second force values by dividing a difference between the second force value and the first force value by a difference between time T2 and time T1, and determining if the slope relationship departs from an expected slope relationship by comparing the slope relationship to the expected slope relationship, wherein an indication of an occlusion is provided if the slope relationship between the first and second force values departs from the expected relationship. In other words, it involves no more than determining two force values at two different times, deducing a relationship and making a comparison in order to be able to give an indication of a possible occlusion. The Board fails to see how such experimental determination and mathematical comparison of two values has a functional link with the medicine being injected into the patient for his therapy. The execution of the said claimed method has in itself no influence whatsoever on the quantity, frequency or speed of delivery of a given medicine present in the pumping system. The method appears to be a monitoring method which will indicate whether or not there is a risk of occlusion in the downstream fluid line, but it does not influence the ongoing process of delivering medicine to the patient, let alone give the medical doctor an indication of any measure to be taken in relation to the therapeutic

treatment of the patient in case an occlusion is likely to be present.

4.5 Claim 2 adds a more precise definition of the different mechanical parts composing the pumping system used and some steps necessary in order for the pumping sequence, during which the force values will be determined, to exist, namely mounting the syringe onto the housing with the plunger end extended, coupling the pusher to the end of the plunger and initiating the pumping sequence to cause the fluid to flow into the fluid line.

4.6 The respondents/opponents and the Opposition Division considered that the step of initiating the pumping sequence had to be considered a therapeutic step as it would change the status of the patient.

The Board does not share this view. This step has to be read in the context of the claimed invention, in particular bearing in mind the specific steps of the method as defined in claim 1. The method according to claim 1 requires the force values to be determined during a pumping sequence or, in other words, while fluid is steadily flowing through the downstream fluid line. Hence, the initiation of the pumping sequence (so that a pumping sequence exists) is already a necessary step to be able to carry out the method of claim 1 during such a pumping sequence. The fact that the method per se of detecting an occlusion should actually be guaranteed to be carried out during a pumping sequence as required by claim 1 is further emphasised in claim 5 and the following claims, where it is indicated that the steady-state condition is determined. Hence, this step of claim 2, when read in context, does no more than guarantee that there is a

pumping sequence during which the actual detection method of claim 1 can be carried out.
It is further emphasised that in the Board's opinion such a step of initiating the pumping sequence in claim 2 is no different to the statement in claim 1 that the method is carried out during a pumping sequence. Of course, during a pumping sequence the patient will receive the medicine and after initiation of the pumping sequence he will receive the medicine as well. However, the experimental and mathematical determination of a possible occlusion in the fluid line has no effect on this steady or initial pumping and does not give the medical doctor any clue as to what should be done in the then ongoing particular therapeutic treatment in the event that the possible presence of an occlusion is indicated, i.e. as to the therapy. The present Board considers that the statement by the board in T 245/87 under point 3.2.2 is applicable in the present case: "*The Board regards such a method as solely a matter for the apparatus designer. The operating parameters measured according to the method claimed allow the doctor complete liberty to plan the operating timetable of the pump - and thus the drug intake required for treatment - with medical discretion*."

4.7 The respondents/opponents considered that the wording of claim 1 in T 245/87 did not include the patient whereas the wording of present claim 1 did, which would be an additional indication that the method was for therapy.

The Board does not share this opinion. While mentioning the patient in the wording of a method claim might be an additional sign that the claim merits careful examination as to its possible falling under the

exceptions to patentability pursuant to Article 53(c) EPC, such mentioning of the patient is in itself not the decisive issue. What is decisive for the assessment of the question whether or not a method has to be considered a method for treatment of the human body by therapy is whether there is a functional link or a direct influence of the method claimed in itself on a given therapy, such that the medical doctor's freedom of choice and of practice in this respect is hindered. As explained above, the Board considers that this is not the case for the present method claims in the same way as this was the case in T 245/87.

4.8 For the same reasons as above, the necessary puncturing of the patient to connect him to the pumping system is, in the present case, irrelevant for the question of whether or not the method falls under the exceptions to patentability pursuant to Article 53(c) EPC.

4.9 Hence, in the present case the Board considers that the claimed method only concerns the operation of a device, without any functional link to the effects of the device on the body, and so the method does not fall under the exception to patentability pursuant to Article 53(c) EPC concerning methods for treatment of the human body by therapy or by surgery.

5. Main request – added subject-matter - Articles 100(c)/ 123(2) EPC

The respondents/opponents objected that paragraph [0028] indicated by the appellant/patent proprietor as a basis for the "downstream fluid line" is more precise, such that this amendment in claims 1 and 21 was an unallowable intermediate generalisation because it concerned a downstream "fluid" line and not a

downstream "infusion" line. Moreover, paragraphs [0011] and [0046] could not form a basis for "slope relationship" because they distinguished between "slope" and "relationship" without ever defining anything like a "slope relationship".

The paragraph cited by the appellant/patent proprietor is [0029] of the granted version, which corresponds to [0028] of the application as published. The first sentence of the paragraph reads: *"The syringe 13 drives medication into the downstream infusion line 22 at a controlled rate."* This paragraph is part of the description where the specific embodiment is presented. While it is true that this sentence explicitly mentions a downstream infusion line, it is technically self-evident that the method is applicable to any fluid line under pressure; it does not have to be an infusion line. That the method should be applicable to a fluid line under pressure was already present in claim 1 as filed ("*A method of automatically detecting an occlusion in a fluid line (22) of a medical pumping system (10), the fluid line (22) being configured to carry fluid under pressure between a fluid source (13) and a patient (24)...*") and is still present in the present claim. In the Board's opinion, this indication that the fluid is carried under pressure in the fluid line already means that the fluid line is a downstream fluid line. Indeed, in a normal situation it is only the downstream fluid line after the pump which is under pressure.

The second and third sentences of paragraph [0011] read as follows: "*A relationship between the pressure values is determined. This relationship typically comprises a slope.*" ; and paragraph [0046] reads as follows: "*The system 10 at block 207 of Fig. 3 uses the force values*

obtained at blocks 204 and 206 to determine a relationship between them. For instance, the system 10 may determine a slope at block 207. More particularly, the difference between the obtained force values may be divided by the difference in the times that the respective force values were obtained. One or more force values may be stored at block 205 for later use."

In the Board's opinion these paragraphs are basis enough for the slope relationship defined in claim 1, the term "slope relationship" in the context of the patent in suit having to mean that the relationship is a slope. In present claim 1 this is clarified anyway, as the slope relationship is additionally defined as the division of a difference between the second force value and the first force value by a difference between time T2 and time T1, which is nothing else but a slope.

Hence, the amendments introduced into claims 1 and 21 fulfil the requirements of Article 123(2) EPC.

6. Main request - novelty in view of D1

6.1 The respondents/opponents considered that the disclosure of D1 was novelty-destroying at least for the subject-matter of method claim 1. In relation to the force determining step they considered that in D1 it was not exclusively described that the values used for the calculations had to be mean values and that moreover this had no importance anyway, because the wording of claim 1 did not exclude determination of the mean force values. Furthermore, the calculation as explained in column 5 of D1 comprising comparing a pressure difference to a reference gradient multiplied by a time interval anticipated the comparison made in claim 1 of a ratio of a difference of force values

divided by a difference of measuring times with a reference ratio, because such calculations were mathematically equivalent. The other features also being disclosed by D1, this document anticipated the subject-matter of claim 1.

6.2 The same problem of detecting an occlusion in a medical pumping system is addressed in D1. Two pressure values (obtained by detecting the force applied on the plunger by means of a force transducer, see column 4, lines 1 to 5) are detected for two different time intervals in order to deduce a pressure difference. On the other hand, a reference or acceptable predetermined gradient So is stored in a microprocessor for the purpose of being compared with the measured values. Column 5, lines 9 to 15: "*The microprocessor 46 is programmed to calculate the difference between the pressures at the end of succeeding time intervals and then compares it to a constant deduced from a number representative of an acceptable predetermined gradient of the pressure/ time curve (So) and of the amplitude of the time interval Δt.*"

The first sentence of the following paragraph is then more precise: "*Thus, the microprocessor subtracts Pi from Pi+1 and compares the result to So.Δt.*" As explained further on in the same paragraph, this comparison will be used to generate an alarm signal or not. From the above it follows that in D1 a measured pressure difference is compared with a calculated reference pressure difference to make a decision on whether or not an alarm signal should be generated.

6.3 On the other hand, for the indication of an alarm signal claim 1 requires a slope relationship between the first and second force values to be determined by

dividing a difference between the second force value and the first force value by a difference between time T2 and time T1, and determining if the slope relationship departs from an expected slope relationship by comparing the slope relationship to the expected slope relationship. In other words, the test steps of claim 1 require the comparison of an actual slope relationship with a reference slope relationship, or in other words a comparison of ratios or gradients.

While it is accepted that, in the context of a syringe pump as described in D1, measuring or determining the pressures is equivalent to measuring or determining forces because the diameter of the syringe, and thus the surface on which the force is applied, is constant over the length of the syringe body (and thus over the injection time), the way the comparison is made is different from that claimed, even though the conclusion drawn may be equivalent.

More precisely, while both in the method described in D1 and in the claimed method a reference slope relationship (or acceptable gradient So) is memorised for comparison, the step of dividing the difference between the actual force (or pressure) values by the time difference required by the method according to claim 1 is not present in the method according to D1 and thus is not disclosed in D1.

6.4 For this reason alone the subject-matter of claim 1 is novel over D1.

6.5 The Board would like to add that in its opinion the wording "*determining a first, respectively a second, force value indicative of force in the downstream fluid line at time T1, respectively T2*" used in claim 1 does

not require or impose the measuring of an instantaneous or discrete force value, since the word “determining” does not define a precise way of doing so, and the wording “indicative of” also leaves the method of indication open.

6.6 The parties accepted that the other features of claim 1 were disclosed by D1, and the Board is satisfied that this is so.

6.7 Hence, the subject-matter of claim 1 fulfils the requirements of Article 54 EPC.

6.8 Independent claims 21 and 40 including features corresponding to the novel feature of claim 1, their subject-matter is novel as well.

7. Remittal

The appellant/patent proprietor requested that the case be remitted to the first-instance department for further prosecution if the subject-matter of claim 1 were found to be novel over D1, as this was the only substantive and substantiated reason for revocation in the decision under appeal. At the oral proceedings, the respondents/opponents clearly indicated that they did not object to such a remittal. Moreover, all parties requested remittal for examination of inventive step. Considering that the Opposition Division did not substantiate its statement concerning lack of novelty of the then examined claim 1 in view of D2, D6 and D7, that the present version of claim 1 was not on file in the opposition proceedings and the decision had to be set aside on that basis, and finally that all parties agreed to a remittal, the Board sees no reason for not allowing this request.

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 for further prosecution.

The Registrar: The Chairman:

D. Hampe E. Dufrasne

Decision electronically authenticated