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D E C I S I O N
of 13 March 1997

Case Number: T 0497/95 - 3.2.2

Application Number: 89305062.5

Publication Number: 0344949

IPC: A61H 23/04

Language of the proceedings: EN

Title of invention:
Medical appliance for the hand

Applicant:
NOVAMEDIX LTD.

Opponent:
-

Headword:
-

Relevant legal provisions:
EPC Art. 51, 56

Keyword:
"Novelty (yes)"
"Inventive step (no)"

Decisions cited:
T 0181/82

Catchword:
-



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Boards of Appeal

Chambres de recours

Case Number: T 0497/95 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 13 March 1997

Appellant: NOVAMEDIX LTD.
Viscount Court
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Hants SP10 5NW (GB)

Representative: Allsop, John Rowland
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted on 15 November 1994
refusing European patent application
No. 89 305 062.5 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: H. J. Seidenschwarz
Members: D. Valle
J. C. M. De Preter

Summary of Facts and Submissions

- I. The appellant (applicant) lodged an appeal received on 13 January 1995 against the decision of the examining division, dispatched on 15 November 1994, refusing of application No. 89 305 062.5. The statement setting out the grounds of appeal was received on 22 March 1995. The appeal fee was paid on 16 January 1995.

The examining division held that the application did not meet the requirements of Article 56 EPC, having regard to the following documents:

- (1) EP-A-0 228 768 and
- (2) EP-A-0 221 636.

- II. Claim 1 reads as follows:

"A medical appliance comprising a circumferentially tying inflatable bag (60) shaped for radially inward active engagement solely with the human hand and substantially only in the region of the palm of the hand, and cyclically operable automatic means (15) for pressuring the bag at periodic intervals of up to 60 seconds each, each interval including an initial pressure rise to a predetermined maximum of 220 mm Hg or less within two seconds before the pressure is allowed to drop, characterised in that said medical appliance includes means for holding said predetermined maximum pressure for a period of up to five seconds before the pressure is allowed to drop."

- III. In its communication of 29 November 1996, the board issued a non-binding opinion which can be summarised as follows: the state of the art coming closest to the subject-matter of claim 1 was disclosed by

document (1), which also related to a medical appliance for the hands as specified in the pre-characterising portion of said claim. With respect to the results achieved by this known appliance, the purpose of the invention was to be seen in obtaining an improvement in the blood-flow, in particular for the arteries. The skilled person looking for a solution to this problem, would have come across document (2), cited in the description of document (1). This latter document addressed the same problem of the invention and disclosed the same solution of the invention for the foot. Since it was common in this medical field to consider both extremities, ie foot and hand, together, as shown in the document: "Biomedizinische Technik", volume 32, No. 3, 1987, pages 50 to 54 (referred to in the following as document (3)), the board held that the combination of teachings known from documents (1) and (2) leading to the subject-matter of claim 1 did not imply an inventive step.

The appellant did not reply in writing to the observations of the board.

IV. Oral proceedings took place on 13 March 1997.

During the oral proceedings the appellant argued referring to its statement of grounds, that the skilled person would not combine the teaching of document (1) with that of document (2), since document (1) referred to the activation of a natural venous pump mechanism relating to the clenching of the fist, whereas document (2) referred to the activation of venous and arterial pump mechanisms by mimicking the transient flattening of the plantar arch during ambulation. There was no technical teaching whatsoever indicating that

such an improvement in arterial throughput in the foot might be obtained in any other part of the body. The purpose of the invention, however was to achieve an arterial flow enhancement in the arm to be treated.

The applicant warned against an ex post facto analysis and referred to the following passage in the Guidelines, C-IV, page 51, third paragraph: "the question to be answered is whether there is any teaching in the prior art as a whole that would (not simply could, but would) prompt the skilled person, faced with the technical problem, to modify or adapt the closest prior art while taking account of that teaching, thus arriving at something within the terms of the claims and thus achieving what the invention achieves."

Regarding document (3), the appellant pointed out that this related to the squeezing of the limbs, ie to a gentle massage, whereas the invention related to a pulsating effect caused by a periodic pumping of an inflatable bag for the hand which produced a rapid inflation of the bag and therefore a rapid increase of the pressure on the hand. Therefore the teaching of document (3) was not related to the invention. To apply the teaching of document (3) to the teaching of document (1) and (2) was the result of hindsight.

The appellant submitted further evidence to support of its arguments in the shape of a book with the title: "The return of blood to the heart" by A. M. N. Gardner and R. H. Fox, 2nd ed., Whitstable, United Kingdom. The book was written by the inventors of the appliance to which the present patent application relates. In the appellant's view, the passage on page 84, at the end of the second paragraph - "Much less is known about the venous anatomy and physiology in the arm than in the leg since venous problems are less common and hence

investigations, particularly phlebography, are more seldom performed" - supported its statement that the phenomena involved in the hand are substantially different from those involved in the foot. The inventors would have therefore needed to overcome a prejudice by applying the knowledge concerning an appliance for the foot as known from document (2) to an appliance for the hand as disclosed by document (1), which would prove the inventive step of claim 1.

IV. The appellant requested that the decision under appeal be set aside and that a patent be granted on the basis of the following documents:

Claims: 1 filed during the oral proceedings on 18 October 1994;
2 to 8 as filed by letter of 3 March 1994;

Description: pages 1 and 2 filed by letter of 24 May 1994;
page 3 filed by letter of 3 March 1994;
pages 4 to 14 as originally filed;

Drawings: as originally filed.

Reasons for the Decision

1. The appeal is admissible.
2. *Prior art and novelty*

The invention relates to a medical appliance and particularly to an appliance for applying local pressure to a part of the hand for the purpose of stimulating blood circulation through enhanced venous-return flow (see application as filed, page 1, lines 1 to 5).

- 2.1 Document (1) discloses a medical appliance comprising a circumferentially tying inflatable bag (see claims 7 and 11, pages 8, lines 15 to 29, and 11, second and third paragraph), shaped for radially inward active engagement solely with the human hand and substantially only in the region of the palm of the hand (see figures) and cyclically operable automatic means (see claims 12 and 14) for pressuring the bag at periodic intervals of up to 60 seconds each (see page 14, line 17), each interval including an initial pressure rise to a predetermined maximum of 220 mm Hg or less (see page 13, fourth line from the bottom) within two seconds before the pressure is allowed to drop (see page 14, line 6).

The subject-matter of claim 1 is distinguished from this known medical appliance by the characterising part, ie in that said medical appliance includes means for holding said predetermined maximum pressure for a period of up to five seconds before the pressure is allowed to drop.

2.2 Document (2) relates to a medical appliance shaped for engagement with the plantar arch of the human foot, comprising a circumferentially tying inflatable bag and cyclically operable automatic means (see column 6, lines 5 and 6) for pressuring the bag at periodic intervals of up to about 60 seconds each (see column 9, line 8, to column 10, line 18; figure 9, claims 2 to 6), each interval including an initial pressure rise to a predetermined maximum of 220 mm Hg or less (see claim 7) within two seconds (see claim 4) before the pressure is allowed to drop, whereby said medical appliance includes means for holding said predetermined maximum pressure for a period of up to five seconds before the pressure is allowed to drop (see claim 2).

The subject-matter of claim 1 differs from the device disclosed in document (2) in that the bag is shaped for radially inward active engagement solely with the human hand and substantially only in the region of the palm of the hand.

2.3 Document (3) describes an intermittent pneumatic compression device directed to avoiding venous and arterial insufficiency (see page 51, introduction). This system produces a proximally moving and damping pressure wave on the leg or the upper arm and is designed to hold the peak pressure for a short period (see page 52, left column, last paragraph, and figure 3).

2.4 From the foregoing it follows that the subject-matter of claim 1 is novel within the meaning of Article 54 EPC.

3. *Inventive step*

3.1 Document (1) relates - as does the application in suit - to a medical appliance for the hand, consisting of a bag shaped to engage the hand, and is directed to the stimulation of blood circulation through enhanced venous-return flow. The stimulation imparts a jerk, ie a sharply pulsed action to the return-blood flow and such action is believed to be helpful in reducing swelling and pain due to venous obstruction (see page 1, lines 2 to 6; page 13, lines 3 to 6; page 14, lines 12 to 14).

Since according to the description in the application as filed (see page 11, line 28, to page 12, line 11) arteries and veins are connected through capillaries, an external additional pressure influences both the arterial and the venous flow. Also according to the aforementioned description, maintaining the maximum pressure for a predetermined period as claimed by the invention leads to an improvement of the blood-flow, in particular for the arteries. From this it follows that the objective purpose of the invention is to achieve an arterial flow enhancement in the hand to be treated.

3.2 The solution put forward by the invention consists of providing means for holding the predetermined maximum pressure for a period of up to five seconds before the pressure is allowed to drop. The time during which the maximum local compression is maintained produces a greatest arterial flow enhancement, which can be described as improved "throughput", and which produces a beneficial therapeutic effect in arm-artery afflictions involving ischemia from various causes, such as atherosclerosis and diabetes.

3.3 The skilled person in the field of apparatuses for improving blood-flow, facing the problem of improving the blood-flow in the hand which was achieved by document (1), would first consider the prior art cited in the same document (1), and would then come across to document (2), which is cited on page 2 of document (1).

Document (2) addresses the same general problem as document (1) and the application, ie the problem of improving the blood-flow. Document (2) is also especially directed to the improvement of arterial affliction, in particular due to ischemia (see column 9, lines 41 to 52).

According to the teaching of document (2), the solution to this problem is to maintain the bag in its inflated state for a period of up to five seconds after each inflation (see claims 1 and 2); ie the solution suggested by document (2) is the same as that suggested by the invention. The combination of the teaching of document (1) with that of document (2) is obvious to the skilled person facing the problem of efficiently stimulating arterial blood-flow since no surprising effect can be seen in such a combination, no particular prejudice had to be overcome, and both documents relate to the same non-invasive technique. This is already indicated by the reference in document (1) to document (2).

The objection of lack of inventive step is further supported by the consideration of document (3), which describes the use of a pneumatic compression device. Venous and arterial insufficiency is avoided (see page 51, introduction) by providing for holding the peak pressure for a short period (figure 3) as in the

alleged invention. The device is designed for use on both limbs (see abstract and page 52, left-hand column, last paragraph, line 3), even if not specifically for the hand and the foot. This suggests that it is common in the field to consider both extremities together.

- 3.4 Regarding the appellant's argument that the teaching of document (1) is not combinable with the teaching of document (2) because the medical appliance according to document (1) is directed to mimicking the clenching of the fist whereas the medical appliance known from the document (2) is directed to mimicking the transient flattening of the plantar arch during ambulation, the following is observed:

The appliances known from documents (1) and (2) are primarily directed to a periodic pressure enhancement in order to improve blood-flow and not to mimic the normal movements of the extremities. It can be agreed that the above result can also be achieved - in the hand - by tightening the fist, or - in the foot - during ambulation. However, in cases where the movements of the extremities are hindered by illness, these natural ways of enhancing the pressure are not practicable, and appliances as disclosed in the state of the art are necessary. The statement in column 1, lines 27 to 33, of document (2) that the described appliance stimulates the arterial flow "in a particular manner which is not analogous to the normal walking conditions for the foot" confirms the point made above by denying the similarity between the natural and the induced processes.

Regarding the appellant's further complaint that the decision under appeal was arrived at on the basis of an ex post facto analysis, which - according to decision T 181/82 (OJ EPO 1984, 401) - is not permissible, the following considerations apply:

The skilled person, starting from document (1) and facing the problem of improving blood-flow in the hand will consider document (2), where such improvement has been achieved for the foot, because - according to document (3) (see also point 2.3 above) - intermittent pneumatic compression therapy can be applied to any limb of the human body, such as the leg, thigh or upper arm.

Concerning the objection made by the appellant that the appliance known from document (3) would be operated by squeezing, contrary to the periodic pumping actuated by an appliance according to claim 1 of the patent in suit, reference is made to figure 3 in document (3) which shows that the known appliance also operates by periodic pumping, and to the description of the claimed appliance (see page 3, lines 2 to 7), according to which local pressure is obtained by periodic application of a squeezing force.

Regarding the quotation from the inventor's book, it has been noticed that the book stresses the similarities of the blood-flow in the hand and foot, rather than the differences. On the quoted page 84 it is also stated that "As in the foot there is a venous pump in the hand" (first line), and: "Again like the foot, outflow from the hand pump can be into either superficial or deep veins" (first and second paragraph). This book does therefore not make it possible to derive, in particular, the teaching that the treatment of the foot should be different from the treatment of the hand for the purpose of stimulating blood circulation.

4. Consequently, the subject-matter of claim 1 does not involve an inventive step.

Order

For these reasons it is decided that:

The appeal is dismissed

The Registrar:



S. Fabiani

The Chairman:



H. Seidenschwarz



