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**Datasheet for the decision
of 17 July 2019**

Case Number: T 1453/14 - 3.2.02

Application Number: 03749989.4

Publication Number: 1495774

IPC: A61M1/14

Language of the proceedings: EN

Title of invention:
Blood purifying device

Patent Proprietor:
Nikkiso Company Limited

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:

Relevant legal provisions:
EPC Art. 83, 123(2), 54(1), 56
EPC R. 80, 124(1)
RPBA Art. 12(2)

Keyword:

Novelty - main request (no)
Admissibility of auxiliary request 1 (yes)
Amendments according to Rule 80 - auxiliary request 1 (yes)
Added subject-matter - auxiliary request 1 (no)
Sufficiency of disclosure - auxiliary request 1 (yes)
Inventive step - auxiliary request 1 (yes)
Request to record a statement in the minutes of oral proceedings (refused)

Decisions cited:

T 2185/15

Catchword:



Beschwerdekammern

Boards of Appeal

Chambres de recours

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Case Number: T 1453/14 - 3.2.02

D E C I S I O N
of Technical Board of Appeal 3.2.02
of 17 July 2019

Appellant:
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Decision under appeal:

**Interlocutory decision of the Opposition
Division of the European Patent Office posted on
23 April 2014 concerning the maintenance of
European Patent No. 1495774 in amended form.**

Composition of the Board:

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

Summary of Facts and Submissions

- I. Appeals were lodged by the patent proprietor and the opponent against the interlocutory decision of the Opposition Division posted on 23 April 2014 concerning the maintenance of European patent No. 1 495 774 in amended form.
- II. The appellant/patent proprietor (hereinafter "the patent proprietor") filed notice of appeal on 3 July 2014, paying the appeal fee the same day. A statement setting out the grounds of appeal was received on 2 September 2014.
- III. The appellant/opponent (hereinafter "the opponent") filed notice of appeal on 30 June 2014, paying the appeal fee the same day. A statement setting out the grounds of appeal was received on 3 September 2014.
- IV. The following documents are relevant for the present decision:
- D1: WO-A-96/41 292
D7: EP-A-1 088 523
D8: WO-A-01/49 369
D9: DE-A-197 47 353
- V. Oral proceedings were held on 17 July 2019 at the same time as the oral proceedings for case T 2185/15 concerning the patent granted for divisional application 11 180 924.0.

The patent proprietor requested that the decision under appeal be set aside and that the patent be maintained as granted, or, in the alternative, on the basis of one of auxiliary request 1 filed with letter dated

2 September 2014 and mentioned in letter dated 13 January 2016, auxiliary requests 2 to 5, filed with letter dated 13 January 2016, and auxiliary request 6, filed with letter dated 16 July 2019.

The opponent requested that the decision under appeal be set aside and that the patent be revoked.

VI. Claim 1 of the **main request** (patent as granted) reads as follows (feature numbering in square brackets added by the Board):

"[1] A medical device (1) comprising:
an operation input unit (12) for an operator to enter instructions;
[2] an operation unit (20) for performing prescribed operations required for medical treatment based on input from said operation input unit (12);
[3] a human body detection means (18) for detecting the operator's presence in the vicinity of said operation input unit (12) unit [sic] and
[4.1] a control unit (19) that provides a control function for allowing said input operation unit (12) to instruct said operation unit's (20) operations, or
[4.2] allowing the operation unit (20) to operate based on the input entered into said operation input unit (12), only when said human body detection means (18) is detecting the operator characterized in that
[5.1] said human body detection means (18) comprises either an illumination means (18a) for irradiating an infrared light and a light receiving means (18b) for receiving its reflection, and the presence of an operator in the vicinity of said operation input unit (12) is detected as said light receiving means receives the reflection, or

[5.2] a sensor that detects the heat a human body emits, or

[5.3] image recognition means that detects the operator based on an image of the vicinity of operation input unit."

Claim 1 of **auxiliary request 1** (held allowable by the Opposition Division) reads as follows (amendments to claim 1 of the main request highlighted by the Board):

"[1] A blood purifying ~~medical~~ device ~~(1)~~ comprising: an operation input unit (12) for an operator to enter instructions;

[2] an operation unit (20) for performing prescribed operations required for medical treatment based on input from said operation input unit (12);

characterized in that

[3] a human body detection means (18) for detecting the operator's presence in the vicinity of said operation input unit (12) ~~unit~~ and

[4.1] a control unit (19) that provides a control function for allowing said input operation unit (12) to instruct said operation unit's (20) operations, or

[4.2] allowing the operation unit (20) to operate based on the input entered into said operation input unit (12), only when said human body detection means (18) is detecting the operator

~~characterized in that~~

[5.1] said human body detection means (18) comprises either an illumination means (18a) for irradiating an infrared light and a light receiving means (18b) for receiving its reflection, and the presence of an operator in the vicinity of said operation input unit (12) is detected as said light receiving means receives the reflection, or

[5.2] a sensor that detects the heat a human body emits, or

[5.3] image recognition means that detects the operator based on an image of the vicinity of operation input unit."

Claims 2 to 6 are dependent claims.

VII. The arguments of the patent proprietor relevant for the present decision are summarised as follows:

The subject-matter of claim 1 of the main request was novel. Document D7 related to a laser photocoagulation apparatus for ophthalmic treatment. Since such a treatment could be a cosmetic treatment, the device of D7 was not necessarily a medical device as claimed. Moreover, D7 did not disclose detection means which were suitable or meant to detect the presence of the operator in relation to the operation input unit, which in D7 was given by the footswitch 5 or the control board 2. The detection means in D7 detected the presence of the operator only in relation to the eyepieces 3a. These were at a considerable distance from the input unit and hence not in the vicinity of the input unit. As a consequence, in D7 the human body detection means did not detect the operator's presence in the vicinity of the operation input unit. Whereas D7 required an operator to carry out the treatment once the operator's presence was detected, the device of claim 1 was an autonomously operating device.

The arguments regarding the objections under Articles 123(2), 83 and 56 and Rule 80 EPC raised against auxiliary request 1 which are relevant for the present decision are essentially those on which the reasons set out below are based.

VIII. The arguments of the opponent relevant for the present decision are summarised as follows:

Main request

The subject-matter of claim 1 of the main request lacked novelty over document D7. In this respect, the arguments are essentially those on which the reasons set out below are based.

Auxiliary request 1

The request was not admissible since it had been filed only one month before the oral proceedings in opposition proceedings, and therefore it had been filed late. This short time span had not allowed the opponent to properly carry out a search of the claimed subject-matter. Moreover, the request was prima facie not allowable under Articles 123(2) and 84 EPC. For these reasons, the Opposition Division should have held the request to be inadmissible.

The modification of the two-part form of claim 1 had not been occasioned by a ground of opposition. The amendment was consequently not allowable under Rule 80 EPC.

There was no basis in the application as filed for the generalised expression of a "blood purifying device". Only a specific blood purifying device had been originally disclosed, namely, a "blood purifying device for purifying the patient's blood by means of extracorporeal circulation" (page 1, lines 7 to 9; page 5, lines 2 to 8; page 12, lines 7 to 10). It was clear that the expression "blood purifying devices"

appearing on line 11 of page 12 referred to the "blood purifying devices wherein blood is purified through extracorporeal circulation" which was mentioned in the immediately preceding lines 7 to 10 on that same page. Hence, the subject-matter of claim 1 was an unallowable intermediate generalisation of the original disclosure, contravening Article 123(2) EPC.

Objections under Articles 123(3) and 84 EPC as raised in the written proceedings were withdrawn at oral proceedings.

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 (Article 83 EPC). Regarding feature [5.1] of claim 1, the patent did not provide the reader with enough information to ensure that actually a human body was detected and not, for example, an insect. Moreover, it was not clear how a human body could be recognised by its temperature (feature [5.2]) since the temperature of the environment of the person could vary. For example, if the room temperature rose to 32°C, it would be impossible to detect the human body's skin which normally had a temperature of 32°C. Finally, it was not clear how the means defined in features [4.1], [4.2], [5.1] and [5.2] could distinguish between a person trained for operating the device and other persons such as children or cleaning personnel.

Starting from D1, the objective technical problem consisted in increasing the safety level of the device. Documents D7, D8 and D9 each disclosed safety means which the skilled person would have readily incorporated in the device of D1, thus arriving at the subject-matter claimed. D7 disclosed an infrared photo-

sensor (57) comprising an infrared emitter and detector which detected whether the operator was observing the patient's eye through the eyepieces 3a. Alternatively, the photo-sensor (57) could be disposed on a joystick (6) for positioning the slit lamp delivery (3) on a table. Hence, D7 taught that the control unit should allow the operation unit to operate only when the human detection means was detecting the operator in the vicinity of the device's operating input unit, as presented in paragraphs [0005] and [0006] of the patent. Document D8 disclosed a user identification system which provided authorized access to operational hardware and software tools in medical devices, particularly implanted medical devices. The identification process disclosed included the detection of a fingerprint, an image or an iris scan. Document D9 disclosed a patient treatment monitoring system with several patient terminals which required treating personnel to be identified by detection of fingerprints or face recognition. Hence, the combination of D1 with document D7, D8 or D9 rendered obvious the claimed subject-matter (Article 56 EPC).

Similarly, the skilled person would have readily arrived at the claimed subject-matter by departing from document D7, D8 or D9 and applying the safety measures disclosed therein to a dialysis device as in D1 (Article 56 EPC). The skilled person aware of the safety features of D7, D8 or D9 would have naturally thought of other types of medical devices, such as a dialysis device as known from D1, in which to incorporate them.

The Board was requested to state in the minutes of oral proceedings that it intended to accept the patent proprietor's argument that a control unit which allows

the operation unit to be instructed or to operate "only when said human body detection means is detecting the operator" (as defined in features [4.1] and [4.2] of claim 1) was equivalent to a control unit allowing the operation unit to be instructed or to operate while the human body detection means was detecting the operator.

Reasons for the Decision

1. The appeals are admissible.
2. *The invention*

The invention relates to a medical device which comprises an operation unit (20), an operation input unit (12) for an operator to enter instructions, a control unit (19) and a human body detection means (18) for detecting the operator's presence in the vicinity of the device's operating input unit, the control unit providing a control function for allowing:

- (a) the input operation unit to instruct an operation unit's operation or
 - (b) the operation unit (20) to operate based on the input entered,
- only when said human body detection means (18) is detecting the operator.

The human body detection means are claimed in three alternative variants: for irradiating and detecting infrared light, for detecting the human body heat and for detecting the operator based on an image.

The human body detection means of the invention prevent the medical device being operated due to a malfunction

of the operation input unit or an external noise while in fact the operator is not operating the device (paragraphs [0005] and [0006] of the patent).

3. *Main request - Novelty*

3.1 Document D7 discloses a laser photocoagulation apparatus for ophthalmic treatment (paragraph [0020]; Figure 1). As it is inconceivable that such an apparatus could be operated by anybody not specialised in ophthalmology, the apparatus is certainly a "medical device", contrary to the patent proprietor's view.

3.2 The apparatus of D7 comprises a control board (2) for inputting irradiation conditions (paragraph [0021]) and a joystick (6) for moving a slit lamp delivery (3) and for allowing the operator to perform sighting (alignment) with respect to the affected part (column 4, lines 37 to 40; column 7, lines 8 to 11). Hence, the control board (2) and the joystick (6) form an "operation input unit" as defined in feature [1] of claim 1. The apparatus of D7 comprises, moreover, a controller (60) controlling a laser source (10) in accordance with the irradiation conditions and mode set with the control board (paragraph [0031]). The laser source (10) is thus an "operation unit" as defined in feature [2] of claim 1.

3.3 The apparatus further comprises an infrared photo-sensor (57) comprising an infrared emitter and detector which detects whether the operator is observing the patient's eye (E) through the eyepieces (3a) (paragraphs [0030] and [0036]). Alternatively, the photo-sensor (57) may be disposed on the joystick (6) (paragraph [0038]). Hence, the photo-sensor (57) on the joystick (6) is "a human body detection means for

detecting the operator's presence in the vicinity of said operation input", as defined in features [3] and [5.1] of claim 1.

According to paragraph [0031], a control unit (controller 60) controls the laser source (10) in accordance with the presence/absence signal from the photo-sensor (57). Laser irradiation is enabled when the control unit (60) continuously receives a detection signal from the photo-sensor (57) and is disabled when no detection signal is received (paragraphs [0035] and [0036]). Hence, the control unit (60) "provides a control function for allowing the operation unit (laser source 10) to operate based on the input entered into said operation input unit (control board 2 and joystick 6) only when the human body detection means (photo-sensor 57) is detecting the operator", as defined in feature [4.2] of claim 1.

3.4 As a consequence, the subject-matter of claim 1 of the main request lacks novelty within the meaning of Article 54(1) EPC.

4. *Auxiliary request 1*

4.1 *Admissibility*

Auxiliary request 1 is the request held allowable by the Opposition Division. The opponent considered it should not be admitted into the appeal proceedings, mainly because it had been filed only one month before the oral proceedings in the opposition proceedings, and therefore it had been filed late. It alleged that this short time span had not allowed it to properly carry out a search of the claimed subject-matter. Moreover, the request was prima facie not allowable under

Articles 123(2) and 84 EPC. For these reasons, the Opposition Division should have not admitted the request.

The same arguments had been brought forward during opposition proceedings for supporting the opponent's request that the Opposition Division should not admit auxiliary request 1. The Opposition Division was not persuaded for the reasons given in the impugned decision and consequently rightfully exercised its discretion to admit auxiliary request 1.

In appeal proceedings, the patent proprietor submitted this auxiliary request again with its statement of grounds of appeal, which is hence a part of its case under Article 12(2) RPBA.

The opponent did not present any reason why the Opposition Division might have exercised its discretion to admit the request in an unreasonable way or disregarding the right principles. Neither can the Board see any. Under these circumstances and following established case law, the Board should not overrule the way in which the department of first instance has exercised its discretion (decisions cited in Case Law of the Boards of Appeal, 8th edition 2016, IV.E. 4.3.2(a)). The Board's function is not to review all the facts and circumstances of the case as if it were in the first-instance department's place and to decide whether it would have exercised such discretion in the same way.

The Board therefore admits auxiliary request 1 into the appeal proceedings.

4.2 *Rule 80 EPC*

Auxiliary request 1 had been filed as a fall-back position in view of the objections of lack of novelty and inventive step raised against claim 1 of the granted patent. As a consequence of introducing the limitation to a blood purifying device, the patent proprietor considered that also the two-part form needed adaptation to correctly reflect what was known from the closest prior art D1 cited in paragraph [0009] of the amended description of auxiliary request 1.

Therefore, the modification of the two-part form of claim 1 is in fact occasioned by the grounds of opposition raised, in conformity with Rule 80 EPC.

4.3 *Articles 123 and 84 EPC*

4.3.1 Claim 1 of auxiliary request 1 restricts the "medical device" claimed in the main request to a "blood purifying device".

Basis for such a restriction is given on page 12, lines 11 and 12 of the application, where it is stated that "the invention is also applicable, in addition to blood purifying devices, to infusion devices comprising ...". The skilled person would not consider that this statement refers to the immediately preceding paragraph dealing with particular embodiments of blood purifying devices having, indeed, means of extracorporeal circulation. In fact, the paragraph further down, at lines 20 to 23 of page 12, clearly refers to the devices mentioned previously by employing the expression of blood purifying devices and infusion devices "*mentioned above*". The skilled person would therefore have considered that the disclosure of a

blood purifying device is not inextricably linked with the means for purifying blood through extracorporeal circulation. Hence, the feature of a "blood purifying device" does not constitute an unallowable intermediate generalisation as argued by the opponent.

4.3.2 Claim 1 therefore satisfies the requirements of Article 123(2) EPC.

4.3.3 Objections under Articles 123(3) and 84 EPC which had been raised in the written proceedings were withdrawn by the opponent during the oral proceedings.

4.4 *Article 83 EPC*

4.4.1 Regarding feature [5.1] of claim 1, the opponent considered that the patent did not provide the reader with enough information to ensure that actually a human body was detected by infrared radiation in the vicinity of the operation input unit, and not, for example, an insect.

Claim 1 calls for a device capable of detecting a human body in the vicinity of the operation input unit. It is within the normal engineering capability of the person skilled in the art to provide filtering means for enhancing detection selectivity and eliminating spurious signals, if this should become necessary, particularly to differentiate signals originated from other sources, for example, an insect.

4.4.2 The opponent objected, moreover, that it was not clear how a human body could be recognised by its temperature (feature [5.2]), since the temperature of the environment of the person could vary. For example, if the room temperature rose to 32°C, it would be

impossible to detect the human body's skin which normally had a temperature of 32°C.

The opponent did not raise any objection against the detection capability of the claimed device at normal environmental temperatures. The Board considers that the invention does not lack sufficient disclosure just because under very special conditions the sensitivity of the detection means may be affected.

- 4.4.3 Finally, the opponent objected that it was not clear how the means of features [4.1], [4.2], [5.1] and [5.2] could distinguish between a person trained to operate the device and other persons such as children or cleaning personnel.

The Board considers that claim 1 does not require the device to carry out any such differentiation between the operator trained for operating the device and other persons such as children or cleaning personnel. The operator in the context of the present invention is not limited to a person having an authorisation for carrying out the treatment.

- 4.4.4 The Board therefore comes to the conclusion that the patent discloses the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art, in accordance with Article 83 EPC.

4.5 *Inventive step*

Departing from D1

- 4.5.1 Document D1 discloses a dialysis device comprising means for entering and validating information from an operator, such as a touch screen (130) (page 2,

lines 22 to 26; page 3, lines 25 to 28; page 30, lines 14 to 23; Figure 3). Such means constitute an operation input unit as defined in feature [1] of claim 1. The input entered into the device is validated by safety microcontroller 122 (Figure 3; paragraph bridging pages 15 and 16). As a result, the operator is less likely to make mistakes arising from boredom or inattention (page 30, lines 7 to 23).

The opponent considered that touch screen 130 was a means for detecting the operator's presence in the vicinity of the operation input unit as recited in feature [3] of claim 1. The Board notes, however, that touch screen 130 has already been identified as the operation input unit according to feature [1]. As a consequence, in D1 there are no separate means additional to the operation input unit for detecting the operator's presence in the vicinity of the operation input unit as defined in feature [3]. Consequently, D1 also lacks a control unit as defined in features [4.1] or [4.2] of claim 1, i.e. a control unit that provides a control function for allowing the input operation unit to instruct the operation unit's operation or allowing the operation unit to operate, only when the human body detection means is detecting the operator. Moreover, touch screen 130 does not possess any of the alternative characteristics of irradiating and detecting infrared light, detecting the human body heat or detecting the operator based on an image as defined in features [5.1], [5.2] and [5.3] of claim 1.

- 4.5.2 The opponent considered that the objective technical problem posed by the differentiating features with respect to D1 consisted in increasing the safety level of the device of D1. The opponent considered that

documents D7, D8 and D9 each disclosed safety means which the skilled person would have readily incorporated in the device of D1, thus leading him to the subject-matter of claim 1.

4.5.3 These lines of argument are unconvincing for the following reasons.

As explained above, D1 is a dialysis device with a specific safety feature for validating data which is input by the operator. In contrast, D7 is an ophthalmological laser treatment apparatus with different safety features which are entirely specific to the application of laser treatment to the eye, such as the aforementioned infrared photo-sensor (57) on a joystick (6) which detects the presence of the operator (see point 3.3 above). The skilled person would have not considered applying these specific safety features of an ophthalmological laser treatment apparatus to a dialysis device.

Document D8 discloses a user identification system to provide authorised access to operational hardware and software tools in medical devices, particularly implanted medical devices (page 1, lines 4 to 7 and 20 to 21; claim 1). The identification process disclosed includes the detection of a fingerprint, an image or an iris scan of the user (page 8, lines 13 to 17). If a match with stored data is confirmed, user access to the device is allowed based on the authorisation level (page 8, lines 17 to 20). The identification only occurs at a certain time, after which access is allowed or denied. In contrast, features [4.1] and [4.2] of claim 1 require that the control unit allows the operation unit to be instructed or to operate "only when said human body detection means is detecting the

operator", in other words, while it is detecting the operator. Thus, even if the skilled person would have had convincing reasons to incorporate the safety features of D8 into the dialysis device of D1, he would have not arrived at the subject-matter claimed.

Document D9 discloses a patient treatment monitoring system with several patient terminals which requires treating personnel to be identified by fingerprint detection or face recognition (column 3, lines 13 to 18). In this respect, as in D8, the identification only occurs at a certain time, after which access is allowed or denied. Thus, also D9 fails to disclose a control unit which allows the operation unit to be instructed or to operate "only when said human body detection means is detecting the operator" (as defined in features [4.1] and [4.2] of claim 1), in other words, while it is detecting the operator. Thus, even if the skilled person would have had convincing reasons to incorporate the safety features of D9 into the dialysis device of D1, he would have not arrived at the subject-matter claimed.

- 4.5.4 The Board therefore concludes that the subject-matter of claim 1 is not rendered obvious when starting from D1 as closest prior art.

Departing from D7, D8 or D9

- 4.5.5 As indicated above, D7 relates to an ophthalmological laser treatment apparatus with safety features entirely specific to the application of laser treatment to the eye, such as a joystick for moving a slit lamp with an infrared photo-sensor for detecting the presence of the operator. These are specific safety features of an ophthalmological laser treatment apparatus which would

make no technical sense in a dialysis device like that of D1. It is moreover unclear how the skilled person would have adapted the general concept underlying the safety features of D7 to a dialysis device like that of D1.

As indicated above, D8 and D9 relate to user identification systems providing authorised access to users in which the identification only occurs at a certain time, after which access is allowed or denied. These documents fail to disclose a control unit which allows the operation unit to be instructed or to operate "only when said human body detection means is detecting the operator" (as defined in features [4.1] and [4.2] of claim 1), in other words, while it is detecting the operator. Since the dialysis device of D1 also lacks these features, as explained under point 4.5.1 above, the combination of D8 or D9 with D1 would not have led the skilled person to the subject-matter claimed.

Hence, the subject-matter of claim 1 is not rendered obvious when departing from D7, D8 or D9.

4.5.6 The Board comes to the conclusion that claim 1 of auxiliary request 1 satisfies the requirements of an inventive step within the meaning of Article 56 EPC. This applies a fortiori to the preferred embodiments defined in dependent claims 2 to 6.

4.6 Hence, none of the grounds raised prejudices the maintenance of the patent on the basis of auxiliary request 1.

5. *Request to include a statement in the minutes of oral proceedings*
 - 5.1 During oral proceedings, the opponent requested that the Board states in the minutes of oral proceedings that the Board intended to accept the patent proprietor's argument that a control unit which allows the operation unit to be instructed or to operate "only when said human body detection means is detecting the operator" (as defined in features [4.1] and [4.2] of claim 1) was equivalent to a control unit allowing the operation unit to be instructed or to operate while the human body detection means was detecting the operator.
 - 5.2 Pursuant to Rule 124(1) EPC, the minutes of oral proceedings must contain the essentials of these proceedings and the relevant statements made by the parties. As is common practice in the Boards of Appeal, it is not the function of the minutes to record statements - such as the one in question - which a party considers to be possibly relevant. It is, instead, left to the discretion of the Board to decide what it considered "essential" or "relevant" in this respect. In the present case, the Board does not consider the statement in question to be more essential or relevant just because one of the parties requested it to be recorded in the minutes. At the same time, the Board does not recognise that the statement in question should be any more essential or relevant than other statements made during the oral proceedings which were not requested to be included in the minutes. The statement is incorporated into the reasoning given above, under point 4.5.1, second paragraph, and point 4.5.3, third and fourth paragraphs.

5.3 The Board consequently decides that the statement is not a proper subject for the minutes according to Rule 124(1) EPC, and the appellant's request to include the statement in the minutes is therefore refused.

Order

For these reasons it is decided that:

The appeals are dismissed.

The Registrar:

The Chairman:



D. Hampe

E. Dufrasne

Decision electronically authenticated