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Datasheet for the decision of 4 September 2008

Case Number: T 0787/07 - 3.2.04

Application Number: 00925084.6

Publication Number: 1180215

IPC: F04B 43/12

Language of the proceedings: EN

Title of invention:
Peristaltic fluid pump

Patentee:
DIA Medical A/S

Opponent:
Fresenius Medical Care Deutschland GmbH

Headword:
-

Relevant legal provisions:
EPC Art. 52, 54, 56

Keyword:
"Novelty (no) (main, 1st, 2nd auxiliary requests)"
"Novelty - enabling disclosure (yes)"
"Inventive step (yes) (3rd auxiliary request)"

Decisions cited:
T 0190/99

Catchword:
-

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Case Number: T 0787/07 **-** 3.2.04

D E C I S I O N
of the Technical Board of Appeal 3.2.04
of 4 September 2008

Appellant: (Opponent)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 30 March 2007 rejecting the opposition filed against European patent No. 1180215 pursuant to Article 102(2) EPC.

Composition of the Board:

Chairman: M. Ceyte
Members: A. de Vries
C. Heath

Summary of Facts and Submissions

I. The Appellant (Opponent) lodged an appeal, received 9 May 2007, against the decision of the Opposition Division posted 30 March 2007 to reject the opposition, and simultaneously paid the appeal fee. The statement setting out the grounds was received 25 July 2007.

Opposition was filed against the patent as a whole and based on Article 100 (a) together with Articles 52(1), 54 and 56 EPC 1973, for lack of novelty and inventive step.

The Opposition Division held that the grounds for opposition under Article 100 EPC 1973 did not prejudice the maintenance of the patent as granted having regard in particular to the following documents:
D1: US-A-3 787 148
D2: US-A-4 363 609

II. During the appeal proceedings the following document filed with the statement of grounds also played a role:
D9: WO 96/05432

III. The Appellant (Opponent) requests that the decision under appeal be set aside and the patent be revoked in its entirety.

The Respondent (Proprietor) requests that, as main request, the appeal be dismissed, or, in the alternative, that the patent be maintained on the basis of any of 1st to 4th auxiliary requests, all filed with letter dated 7 December 2007

IV. Oral proceedings were duly held before this Board on 4 September 2008.

V. The wording of claim 1 (the sole independent claim) of the requests is as follows :

Main Request

1."A peristaltic fluid pump having a suction side and a pumping side and of the kind that comprises,
- a pump housing (1) having a mainly arcuate support surface (4),
- a flexible tube (3) extending along this surface,
- a rotor (2) having two opposite rollers (10',10'') for during operation rolling over the flexible tube along an entrance section (a-d) where the tube successively is compressed, a pumping section (d-e) extending across an angle of an arc of less than 180°, and an exit section (e-g) where the compression successively is ended, whereby both sections (a-d) and (e-g) have an idling zone (a-b) and (f-g), respectively, without pumping action and a pumping zone (b-d) and (c-f), respectively, with pumping action,
- means (12) for during operation making the rotor rotate,
- that the arcuate support surface (4) is constructed in such a way that the two opposite rollers (10',10'') do not operate in synchronous phase opposition during operation,
- characterised in that the angle (α) between the ending (d) of the entrance section (a-d) and the beginning (e) of the exit section (e-g) is smaller than 180°."

First Auxiliary Request

Claim 1 is as in the main request but for the addition after the final feature (following "smaller than 180°") of:

"and that the arcuate support surface (4) is constructed in such a way that the diametrically opposite rearmost roller at a point (C) has entered so far into the pumping zone (b-d) of the entrance section (b-d) that the roller has been able to built up the pressure between the foremost and rearmost roller to the same level as the pumping pressure."

Second Auxiliary Request

Claim 1 is as in the main request but for the addition after the final feature (following "smaller than 180°") of:

"and that the pump comprises a device (18) for affecting the tube (3) with a spring power in the entrance section (a-d) of the tube."

Third Auxiliary Request

Claim 1 is as in the second auxiliary request but for the addition after the final feature (following "the tube") of:

"and that the pump comprises a device (19) for affecting the tube with a spring power in a zone downstream of the exit section (e-g) of the tube (3)."

Fourth Auxiliary Request

Claim 1 is as in the main request but for the addition after the final feature (following "smaller than 180°) of:

"and that the pump comprises pressure means (13) consisting of two disc springs (13) placed on each side of the tube (3) for elastically pressing against the sides of the tube (3) and for outside the area of engagement of the rollers (10',lO") keeping the tube (3) in a predetermined shape.

VI. The Appellant argued as follows :

All of the features of claim 1 of the main request are disclosed, either directly or implicitly, in D1, see in particular figure 3, and D2, see figure 4. Particularly, the pumping section extends between points 62 and 63 over an angle less than 180°. Idling is a necessary consequence of the gradual contact between roller and tube on the ramps 60, 61. Finally, when roller 10 is at point 62, at the end of the pumping section, opposed roller 11 is in the entrance ramp, and they are not in phase opposition. These features were also disclosed in D2, see figure 4 in particular.

D1 and D2 essentially teach that the actual pumping section should be reduced to an angle below 180° to prevent torque and pressure pulses. This is not contradicted by a reasonable reading of the passages cited by the proprietor in D1, column 2, and D2, column 4. Likewise, D1 and D2 describe gradual engagement and disengagement in the ramp areas, rather

than some sudden, simultaneous change. In all respects D1 and D2 are thus enabling.

Prevention of backflow as described in D1 and D2 implies an equalization of pressure as effectively claimed in claim 1 of the first auxiliary request.

D2, see figure 3 and 5, moreover, also discloses a spring-loaded mechanism which applies a spring force to the tube in all zones of contact, including the entrance zone, as in claim 1 of the second auxiliary request.

The provision of a device exerting a spring power downstream of the tube exit section (third auxiliary request) applies common general knowledge in the field of medical pumps, where it is vital that any backflow be avoided. This is borne out by the first set of fingers in the finger pump of D9 which serve that specific purpose. In standard 180° peristaltic pumps, backflow prevention is guaranteed by the diametrically opposed arrangement of rollers, which ensures that there is always a roller fully squeezing the tube at some point. When the angle is reduced below 180° as in D1 or D2 this is no longer the case, as will be immediately apparent to the skilled person in this field, who will strive to provide some countermeasure to stem possible backflow. A commonly known solution is a non-return valve near the exit. This will be in a form suitable for a blood-pump, i.e. external to a flexible tube, such as by application of spring force.

VII. The Respondent argued as follows :

Key passages in column 2 of D1 and column 4 of D2 specifying simultaneous disengagement and squeezing are in contradiction to figure 3 of D1 and figure 4 of D2. As this is not obvious to the skilled person he would be unable to carry out their teaching.

In any case, novelty is based on an assumption that the above figures and figure 10 of the patent are geometrically the same or similar. The various sections in these figures are however functionally different from the zones shown in figure 10 of the patent. For example, the zone where full pumping action exists, section d-e, does not correspond to bearing surface 40 in D1, as full pumping action extends into the ramp areas and thus over an angle over and above 180°. In addition to maximum compression shown in figures 8 and 9 full pumping action is determined by a variety of other factors. The above cited passages show that if there is simultaneous squeezing and disengagement they are thus still in synchronous phase. Finally, neither D1 nor D2 recognize an idling zone.

The additional feature of claim 1 according to the auxiliary request offers a specific solution to the general teaching of D1, which is not apparent from either D1 or D2. These documents also fail to show a device for applying spring force specifically provided in the entrance section as required by claim 1 of the second auxiliary request.

With regard to the third auxiliary request, the problem of backflow is already solved in D1 and D2. The skilled

person is therefore not motivated to adopt a further measure against backflow. Even if he would be, he would not do so using a spring-force.

Reasons for the Decision

1. The appeal complies with Articles 106 to 108 and Rule 64 EPC 1973 and is therefore admissible.

2. *Background*

The invention concerns a peristaltic fluid pump with a flexible tube resting on an arcuate support surface and a rotor with rollers at opposite ends, each of which in use successively engage, compresses and disengage the tube in corresponding entrance, pumping and exit sections. In this manner fluid is peristaltically pumped through the tube.

Claim 1 as granted requires in particular that the entrance and exit sections each comprise a pumping and an idling zone, with and without pumping action respectively, while the pumping section extends over an arc angle of less than 180°. Moreover, the arcuate support surface is such that the rollers "do not operate in synchronous phase opposition during operation". The characterizing feature, finally, specifies that the angle between the ending of the entrance section and the beginning of the exit section is smaller than 180°.

These features ensure smaller pressure differences and compressive pulsations, and thus a more constant

discharge pressure of the pump, see the specification, paragraphs [0013], [0014].

3. *Interpretation of claim 1*

To enable a proper comparison with the prior art, it is first necessary to construe various features of claim 1 as they appear throughout the requests. This is done in the light of the description.

3.1 The features of pumping, entrance and exit sections are best understood in reference to figure 4 to 9 and 10, and as filed description pages 10-12. The ***entrance section*** corresponds to section **a-d** in figure 10, where the surface bearing the tube gradually moves radially inwardly as the roller moves from **a,** where it first engages the tube, to **d.** During movement compression ***gradually increases,*** paragraph [0066] in reference to figures 4 to 7, until at **d** it reaches a maximum value. Here the roller enters the ***pumping section*** corresponding to arc **d-e,** which in figure 10 is shown as concentric with roller path 20 and subtending an angle smaller than 180°. In this section the roller compresses the tube constantly to a ***maximum*** as it moves toward **e**, resulting in constant and ***full pumping action***, paragraph [0067] and figures 8 and 9. From **e** onward the bearing surface starts to gradually fall away and compression slowly decreases as the roller moves toward **g,** where the roller finally lifts away from the tube. Section **e-g** is the ***exit section***.

3.2 As sections **a-d**, **d-e** and **e-g** are contiguous it follows that the requirement of the characterizing feature that "the angle (α) between the ending (d) of the entrance

section (a-d) and the beginning (e) of the exit section (e-g) is smaller than 180°" merely restates the preamble feature that the "pumping section [extend] across an angle of an arc of less than 180°". Angle α is the angle subtending d-e, which corresponds to the pumping section.

3.3 The phrase "not in synchronous phase opposition" is not defined explicitly in the application as filed. The only relevant passage, page 3, lines 21 to 29, of the description as filed, specifically attributes this quality to the entire arcuate support surface 4, including exit and entrance sections. It links it to the compensation of differences between the processes "in the two sections", namely these entrance and exit sections, as is apparent from the preceding discussion on page 2 in relation to D1.

In this context a reasonable, technically meaningful interpretation reads "phase opposition" in relation to the rollers in a ***qualitative*** sense, in terms of their relative action over their entire path of movement. Thus, they are opposed in phase when one is in the pumping section (full compression) while the other is free of any section (no compression); or when one is in the entrance section (engagement, compression increasing) while the other is in the exit section (disengagement, compression decreasing). If ***synchronous*** is interpreted as in, for example, synchronous swimming, meaning that swimmers' movements are ***always*** in step, "not in synchronous phase opposition" will mean that they are ***not always*** opposed in phase. This is the case if at the same time the two rollers are either in the same section or in non-opposing sections, for example

if one is in an exit or entrance section while the other is in the pumping section or free of any section. This reduces to the requirement that entrance and exit sections are not equal in angular length or, if they are, that neither extends over an equal angle either side of an axis perpendicular to the axis of symmetry of the cross-section.

4. *Main request*

4.1 It is undisputed that D1 describes a peristaltic pump or roller pump such as used for pumping blood, see e.g. its opening lines. The standard features of such a pump are set out in column 1, line 56, to column 2, line 13, in reference to figure 1 : it naturally has pumping and suction sides (arrows in figure 1) and houses a flexible tube 30 on a mainly arcuate support surface, made up of a bearing surface 40 and, at either end, ramp sections 60,61. Rotor 25 with opposing rollers 10,11 rotates under the action of means in the form of electromotor 28, see figure 2, so the rollers roll along the tube 30 while compressing it varying degree against the surface.

4.1.1 The path of the rollers' axes is concentric to the bearing surface 40, see column 1, lines 64 to 66. This section, where compression is constant and at a maximum, is the main pumping section of the pump, as may be inferred e.g. from column 1, lines 5 to 15 discussing then conventional roller pumps. It corresponds to section d-e in figure 10 of the present patent, where path 20 and support surface are clearly seen to be concentric. D1, see column 2, lines 19 to 21,

specifically chooses ***an angular length of less than 180°*** for this section.

4.1.2 ***Exit and entrance sections*** can be identified in lead ramps 60, 61 shown in figure 3 at the ends 62, 63 of surface 40. As detailed in column 2, lines 21 to 34, each extends at an angle 44 outwardly away from the tangent 65 at the respective end point 62, 63 of surface 40 to the circle on which the surface 40 lies. It follows that as the roller moves along ramps 60 and 61 the ramp surface approaches, respectively recedes, so that the tube is compressed more respectively less. Consequently, as stated in column 2, lines 34 to 38, the ramps "provide for disengagement of roller 10 to begin as roller 11 begins to squeeze the tube 30".

D1 does not specifically mention "***idling zones***" within the ramp sections and where there is compression but no pumping action. As explained in the patent, see e.g. paragraph [0064], "pumping does not begin until the roller has compressed the tube sufficiently", i.e. above some threshold amount. In any section of the roller path where it first contacts the tube and then gradually compresses it to some maximum (pumping) amount, or where it moves in the opposite direction from a maximum compression to some point where it finally lifts away from the tube, there will be a point where squeezing of the tube starts (or stops) producing a pumping effect. Disengagement ramp 61 and squeezing ramp 60 range from full engagement to final contact and thus necessarily include zones with and without pumping effect, i.e. "***idling***" and "***pumping zones***" in the sense of claim 1. The Board stresses that even if the inventor may have been the first to recognize such an

inherent feature, that feature is not thereby rendered novel.

4.1.3 Finally, drawing upon the interpretation of the phrase "*not in synchronous phase opposition*" as set out above, figure 3 shows ramps which extend much further below than above the horizontal or 180°axis shown in the figure, and which is perpendicular to figure's axis of symmetry in the y-direction. Though the figure is schematic to a large degree, nevertheless in its depiction of the essential positional relationship of tube, rollers and bearing surfaces, it provides sufficient detail to allow the skilled person to recognize plainly and clearly that the ramps extend different angular lengths either side of the horizontal. The "mainly arcuate surface" of the D1 pump, including ramps 60,61, is thus so constructed that there are parts of the cycle where when one roller is on a ramp, the other in the pumping section, so that they are *not always* of opposite phase, and so do not operate in synchronous phase opposition.

4.2 D2 sets out explicitly to optimize the design of the D1 pump (see column 1, lines 35 to 56). It does so, see its summary of invention, columns 1 and 2, by shortening the angular length of the pumping section and by gentler tilting of the ramps to provide an "optimal graduated change" in tube bore cross-section as the rollers "approach and recede from the points of [maximum] occlusion". Figure 4 (see also column 3, line 44, to column 4, line 21) shows arcuate bearing surface 520 extending over an angle of 168°, i.e. less than 180°, against which is compressed flexible tube 522 under action of rollers 500, 502 of an actuated

rotator. Ramps 530, 532 are shown at either end 534, 536 of surface 520. As above, in figure 4 these ramps can plainly be seen to extend to different angular lengths on opposite sides of the horizontal or 180° axis.

4.3 The Board has no doubt that D1 and D2 are "enabling" disclosures. Both documents describe the structure of the pump, and arrangement and shapes of the arcuate portion and ramps therein in great detail, for example specifying angles and dimensions (D1, in the paragraph bridging columns 2 and 3). The person skilled in the field of peristaltic pump reading the relevant passages, thus easily understands how the rollers move and compress the tube throughout the pump cycle, in particular in relation to the effects of torque suppression and smoother pumping pressure specifically associated with the ramps in D1 and D2.

Not differently from the interpretation of claims(see e.g. T 190/99) the skilled person reads a prior art disclosure with a mind willing to understand. He does so reading a given document contextually, in the light of its entire disclosure, while taking into account what may be implicit and using his common general knowledge. This enables him to recognize and resolve most textual imprecision or ambiguity.

For this reason, the Board is unconvinced that lines 34 to 38 (or 14 to 17) of column 2, and figure 3 present the skilled reader with some insurmountable contradiction. Figure 3 is meant to illustrate the counteracting, beneficial effects at the two ramps. This is why it shows the two rollers in the position in

which the torque problem would occur in a classical 180° roller pump. Lines 34 to 38 (or 14 to 17) formulate these effects in arguably inaccurate terms. However, the skilled reader who wishes to make sense of the text realizes perfectly well, in particular by considering shape and position of the ramps, that the two rollers are not literally meant to begin these opposing actions simultaneously. Nor would he read "roller 11 begins to squeeze tube 10" as referring to the roller having arrived at point 63 where full compression starts. He understands "disengagement" as reduction of compression and therefore occlusion (see also column 2, lines 36 to 38) while "squeeze" is shorthand for the opposite, i.e. increasing compression and occlusion.

4.4 As regards any functional distinctions that might exist with respect to the prior art - in particular in relation to "full pumping action"-, the Board notes firstly that these are not evident from the claim's wording. In any case a firm definition of this term is lacking in the disclosure, nor are any criteria and conditions determining when a pump produces "full pumping action" provided. The term is unclear in definition and in execution and is therefore unsuitable to clearly differentiate the claimed pump from prior art pumps.

4.5 In conclusion all features of granted claim 1 (main request) are clearly and directly derivable from either of D1 or D2. The subject-matter of claim 1 as granted thus lacks novelty.

5. *First Auxiliary Request*

The feature added to claim 1 relates to the pressure conditions for preventing backflow when the rollers are in the exit and entrance sections, as explained in paragraphs [0071] to [0073] of the specification. Thus, to maintain pumping pressure against some outside pressure, any fall in pumping pressure at the foremost roller (as it disengages and the tube opens up) must be compensated for by an increase in pressure at the rearmost roller. Backflow prevention is in fact one of the purposes of the ramps in D1, se column 2, lines 38 to 46, and D2, see column 4, lines 2 to 11, which specify that the two rollers "*together* provide sufficient occlusion .. to prevent backflow" (emphasis added). The claimed pressure compensation is thus inherent in the prior art ramp configuration.

The subject-matter of claim 1 according to the first auxiliary request thus also lacks novelty over either of D1 or D2.

6. *Second Auxiliary Request*

D2, in column 4, line 22, to column 5, line 27, in reference to figures 3 and 5, describes a device intended for adjusting the force applied by the rollers when compressing the tube. This device includes springs 558 and 560 which exert a spring force (adjustable via wheel 548 and 550) on the roller and thus on the tube. This device acts in those parts of the cycle where the roller contacts the tube including along lead ramp 532, corresponding to the entrance section.

D2 therefore also discloses the additional feature of claim 1 in this request, which as worded merely specifies the location of force application, but not that of the device. The subject-matter of this claim thus also lacks novelty.

7. Third auxiliary request

7.1 Claim 1 of this request introduces into granted claim 1 the features of granted claims 8 and 9 corresponding to the claims 9 and 10 as originally filed. This amendment is allowable under Article 123(2) EPC.

7.2 It is undisputed that neither D1 nor D2 disclose the further feature of a device affecting the tube with a ***spring power*** in a zone ***downstream of the exit section of the tube***. D1 does not disclose any spring loaded device, while the spring-loaded rollers of D2 apply force only where they contact the tube, i.e. in the area of the arcuate surface with exit and entrance sections, but not beyond.

7.3 According to specification paragraph [0056] this device acts as a non-return valve to prevent back flow in case of a drop of pressure. As backflow is in the first place prevented by the rollers in conjunction with the support surface in the pumping, exit and entrance sections, this device provides an additional safeguard against what must necessarily be unforeseen or sudden drops in pumping pressure. The technical problem addressed by this feature can be formulated accordingly, as providing an additional safeguard against backflow due to drop in pressure.

7.3.1 The solution as set out in claim 1 is neither known nor suggested by any of the available prior art. The Board is also unconvinced it belongs to the common general knowledge of the skilled person in the present field.

7.3.2 Backflow is without a doubt a central concern in this field; it is already clearly addressed in D1 and D2. Why the skilled person would consider an ***additional*** safeguard is however not apparent to the Board. It is true that reduction of the pumping section angle below 180° would without any further measures produce a brief drop in pumping pressure and thus the likelihood of backflow (in the short period of time when both rollers are both outside the pumping section and the tube is not occluded anywhere). However, it is exactly for this reason that the ramps are introduced in D1 and D2, see section 5 above. In so far there is a residual risk that needs to be addressed this is not obvious; in the Board's view addressing this risk by itself already implies inventive activity.

7.3.3 Even if the skilled person would as matter of course consider the use of some failsafe mechanism, such as a non-return valve, he could not arrive at the claimed solution without inventive activity. He might exclude from consideration common non-return valves of the ball and seat type as unsuitable for a pump used to handle blood. However, he would then have to look for suitable alternatives. Failing any evidence of what the skilled person might consider as suitable, the Board can only conclude that a device applying a spring force downstream of the exit zone is not only not known, but also not obvious.

7.3.4 In this regard D9 also fails to shed any light on the matter. From the final paragraph of page 18 it becomes clear that the pinching fingers mentioned on page 5, lines 1 to 3, do not in fact stem backflow, but rather serve to prevent "uncontrolled free flow from the fluid reservoir [from which the pump administers an IV fluid in accurate amounts - see page 1] to the patient", i.e. forward flow.

7.3.5 In conclusion therefore the Board finds that the subject-matter of claim 1 of this request is both novel and involves an inventive step having regard to the prior art. Claim 1 as amended in accordance with the third auxiliary request therefore meets the requirements of the EPC.

Order

For these reasons it is decided that:

1. The decision under appeal is set aside.

2. The case is remitted to the department of first instance with the order to maintain the patent as amended in the following version:

   Description: Columns 1 to 8 as filed at the oral proceedings

   Claims: No. 1 to 7 according to the third auxiliary request filed with letter of 7 December 2007

   Drawings: Sheets 1-5 of the patent specification

The Registrar The Chairman

G. Magouliotis M. Ceyte