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Datasheet for the decision of 17 May 2011

Case Number: T 1075/06 - 3.2.02

Application Number: 00961403.3

Publication Number: 1126896

IPC: A61M 37/00

Language of the proceedings: EN

Title of invention:
Blood separation systems and methods using a multiple function pump station to perform different on-line processing tasks

Applicant:
Fenwal, Inc.

Headword:
-

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

Relevant legal provisions (EPC 1973):
EPC Art. 52(4)

Keyword:
"Exclusion from patentability (yes)"
"Novelty (no)"

Decisions cited:
G 0001/04, G 0001/07, T 0245/87, T 0329/94, T 0663/02

Headnote:

I. Venipuncture of blood donors and the extraction of blood from a donor's body represent substantial physical interventions on the body which require professional medical expertise to be carried out and which entail a substantial health risk even when carried out with the required professional care and expertise. A method claim comprising steps encompassing such procedures is a method for treatment of the human body by surgery which is excluded from patentability under Article 53(c) EPC (Reasons, 2.1.1).

II. A method claim comprising the step of returning processed blood, depleted of some of its components and charged with an anticoagulant, to a donor is a method for treatment of the human body by therapy which is excluded from patentability under Article 53(c) EPC (Reasons, 2.1.2).

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Case Number: T 1075/06 - 3.2.02

D E C I S I O N
of the Technical Board of Appeal 3.2.02
of 17 May 2011

Appellant: Fenwal, Inc.
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Decision under appeal: **Decision of the Examining Division of the European Patent Office posted 13 February 2006 refusing European patent application No. 00961403.3 pursuant to Article 97(1) EPC 1973.**

Composition of the Board:

Chairman: M. Noël
Members: C. Körber
A. Pignatelli

Summary of Facts and Submissions

I. On 13 February 2006 the Examining Division posted its decision to refuse European patent application No. 00961403.3 under Article 54(1) and (2) EPC (lack of novelty vis-à-vis D1 and D2) and Article 52(4) EPC 1973 (method for treatment by surgery).

II. An appeal was lodged against this decision by the applicant by notice received on 13 April 2006, with the appeal fee being paid on the same day. The statement setting out the grounds of appeal was received on 22 June 2006.

III. By communication of 15 February 2011, the Board forwarded its provisional opinion to the appellant.

IV. Oral proceedings were held on 17 May 2011.

The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the main request or one of the first to third auxiliary requests filed on 22 June 2006, or one of the fourth to eighth auxiliary requests filed on 16 May 2011, or the ninth auxiliary request filed during the oral proceedings before the Board.

V. The following document is of importance for the present decision:

D1: US-A-4 605 503.

VI. Claims

Main request

The independent claims of the main request read as follows:

"1. A blood processing system (10) comprising
a donor flow channel (266, 300) to convey fluid to and from a donor,
a blood processing flow channel (18, 290, 312) including a blood separation chamber (18) to separate a blood component from donor blood,
a blood component collection flow channel (292, 294, 306) including a blood component collection container (304, 308),
a pump station (PP1, PP3) communicating with and adapted to receive fluid from the donor flow channel, the blood processing flow channel, and the blood component collection flow channel, and
a controller (16) to operate the pump station (PP1, PP3) in multiple modes, including a processing mode, during which the pump station is operated to convey blood in the donor flow channel (266, 300) into the blood processing flow channel (18, 290, 312) for separation of the blood component in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the blood component in the blood processing flow channel into the blood component collection flow channel (292, 294, 306) for collection in the blood component collection container (304, 308)."

"24. A blood processing method comprising the steps of: providing a blood processing circuit comprising a multi-function pump station (PP1, PP3), a donor flow channel (266, 300) for conveying fluid to and from a donor, a blood processing flow channel (18, 290, 312) including a blood separation chamber (18) to separate a blood component from donor blood, and a blood component collection flow channel (292, 294, 306) including a blood component collection container (304, 308), wherein the pump station is coupled to and adapted to receive fluid from the donor flow channel, the blood processing flow channel and the blood component collection flow channel, and
operating the pump station in multiple modes, including a processing mode, during which the pump station is operated to convey blood in the donor flow channel into the blood processing flow channel for separation of the blood component in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the blood component in the blood processing flow channel into the blood component collection flow channel for collection in the blood component collection container."

Claims 2 to 23 and 25 to 37 are dependent claims, with method claims 27 and 33 reading as follows:

"27. A method according to Claim 24 further including coupling the pump station to a utility flow channel including a processing fluid container, and operating the pump station during a blood component return mode to convey processing fluid in the utility flow channel into the donor flow channel for mixing with the blood component that is to be returned to the donor."

"33. A method according to Claim 32 further including coupling the pump station to a utility flow channel including a processing fluid container, and operating the pump station during a blood component return mode to convey processing fluid in the utility flow channel into the donor flow channel for mixing with the red blood cells that are to be returned to the donor."

First auxiliary request

The first auxiliary request corresponds to the main request underlying the impugned decision of refusal, with independent method claim 24 reading as follows:

"24. A blood processing method comprising the steps of:
coupling a multi-function pump station (PP1) to a donor flow channel (266, 270, 300) for conveying fluid to and from a donor, a blood processing flow channel (18, 312) including a blood separation chamber (18) to separate a blood component from donor blood, and a blood component collection flow channel (294, 306, 308) including a blood component collection container (308),
and
operating the pump station in multiple modes, including a processing mode, during which the pump station is operated to convey blood in the donor flow channel into the blood processing flow channel for separation of the blood component in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the blood component in the blood processing flow channel into the blood component collection flow channel for collection in the blood component collection container."

Second and third auxiliary requests

Independent method claim 24 of the second and third auxiliary requests corresponds to claim 24 of the main request and first auxiliary request, respectively, with the expression "fluid pressure actuated" being inserted between the terms "multi-function" and "pump station".

Fourth auxiliary request

Independent method claim 22 of the fourth auxiliary request corresponds to claim 24 of the first auxiliary request, with the additional steps of "coupling the pump station to a utility flow channel including a processing fluid container (288), and operating the pump station in a blood component return mode, during which the pump station is operated to convey processing fluid in the utility flow channel into the donor flow channel for mixing with the blood component returned to the donor".

Fifth auxiliary request

Independent method claim 23 of the fifth auxiliary request corresponds to claim 24 of first auxiliary request, with the additional steps of "coupling the pump station to a utility flow channel including a processing fluid container (288), and operating the pump station in a processing fluid transfer mode, during which the pump station is operated to convey a processing fluid in the utility flow channel into the blood processing flow channel or the blood component

collection flow channel for mixing with the blood component".

Sixth auxiliary request

Independent method claim 14 of the sixth auxiliary request reads as follows:

"14. A blood processing method comprising the steps of:
coupling a multi-function pump station (PP1) to a donor flow channel (266, 270, 300) to convey fluid to and from a donor, a blood processing flow channel (18, 312) including a blood separation chamber (18) to separate red blood cells from donor whole blood, and a blood component collection flow channel (294, 306, 308) including a red blood cell collection container (308) and an in-line filter (293') to remove leukocytes from the red blood cells before entering the red blood cell collection container (308),
operating the pump station in multiple modes, including a processing mode, during which the pump station is operated to convey whole blood in the donor flow channel into the blood processing flow channel for separation of the red blood cells in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the red blood cells in the blood processing flow channel into the blood component collection flow channel for on-line removal of leukocytes and collection in the red blood cell collection container, and a blood component return mode, during which the pump station is operated to convey at least some of the red blood cells in the blood processing flow channel into the donor flow channel for return to the donor,

coupling the pump station to a utility flow channel including a processing fluid container (288), and operating the pump station during the blood component return mode to convey a processing fluid in the utility flow channel into the donor flow channel for mixing with the red blood cells returned to the donor".

Seventh auxiliary request

Independent method claim 15 of the seventh auxiliary request reads as follows:

"15. A blood processing method comprising the steps of: coupling a multi-function pump station (PP1) to a donor flow channel (266, 270, 300) to convey fluid to and from a donor, a blood processing flow channel (18, 312) including a blood separation chamber (18) to separate red blood cells from donor whole blood, and a blood component collection flow channel (294, 306, 308) including a red blood cell collection container (308) and an in-line filter (293') to remove leukocytes from the red blood cells before entering the red blood cell collection container (308),
operating the pump station in multiple modes, including a processing mode, during which the pump station is operated to convey whole blood in the donor flow channel into the blood processing flow channel for separation of the red blood cells in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the red blood cells in the blood processing flow channel into the blood component collection flow channel for on-line removal of leukocytes and collection in the red blood cell collection container,

coupling the pump station to a utility flow channel including a processing fluid container (288), and operating the pump station in a processing fluid transfer mode, during which the pump station (PP1) is operated to convey processing fluid in the utility flow channel into the blood processing flow channel (18, 312) or the blood component collection flow channel (294, 306, 308) for mixing with the red blood cells."

Eighth auxiliary request

Independent method claim 14 of the eighth auxiliary request reads as follows:

"14. A blood processing method comprising the steps of:
providing a multi-function pump station comprising first and second fluid pressure actuated pump stations (PP1, PP3),
providing a fluid pressure actuator (PA1, PA3) operating to selectively apply fluid pressure pump strokes in tandem to the first and second pump stations to convey fluid from a source to a destination,
coupling the pump station to a donor flow channel (266, 270, 300) for conveying fluid to and from a donor, a blood processing flow channel (18, 312) including a blood separation chamber (18) to separate red blood cells from donor whole blood, and a blood component collection flow channel (294, 306, 308) including a red blood cell collection container (308) and an in-line filter to remove leukocytes from the red blood cells before they enter the collection container (308),
and
operating the pump station in multiple modes, including a processing mode, during which the pump station is

operated to convey blood in the donor flow channel into the blood processing flow channel for separation of the blood component in the blood separation chamber, and a collection mode, during which the pump station is operated to convey at least some of the blood component in the blood processing flow channel into the blood component collection flow channel for collection in the blood component collection container, wherein, during at least one of the multiple modes, operation of the pump station is switched between a first flow state, in which the pump strokes draw a fluid volume into the first pump station from the source and expel a fluid volume from the second pump station to the destination, and a second flow state, in which the pump strokes draw a fluid volume into the second pump station from the source and expel a fluid volume from the first pump station to the destination, the control function operating to synchronize the pump strokes so that fluid flow from the source is essentially continuous while fluid flow to the destination is pulsatile."

Ninth auxiliary request

Claims 1 to 23 of the ninth auxiliary request correspond to the system claims 1 to 23 of the main request, without the method claims 24 to 37. Accordingly, the wording of the claim 1 is identical to that of the main request as indicated above.

VII. The appellant's arguments are summarised as follows:

Claim 24 of the main request and the second auxiliary request had been amended to delete the step of coupling a multi-function pump station to a donor flow channel.

The claimed method commenced after the donor flow channel had been established and did not include the step of phlebotomising the donor. Claim 24 of the first and third auxiliary requests also did not claim the step of phlebotomising. Neither was a blood extraction method per se claimed. The claims did not refer explicitly to a step of conveying blood to and from a donor. The various method steps only related to how the flows of blood and of the separated blood components are controlled within the various channels of a blood separation system by means of a multi-function pump station. It should be born in mind that exclusions from patentability should be construed narrowly.

Although on-line blood processing, as was encompassed by the claims, would require the initial step of phlebotomising the donor, this was irrelevant to the assessment of whether the claim defined a method for treatment by surgery, and should hence be disregarded, just as it was in decision T 329/94. In that decision, a claim relating to a blood extraction assistance method for facilitating sustained venous blood flow though a human limb towards a venous blood extraction point was found not to contravene Article 52(4) EPC 1973 even though it implied venipuncture.

The claimed method evidently had no therapeutic purpose or effect and did not define any operation or activity that could be regarded as surgical in nature. No surgical or therapeutic step was actually claimed. There was no functional link or physical causality between the measure implemented (i.e. the control of the multi-function pump station) and any therapeutic effect produced on the body. According to decision

T 245/87, a method was not excluded from patentability by Article 52(4) EPC 1973 as long as there was no such functional link.

Furthermore, direct connection to a human donor was simply one example of a possible blood source. The claimed method could equally be used with blood from a source other than a living human donor. For example, the method could be used for fractionation of previously collected blood that had been stored for a period of time after its removal.

Dl described a single needle, batch-type blood fractionation system for separating plasma from whole blood. The system included a pump 32 that pumped blood from the donor to a blood separation device, viz. a filter 33. However, the pump 32 was not in communication with and adapted to receive fluid from a donor flow channel, a blood processing flow channel and a blood component collection channel, as required by claim 1. In particular, the pump 32 was not in communication with the blood collection channel due to the filter 33 being located there-between. Pump unit 46 operated to withdraw plasma-deficient blood from reservoir 44 for return to the donor interface conduit 27 at T-connector 28 and, as such, did not communicate with the blood processing flow channel. Furthermore, pump unit 46 was also not adapted to receive fluid from a donor flow channel, a blood processing flow channel and a blood component collection channel.

An unduly broad construction of the term "pump station" in claim 1 at issue, so as to include whole pump assemblies or "superstructures" which included a number

of individual pump stations, was not justified by the patent specification. In D1 individual pumps or pump stations communicated with different flow channels, whereas in claim 1 a single pump station communicated with all three channels.

Furthermore, none of the pump units 32 and 46 in D1 could be operated in multiple modes as defined in claim 1. Pump unit 32 simply pumped blood from the donor through the filter device 33. From said filter device, the separated blood components passed on to the plasma reservoir 42 and blood reservoir 44. Thus, pump unit 32 did not have two discrete modes of operation as defined in claim 1. Pump unit 46 operated only to withdraw plasma-deficient blood from the reservoir 44 in which it had been collected for return to the donor conduit 27. Thus, it did not operate in a first (processing) mode to convey whole blood in a donor flow channel into a blood processing flow channel for separation into its components and neither did it operate in a second (collection) mode to convey a separated blood component from the blood processing flow channel into a blood component collection flow channel for collection in a container.

Moreover, pump units 32 and 46 were driven by separate motors which in turn were controlled by different control circuits. Thus, the system in Dl also lacked a controller for operating a pump station in the multiple modes as defined in claims 1 and 24. Finally, it had to be taken into account that D1 explicitly required the pump rates to be different.

Reasons for the Decision

1. The appeal is admissible.

2. Method for treatment of the human body by surgery or therapy - Article 53(c) EPC

Pursuant to the transitional provisions having regard to the Act revising the EPC of 29 November 2000 decided by the Administrative Council on 28 June 2001, Article 53 shall apply to European patent applications pending at the time of its entry into force, and thus to the application under dispute in the present case.

2.1 Main request

The claimed method relates to an on-line blood fractionation technique (page 2, lines 16 to 28; page 3, lines 1 to 17) wherein whole blood is drawn from a donor and separated into its liquid and cellular components, with certain components being collected and the remaining components being returned to the donor. The method is performed intermittently, with a predetermined sequence and repetition of various modes (in particular "collection mode", "processing mode", "processing fluid transfer mode", "blood component return mode" as defined in the claims, each mode comprising various cycles and phases, see section "IV. The Blood Processing Procedures" on pages 37 to 79). It has to be decided whether the claimed blood processing method is a method for treatment of the human body by surgery or therapy falling under the exclusion clause of Article 53(c) EPC. In particular with respect to the aspect of surgery, the criteria developed in decision

G 1/07 of the Enlarged Board of Appeal (EBA, see OJ EPO 2011, 134) have to be taken into consideration. Before dealing with these in detail below and in response to the appellant's assertion that exclusions from patentability should be construed narrowly, it is to be noted that the EBA found in G 1/07 that a provision containing exclusions or exceptions from patentability is to be interpreted in the same manner as any other requirement for patentability, i.e. in such a manner that it takes its effect fully and achieves the purpose for which it was designed (see point 3.1 of the Reasons).

2.1.1 Surgery

Independent method claim 24 comprises the step of "providing a blood processing circuit comprising a multi-function pump station (PP1, PP3), a donor flow channel (266, 300) for conveying fluid to and from a donor ...".

From the description and drawings it becomes clear that the claimed blood processing method is performed on-line and that the donor forms part of the blood processing circuit (see, for instance, page 2, lines 16 to 21; page 12, line 34 to page 14, line 3; Figures 37 to 39). This is also reflected by the expression "for conveying fluid to and from a donor" comprised in method claim 24.

Access to the donor's vasculature is achieved by means of venipuncture, i.e. performing an incision into the donor's vein by means of a phlebotomy needle 268, 268' (see, for instance, the right-most columns of the

tables on pages 42, 43, 53-57, 67, 68, 76, 77). Consequently, the claimed method encompasses the implicit step of venipuncture (see, for instance, page 4, lines 2 to 4, and page 41, lines 7 to 9). According to G 1/07 a claim which comprises a step encompassing an embodiment which is a "method for treatment of the human or animal body by surgery" within the meaning of Article 53(c) EPC cannot be left to encompass that embodiment (see Headnote 2a and last paragraph of point 4.1 of the Reasons). Moreover, the claimed method involves "conveying fluid to and from a donor", wherein the "fluid" may include whole blood conveyed from a donor, or blood components or additives conveyed to a donor (page 13, lines 14 to 34). It therefore has to be decided whether or not the steps of venipuncture and blood extraction are of a surgical nature according to the criteria developed in G 1/07. This has to be done on a case-by-case basis, with each category of cases being assessed on its own merits (G 1/07, point 3.4.2.6 of the Reasons).

2.1.1.1 Venipuncture

As ruled in G 1/07, a method which *"comprises or encompasses an invasive step representing a **substantial physical intervention** on the body which requires **professional medical expertise** to be carried out and which entails a **substantial health risk** even when carried out with the required professional care and expertise, is excluded from patentability as a method for treatment of the human or animal body by surgery pursuant to Article 53(c) EPC"* (see Headnote 1 (emphasis added), see also last paragraph of point 3.4.2.7 of the Reasons).

"Substantial physical intervention"

In this Board's view, venipuncture represents a substantial physical intervention on the body. It is not comparable to treatments such as tattooing, piercing, hair removal by optical radiation, or micro abrasion of the skin, i.e. invasive techniques performed on uncritical parts of the body generally carried out in a non-medical, commercial environment which should not fall under the exclusion clause (G 1/07 point 3.4.2.2 of the Reasons). Donor blood is commonly obtained from the median cubital vein, which can hardly be regarded as an "uncritical part of the body", with a phlebotomy needle of a cannula diameter which is sufficiently large in order to collect and process the desired quantities of blood (for instance up to 1000 ml of red blood cells, see page 38, lines 3 to 5). The procedure generally takes place in a medical environment, usually a blood bank or a transfusion or apheresis centre with the required emergency equipment, under the supervision and presence of a physician.

"Professional medical expertise"

Venipuncture is usually carried out either by a physician or by a phlebotomist specifically trained in blood collection techniques, i.e. a medical practitioner having the necessary skills and knowledge of the respective anatomy, needle and catheter insertion techniques, associated health risks and precautions to be taken. Accordingly, performing a venipuncture belongs to the kind of interventions which represent "*the core of the medical profession's*

activities, i.e. the kind of interventions for which their members are specifically trained and for which they assume a particular responsibility" (G 1/07, point 3.4.2.3 of the Reasons). There is no doubt that venipuncture requires professional medical expertise to be carried out. Even though by itself not decisive ("*whether or not a method is excluded from patentability under Article 53(c) EPC cannot depend on the person carrying it out*" G 1/07, point 3.4.1 of the Reasons, see also G 1/04 (OJ EPO 2006, 334) discussed therein), this criterion gives a further indication that the claimed method might fall under the exclusion clause.

"Substantial health risks"

Even when carried out with the required professional care and expertise, venipuncture entails certain health risks for the donor. In some countries, the responsible physician is legally required to inform the donor about all these risks, including their likelihood and severity, prior to the donation procedure (see for instance § 6 of the German "Transfusionsgesetz"). Known complications associated with venipuncture include infection, bleeding and hematoma, secondary vein perforation, phlebitis, tendon injury, and nerve irritation and injury. While some of these injuries are well treatable if necessary, others may lead to serious irreversible effects. In particular, traumatisation of nerves (for instance the medial antebracheal cutaneous nerve) may lead to chronic pain and even permanent paralysis of the surrounding tissue. Even though these risks may be rare, they are undoubtedly substantial.

If follows that venipuncture of blood donors represents a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise.

Shortly after the present case was decided at the oral proceedings, the Board became aware of the recent decision T 663/02 from another Board, dated 17 March 2011, which deals with the intravenous injection of a contrast agent (see point 3.2 of the Reasons). This is a procedure closely related to yet different from venipuncture for extracting large quantities of blood from a donor. As explained above, the assessment of the present case, following the criteria developed in G 1/07, is also different in a number of respects and would not have changed in the light of T 663/02.

2.1.1.2 Blood extraction

The claimed method includes a "processing mode, during which the pump station is operated to convey blood in the donor flow channel into the blood processing flow channel ...". Moreover, claim 24 states that "the pump station is coupled to and adapted to receive fluid from the donor flow channel". Since the donor flow channel is in fluid communication with the vasculature of the donor (who remains connected to the blood processing circuit during the whole procedure until the final phase: see, for instance, page 50, lines 17 to 19 and page 64, lines 3 to 6), this implies that large quantities of blood are being removed, via the donor flow channel, from the donor's vasculature (if 1000 ml

of red blood cells are to be collected as mentioned above, a considerably larger volume of whole blood has to be processed). Accordingly, the applicant's argument that blood is merely conveyed from the donor flow channel of the blood processing circuit rather than from the donor himself is not accepted by the Board.

Moreover, in a medical sense, blood is a (flowing) organ of the human body, performing numerous functions which are essential to the health of the donor. Accordingly, the withdrawal of blood can be regarded to some extent as partial removal of an organ. As further specified in G 1/07 (point 3.4.2.5 of the Reasons), manipulating a body part is traditionally considered surgical (even if the intervention were not invasive and did not require that tissues are penetrated, as is the case here).

Therefore, in the Board's view, the removal of large quantities of blood from the donor's body also qualifies as a "substantial physical intervention on the body which requires professional medical expertise to be carried out". It may result in hypovolemic reactions of the circulatory system (e.g. dizziness, nausea, fainting, collapse), i.e. "substantial health risks even when carried out with the required professional care and expertise". As mentioned above under point 2.1.1.1, the responsible physician may even be legally required to inform the donor about these risks, at least in some countries, and the transfusion centre or blood bank is required to hold available the necessary emergency equipment and personnel. Furthermore, during the blood extraction process, the donor has to be kept under continuous medical

surveillance by a physician, who must be able to interrupt the procedure in case of health problems and complications.

2.1.2 Therapy

The claimed method (see dependent claim 27) furthermore comprises the step of "operating the pump station during a blood component return mode to convey processing fluid in the utility flow channel into the donor flow channel for mixing with the blood component that is to be returned to the donor". A similar wording is used in claim 33. Since the donor flow channel is in fluid communication with the donor's vasculature as mentioned above, this implies that processed blood components are being returned to the donor (see also page 3, lines 22 to 26). Accordingly, the applicant's argument that blood is merely conveyed to the donor flow channel of the blood processing circuit rather than to the donor himself is not accepted by the Board.

The processing includes the removal of certain blood components such as red blood cells, platelets or plasma (which are to be collected) and the addition of an anticoagulant (see, for instance, reference numerals 276 and 276' in Figures 10 and 34, respectively, page 19, lines 7 to 13, and page 57, lines 16 to 19). As mentioned at page 128, lines 30 to 33, and page 129, line 7, the purpose of the procedure may not only be storage, but also therapeutic ("blood component therapy", "therapeutic plasma exchange"). In patients with pathologically elevated quantities or malignant properties of certain blood components, their removal by the claimed blood processing method and the return

of the remaining components does indeed have a therapeutic effect.

Moreover, anticoagulants are medicaments and their administration to the donor via the return mode also results in a therapeutic effect on the donor's body, namely the reduction of blood clotting, thus preventing, for instance, deep vein thrombosis, pulmonary embolism, myocardial infarction and stroke. According to the established jurisprudence of the boards of appeal, the term "therapy" also covers prophylactic methods for treatment (see "Case Law of the Boards of Appeal of the EPO", 6th ed. 2010, I.B.4.4.1).

Consequently, the blood component return mode according to dependent claims 27 and 33 results in the re-administration of processed blood components which may generate various therapeutic effects on the human body. Methods with both therapeutic and non-therapeutic indications fall under the exclusion clause of Article 53(c) EPC as long as they are not limited to non-therapeutic applications (see "Case Law of the Boards of Appeal of the EPO", 6th ed. 2010, I.B.4.4.2). Independent claim 24, on which claims 27 and 33 depend, also covers the return mode ("conveying fluid to and from the donor") and thereby relates to a method for treatment of the human body by therapy.

2.1.3 Method for operating a device

A method which is only concerned with the operating of a device without any functional link between the claimed method and the effects produced by the device

on the body does not qualify as a method for treatment within the meaning of Article 53(c) EPC 1973. If, on the contrary, there is such a functional link, the method is excluded from patentability. This principle, initially developed for devices for use in a therapeutic treatment (see, for instance, T 245/87, OJ EPO 1989, 171, point 3.2.3 of the Reasons), has been endorsed by the EBA for treatments by therapy as well as surgery (G 1/07, point 4.3.2 of the Reasons). Whether or not a claimed method only concerns the operation of a device without any functional link to the effects of the device on the body "*requires an evaluation of the overall technical circumstances of the case and is therefore a matter to be determined ... in the individual cases under consideration*".

As explained above under points 2.1.1.2 and 2.1.2, the claimed steps of operating the pump station in a processing mode and in a blood component return mode do have direct surgical and therapeutic effects on the donor's body. Consequently, there is a direct functional interaction between the claimed method and the effects produced by the pump station on the body. Since the functional link is necessarily present in the case under consideration here, the method is excluded from patentability.

The present case is quite different from that underlying T 329/94 (OJ EPO 1998, 241), referred to by the appellant, which related to a blood extraction assistance method for facilitating sustained venous blood flow though a human limb towards a venous blood extraction point. In that case it was found that none of the method steps claimed had a therapeutic effect in

themselves, and consequently there was no functional link or physical causality between the measure implemented and any therapeutic effect produced on the body to which the measure was applied. Furthermore, it was found that the blood extraction itself did not form part of the claimed subject-matter. If that would have been the case, it was stated that withdrawal of blood would fall under the exclusion clause of Article 52(4) EPC 1973 three times, namely as treatment by therapy and surgery and as a diagnostic method (point 4 of the Reasons). With respect to the last two aspects it has to be noted, however, that decision G 1/07 and opinion G 1/04 have been subsequently issued by the EBA and the criteria developed therein have now to be taken into consideration.

Finally, the appellant's argument that the claimed method could also be carried out with stored blood is not convincing since the claimed method clearly refers to the donor ("conveying fluid to and from a donor").

2.1.4 From the above it follows that claims 24 to 37 are directed to a method for treatment of the human body by surgery and therapy which is excluded from patentability under Article 53(c) EPC.

2.2 First auxiliary request

Claim 24 comprises the step of "coupling a multi-function pump station (PP1) to a donor flow channel (266, 270, 300) for conveying fluid to and from a donor ...", which also encompasses the implicit step of venipuncture of the donor. The "processing mode" is identical to that defined in claim 24 of the main

request. Claims 27 and 33 of the first auxiliary request correspond to those of the main request. Consequently, the reasoning presented above under point 2.1 with respect to the main request applies mutatis mutandis to this request as well, and claims 24 to 37 are also directed to a method for treatment of the human body by surgery and therapy which is excluded from patentability under Article 53(c) EPC.

2.3 Second to eighth auxiliary requests

The independent method claims of all these requests comprise either the step of "providing a blood processing circuit comprising a multi-function pump station (PP1, PP3), a donor flow channel (266, 300) for conveying fluid to and from a donor ..." (second auxiliary request) or that of "coupling a multi-function [fluid pressure actuated] pump station (PP1) to a donor flow channel (266, 270, 300) for conveying fluid to and from a donor ..." (third to eighth auxiliary requests). A "processing mode" as defined in claim 24 of the main request is comprised in the independent method claims of all these requests. A "blood component return mode" is either comprised in the dependent method claims (second, third, fifth, seventh and eighth auxiliary requests) or in the independent method claim (fourth and sixth auxiliary requests) of these requests. Accordingly, the method claims of all these requests are also directed to a method for treatment of the human body by surgery and therapy which is excluded from patentability under Article 53(c) EPC.

3. Ninth auxiliary request - novelty

Although filed at a very late stage of the proceedings, the ninth auxiliary request was admitted by the Board since the claims directed to the system had not been modified. This request, submitted during the oral proceedings, comprises only claims directed to the blood processing system, after deletion of the method claims of the main request.

Document D1 deals with a blood fractionation system. It discloses a blood processing system as defined in claim 1, comprising:
a donor flow channel 27 to convey fluid to and from a donor,
a blood processing flow channel 30, 31, 33 including a blood separation chamber 33 to separate a blood component from donor blood,
a blood component collection flow channel 41, 42, 43, 44 including a blood component collection container 42, 44,
a pump station 32, 46 communicating with and adapted to receive fluid (Figure 2) from the donor flow channel 27, the blood processing flow channel 30, 31, 33, and the blood component collection flow channel 41 42, 43, 44, and
a controller 81, 107 to operate the pump station in multiple modes (column 11, lines 22 et seq.), including a processing mode (see Figure 8a), during which the pump station 32, 46 is operated to convey blood in the donor flow channel 27 into the blood processing flow channel 30, 31, 33 for separation of the blood component in the blood separation chamber, and a collection mode (see Figure 8b), during which the pump

station 32, 46 is operated to convey at least some of the blood component in the blood processing flow channel 30, 31, 33 into the blood component collection flow channel 41, 42, 43, 44 for collection in the blood component collection container 42, 44.

A "pump station (PP1, PP3)" as defined in claim 1 at issue may well comprise several pumps, as disclosed in D1. According to claim 23 of the present request, the pump station even explicitly comprises several "fluid pressure actuated pump stations (PP1, PP3)". Accordingly, it suffices that the ensemble of pumps 32 and 46 forming the pump station of D1, i.e. either one or both of pumps 32 and 46, is "communicating with and adapted to receive fluid" from the various flow channels, which is clearly disclosed in D1 as indicated above. The Board is not able to share the appellant's argument that D1 only discloses a "superstructure" including a number of individual pump stations, rather than a single pump or pump station as claimed.

Furthermore, the broad wording of the claim does not require the pump station to be communicating with and adapted to receive fluid **directly** from the various flow channels. Accordingly, other components such as the filter 33 of D1 may be located between the pump station and the collection flow channel. Moreover, according to the feature analysis presented above, the filter 33 already forms part of the "blood processing flow channel".

The claimed definition of the "processing mode" does not exclude some of the blood components being conveyed simultaneously to the blood component collection flow

channel, and that of the "collection mode" does not exclude blood being conveyed simultaneously to the blood processing flow channel.

The fact that the pumps 32 and 46 forming the pump station of D1 operate at different rates is of no relevance, since claim 1 is entirely silent with respect to pumping rates.

It follows that the subject-matter of claim 1 is anticipated by D1 and therefore not novel (Article 54 (1) and (2) EPC).

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

D. Sauter M. Noël