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D E C I S I O N
of 11 June 1997



Case Number: T 0329/94 - 3.2.2

Application Number: 88901721.6

Publication Number: 0300026

IPC: A61M 1/02

Language of the proceedings: EN

Title of invention:
Blood extraction assist apparatus and method

Patentee:
BAXTER INTERNATIONAL INC. (a Delaware Corporation)

Opponent:
-

Headword:
Blood extraction method/BAXTER

Relevant legal provisions:
EPC Art. 52(4)

Keyword:
"Therapeutic, surgical or diagnostic method - (no)"

Decisions cited:
G 0005/83, T 0116/85, T 0019/86, T 0290/86, T 0378/86,
T 0385/86, T 0083/87, G 0002/88, T 0245/87, T 0780/89,
T 0182/90, T 0024/91, T 0820/92, T 0082/93

Headnote follows



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Boards of Appeal

Chambres de recours

Case Number: T 0329/94 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 11 June 1997

Appellant: BAXTER INTERNATIONAL INC.
(a Delaware Corporation)
One Baxter Parkway
Deerfield, Illinois 60015 (US)

Representative: MacGregor, Gordon
Eric Potter Clarkson
St. Mary's Court
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Nottingham, NG1 1LE (GB)

Decision under appeal: Decision of the examining division of the
European Patent Office posted 14 October 1993
refusing European patent application
No. 88 901 721.6 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: H. J. Seidenschwarz
Members: M. G. Noel
C. Holtz

Summary of facts and submissions

- I. In the decision under appeal, the examining division refused the application on the ground that claim 12 was not in accordance with Art. 52(4) EPC, the main reason being that the blood extraction assistance method as claimed in claim 12 caused a change in the human body condition which, therefore, needed to be restored. This was an indication that the claimed subject-matter was a surgical as well as a therapeutic method.
- II. The appellant lodged an appeal by notice filed on 28 October 1993 and paid the fee for appeal the following day.

The appellant requests that a patent be granted on the basis of

- (1) Claims 1 to 17 as refused by the examining division (main request), namely:

Claims 1 and 12 (first part), filed with letter of 5 June 1992, and

Claims 2 to 11, 12 (second part), and 13 to 17, filed with letter of 9 August 1990

- (2) Claims 1 to 17 with amended claim 12 in accordance with either the first or second auxiliary request filed as Appendices 1 and 2 respectively with letter of 26 October 1993, or
- (3) Claims 1 to 11 in accordance with the third auxiliary request filed as Appendix 3 with letter of 26 October 1993.

III. Claim 12 of the main request reads:

"A blood extraction assistance method for facilitating sustained venous blood flow through a human limb towards a venous blood extraction point (14), the method comprising engaging means (200, 100) in tactile manner with a lower portion of the limb, **characterised** in that said means is limb stimulus means (200, 100) and in that the method includes selectively activating the limb stimulus means to provide a stimulus to the limb when sustained venous blood flow to the blood extraction point (14) is desired, and deactivating the limb stimulus means when sustained venous blood flow to the blood extraction point (14) is not desired."

IV. In support of the appeal, the appellant argues mainly as follows:

A blood extraction assistance method for facilitating sustained venous flow through a human limb towards a venous extraction point is not a method of treatment. Methods of treatment are concerned with curing diseases and should be interpreted as being methods which a medical practitioner would use. The purpose of Art. 52(4) EPC, as described in the minutes of the Diplomatic Conference establishing the EPO, is that a medical practitioner should not be hampered in the practice of medicine. The case law of the EPO confirms this interpretation (see, for example, decisions T 385/86, T 83/87 and T 245/87). The taking of blood is only distantly related to treatment, in that the purpose is to provide a product, which can be used either directly in a separate medical procedure or can be made into new products for use in such a medical procedure. The medical practitioner does not take blood from the donor, nor does he make the blood into a different usable product.

The examining division has wrongly interpreted the point of Art. 52(4) EPC. The fact that a technician who takes blood from a donor should have medical knowledge or be under the supervision of someone with medical knowledge is irrelevant to the question of whether or not the extraction is a method of treatment.

Decision T 116/85 referred to by the examining division relates to the treatment of pigs and concerns the question whether or not the fact that the application is primarily agricultural overrides the fact that it is a treatment. This decision is not relevant to the question whether the claimed method is a treatment at all.

The examining division is wrong not to have considered Guidelines C-IV, 4.3, which is highly relevant to the present question.

The method of claim 12 involves selectively stimulating the limb, but does not involve the actual extraction of blood. Therefore, it does not involve any surgical modification of the living human body.

Reasons for the Decision

1. The appeal is admissible.
2. The Guidelines, although not binding upon the boards of appeal, may provide useful parameters for defining the content and scope of excluded subject-matter for the purposes of Art. 52(4) EPC.

According to Guidelines C-IV, 4.3, first paragraph: "It should be noted that Art. 52(4), excludes **only** treatment by surgery or therapy or diagnostic methods". Further, at the end of the same paragraph: "Treatment of body tissues or fluids after they have been removed from the human or animal body, or diagnostic methods applied thereon, are not excluded from patentability in so far as these tissues or fluids are not returned to the same body. Thus the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded, whereas a treatment of blood by dialysis with the blood being returned to the same body would be excluded".

In the next paragraph: "Regarding methods which are carried out on, or in relation to, the living human or animal body, it should be borne in mind that the intention of Art. 52(4) is only to free from restraint non-commercial and non-industrial medical and veterinary activities. Interpretation of the provision should avoid the exclusions from going beyond their proper limits (see decision G 5/83, OJ 3/1985, 64)".

The Guidelines then go on to give examples of surgery, therapy and diagnostic methods, referring to decisions of the boards of appeal where appropriate.

3. From the jurisprudence of the boards of appeal, the following principles emerge:

With regard to exceptions to patentability, Art. 52(4) EPC should be construed narrowly (T 385/86, OJ EPO 1988, 308, point 4.1). The object of the exclusion is to ensure that those who carry out methods as part of the medical treatment of humans or animals should not be inhibited by patents (T 116/85, OJ EPO 1989, 13, point 3.7). It is not possible as a matter of law to

draw a distinction between a method as carried out by a farmer and the same method as carried out by a veterinarian and to say that the former, being an industrial activity, is patentable, but the latter is not (*idem*, point 4.3). Both prophylactic and curative treatments of disease are within the meaning of the word "therapy" as used in Art. 52(4) EPC (T 19/86, OJ EPO 1989, 24, point 7). A method is susceptible of industrial application if it can be used with the desired result by a technician without specialist medical knowledge and skills (T 385/86, *supra*, point 3.5.2 and headnote II). A method involving a measuring device is not excluded from patent protection if there is no functional link between the method claimed and the dosing of the drug administered by means of the device (T 245/87, OJ EPO 1989, 171, points 3.1 and 3.2; see also T 83/87, 14 January 1988, not published, point 3). Where a non-therapeutic effect can be distinguished from a therapeutic one, a claim only to the non-therapeutic (eg cosmetic) effect is not excluded from patent protection (T 144/83, OJ EPO 1986, 301, point 4). Where a method has a therapeutic effect it cannot be patented, unless the claimed non-therapeutic effect is clearly distinguishable from the therapeutic one (T 290/86, OJ EPO 1992, 414, point 3 and T 780/89, OJ EPO 1993, 440, points 3 and 4). The question is whether none of the steps of the method fall under the prohibition of Art. 52(4) EPC (T 820/92, OJ EPO 1995, 113, point 5, in particular 5.5 and 5.9). A claim is not allowable if it includes at least one feature defining a physical activity or action which constitutes a method for treatment of the human body by therapy (T 82/93, OJ EPO 1996, 274, point 1.4, following T 820/92).

4. In the light of this established EPO practice it is appropriate therefore to refuse protection for a blood extraction method considered *per se*, since otherwise a large part of medical activities would be hampered. As a matter of fact, withdrawal of blood would fall under the exclusion of Art. 52(4) EPC three times if it could be regarded either

- as a step of a method for treatment by therapy, for example in connection with a dialysis method or with a retransfusion of blood after cleaning, or
- as a step of a method for treatment by surgery when considering that taking blood requires the use of surgical instruments and the operation is performed on the structure of the organism (see T 182/90, OJ EPO 1994, 641, point 2.3), or
- as a step of a diagnostic method, for example with a view to a blood analysis for finding out the cause of a disease.

5. In the present case, it is first to be noted that the subject-matter of claim 12 is directed principally to a blood extraction method in which a limb stimulus means is used, which is activated and deactivated in a pre-determined manner. Of all the inventions discussed in the jurisprudence quoted above, this most resembles the one reviewed in decision T 245/87, which concerned a method for measuring the flow of small quantities of liquid by means of an implanted device for controlled drug administration. In this decision the board found that the miniaturisation of a system for monitoring a

device to ensure that it was in working order had to do exclusively with the production of an effect on the structure of the device and was not itself influenced by the effects produced by the device on the body. The steps claimed thus had no therapeutic effect in themselves and the method claim was accepted.

In determining whether the features under consideration constitute medical or diagnostic therapy, the **purpose** of the claimed subject-matter is to be defined in accordance with the patent application, as understood in the light of the description and drawings (Art. 69 EPC and the Protocol thereto). Applying this method of interpretation, the board concludes that the object of claim 12 according to the main request is principally to facilitate sustained venous blood flow to a blood extraction point located in the vein of a human upper limb by alerting the blood donor to help in maintaining the desired blood flow through a selective automated tactile stimulus.

In this respect, in the board's view, it matters little whether the measure is performed by a medical practitioner or another person having medical knowledge or under the supervision of such a person (see also T 24/91, OJ EPO 1995, 512). This sole criterion is not sufficient to decide whether the method step is objectionable under Art. 52(4) EPC, though the medical competence of the practitioner may be, at first sight, a useful indication. Much more important are the **purpose** and inevitable effect of the feature under consideration.

If the claimed subject-matter is actually confined to operating an apparatus for performing a method with the technical aim of facilitating blood flow towards a blood extraction point, the operating method has **no therapeutic purpose or effect** and, therefore, is not excluded from patentability.

6. The board observes, in addition, that the protection conferred on method claim 12 is already covered by the scope of device claim 1, which relies on a blood extraction assist apparatus for facilitating blood extraction, comprising the same limb stimulus means operated in the same manner as in the method claim. Considering now that a claim to the use of a physical entity (product, device) is already covered by the claim to the physical entity **per se** (G 2/88, OJ EPO 1990, 93, point 5) and that a claim to a method for operating a device confers substantially the same protection as the claim to the device (T 378/86, OJ EPO 1988, 386, points 3.1.5 and 3.1.6), the method according to claim 12 appears **prima facie** as totally superfluous since the same features are to be found in both the device claim and the method claim for operating the device. The latter is acceptable, however, as the presence of claims of different categories that are substantially identical in scope may assist the applicant in obtaining full protection for his invention in different contracting states (G 2/88, supra, point 2.1).

Now, Art. 52(4) EPC, last sentence, states: "This provision shall not apply to products, in particular substances or compositions, for use in any of these methods". Bearing in mind the above considerations, the exception provided in Art. 52(4) applies obviously to all physical entities within the general meaning of G 2/88, ie including also devices and apparatus for use

in any of the methods in question. This is the reason, why, as rightly specified in the Guidelines for Examination (C-IV, 4.2): "Patents may, however, be obtained for surgical, therapeutic or diagnostic instruments or apparatus for use in such methods".

Since the claim 12 in suit actually relates to operating a blood extraction assist apparatus, its subject-matter is covered by the exception provided for in Art. 52(4) EPC and is, therefore, acceptable (see T 82/93, supra, points 1.2 and 1.3).

7. Should, nevertheless, claim 12 be regarded as a plain method claim, the object of this claim is merely to give the donor an order, in the form of a stimulus, to operate the apparatus, so as to facilitate blood flow through the blood extraction point. This indeed requires the contribution of the donor for operating the apparatus, but does not produce **any therapeutic or prophylactic effect** on the donor himself, that is with a view to maintaining or restoring his health by preventing or curing diseases (T 19/86, supra, point 7).

In other words, there is no functional link or physical causality between the measure implemented and any therapeutic effect produced on the body to which this measure is applied. The board can therefore agree with the opinion of the appellant that claim 12 does not cover the actual extraction of blood.

8. Given the above conclusion, the findings of the examining division, although in themselves not incorrect, are irrelevant in so far as the alleged changes in the human body condition are not covered by the claim. Again, the purpose of the claimed blood extraction assistance method is not of therapeutical or

surgical, but merely of technical nature, with the sole aim of improving the efficiency of taking blood from a donor. This method is clearly distinguishable from a therapeutic or diagnostic effect (T 780/89 supra).

9. For the above reasons, the board is satisfied that the subject-matter of method claim 12 and the claims dependent thereon do not fall within the ambit of subject-matter excluded under Art. 52(4) EPC.
10. As the application has not been examined with a view to patentability criteria other than the exclusion under Art. 52(4) EPC, the case has to be remitted for further prosecution with regard to such points.

Order

For these reasons it is decided that:

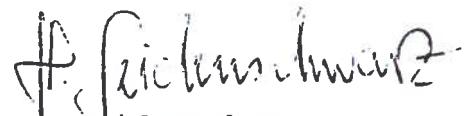
1. The decision under appeal is set aside.
2. The case is remitted to the first instance for further prosecution on the basis of claims 1 to 17 according to the main request (see point II(1)).

The Registrar:



S. Fabiani

The Chairman:



H. Seidenschwarz