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File No.: T 0182/90 - 3.2.2
Application No.: 86 102 544.3
Publication No.: 0 194 517
Classification: A61B 5/02, A61B 5/07, A61J 1/00, A61K 9/50, A61K 49/00
Title of invention: Non-radioactively labeled microspheres and use of same
to measure blood flow

D E C I S I O N
of 30 July 1993

Applicant: See/Shell Biotechnology, Inc.

Proprietor of the patent:

Opponent:

Headword: Blood flow/SEE-SHELL

EPC: Art. 52(4)

Keyword: "Patentable inventions - surgical treatment (no)"

Headnote

- I. *The presence of a surgical step in a multi-step method for treatment of the human or animal body normally confers a surgical character on that method (cf. point 2.5.1).*
- II. *However, a method which includes a surgical step practised on a living laboratory animal and, in addition, a step of sacrificing said animal, which step is also necessary to carry out the method, cannot be regarded in its entirety as a method for treatment of the animal by surgery in the sense of Art. 52(4) EPC (cf. point 2.5.2).*

Case Number: T 0182/90 - 3.2.2

D E C I S I O N
of the Technical Board of Appeal 3.2.2
of 30 July 1993

Appellant: See/Shell Biotechnology, Inc.
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Decision under appeal: Decision of the Examining Division of the European Patent Office dated 23 October 1989 refusing European patent application No. 86 102 544.3 pursuant to Article 97(1) EPC.

Composition of the Board:

Chairman: G. Szabo
Members: P. Dropmann
J. Van Moer

Summary of Facts and Submissions

- I. European patent application No. 86 102 544.3 filed on 27 February 1986 and published under No. 0 194 517 was refused by the Examining Division in a decision dated 23 October 1989. The refusal was based on Claims 1 to 8 filed with the letter of 24 August 1989.
- II. The reason given for the refusal was that the method according to Claim 1 comprised a surgical step and was therefore excluded from patentability under Article 52(4) EPC. In addition, the objection was raised that the subject-matter of independent Claims 6 and 7 relating to microspheres lacked novelty. Furthermore, the Examining Division held that the application, in particular independent Claims 1 and 8, offended against Article 82 EPC in that it lacked unity of invention.
- III. A Notice of Appeal was filed against this decision on 19 December 1989. The appeal fee was paid on the same date. The Statement of Grounds was received on 12 February 1990.
- IV. Following a telephone conversation between the Appellant's Representative and the Rapporteur, the Appellant filed an amended set of Claims 1 to 8 with its letter of 13 July 1993.

Claim 1 of this set is identical with Claim 1 on which the refusal was based. Claims 2 to 8 are dependent on this method claim.

Claim 1 reads as follows:

"A method for measuring bloodflow to a specific tissue of an animal comprising the steps of:

- (a) introducing microspheres into the blood stream of an experimental animal, said microspheres having a size to flow through the circulatory system of the animal so that they can disperse in the blood vessels but of size sufficient to become trapped in the capillaries of the tissue and being non-radioactively labeled with coloured dyes or by linkage to enzymes;
- (b) determining the number of microspheres in a known volume of said animal's blood after introduction;
- (c) sacrificing said animal and recovering a portion of said animal's tissue;
- (d) determining the number of microspheres present in a known sample size of said tissue by counting;
- (e) calculating blood flow to said tissue from the results of said determination."

V. The Appellant requested that the decision under appeal be set aside and a patent be granted on the basis of the amended set of claims. In addition, reimbursement of the appeal fee was requested.

Reasons for the Decision

1. The appeal is admissible.
2. *Interpretation of Article 52(4) EPC - Exclusion of Methods for Surgical Treatment*

2.1 Article 52(4) EPC

Article 52(4) EPC states that "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1". Such methods are thus defined as not being susceptible of industrial application.

It directly follows from this statement in combination with Article 52(1) EPC that European patents shall not be granted for such surgical, therapeutical and diagnostic methods, irrespective of whether or not these methods are, in fact, susceptible of industrial application.

In any case, there is general agreement that treatments may only be excluded from patentability if they are carried out on a living human or animal body.

When interpreting Article 52(4) EPC, it is decisive to know what is to be understood, in the medical and legal usage of the language, by the expression "treatment of the human or animal body by surgery". Therefore, the terms "treatment", "surgery" and "treatment by surgery" will be discussed in the following paragraphs.

2.2 The term "treatment"

According to G. Schwalm, "Chirurgie und Recht - heute" in "Chirurgie der Gegenwart", ed. R. Zenker et al., Vol. 1 "Allgemeine Chirurgie", Urban & Schwarzenberg, München-Wien-Baltimore, 1980, pages 1 to 42, in particular pages 4 to 8, the term "medical treatment" means any non-insignificant intentional physical or psychic intervention performed directly or indirectly by one human being - who need not necessarily be a medical practitioner - on another (or, by analogy, on animals) using means or methods of medical science.

The term "treatment" as used in Article 52(4) EPC and in Schwalm's article is not restricted to methods serving a direct therapeutic (including prophylactic) purpose. (The latter purpose is introduced by the express reference to "therapy" in Article 52(4) EPC.) According to the above definition (see pages 6 to 8 of Schwalm's article), the term "medical treatment" may also include treatments for other, non-curative purposes such as cosmetic treatment, the termination of pregnancy, castration, sterilisation, artificial insemination, embryo transplants, treatments for experimental and research purposes and the removal of organs, skin or bone marrow from a living donor.

It is clear that the general term embraces a variety of possibilities including some which have been recognised as patentable, e.g. cosmetic treatment with substances (cf. T 36/83, OJ EPO 1986, 295 and T 144/83, OJ EPO 1986, 301). It is therefore necessary to consider the specific characteristics of the further relevant term in the Article, i.e. "surgery", as such.

2.3 The term "surgery"

The Guidelines for Examination in the European Patent Office (cf. C-IV, 4.3) state that the term "surgery" defines the nature of the treatment rather than its purpose. This may, however, not be true in all cases (cf. point 2.5.2 below).

According to the "International Dictionary of Medicine and Biology", Vol. III, John Wiley & Sons, 1986, page 2762, the term "surgery" means "that branch of the art, science, and practice of medicine that deals with the diagnosis and correction of bodily defects resulting from injury or disease and the relief of suffering by manual and instrumental procedures". This term even comprises "closed surgery" which, according to said dictionary, means the "manipulation of a part, organ, or tissue without making a skin incision".

Similarly, the "Brockhaus Enzyklopädie" (19th edn., Vol. 4, 1987, page 520) defines "surgery" as the branch of medicine concerned with the healing of disease, accidental injury or bodily defects by operating on the living body - including both conservative (non-invasive) procedures such as repositioning, and the far more numerous operative (invasive) procedures using instruments (cf. also "Roche Lexikon Medizin", 3rd edn., Urban & Schwarzenberg, München-Wien-Baltimore, 1993, page 274).

"Chirurgie" (= "Surgery"), a paperback by M. Reifferscheid and S. Weller (8th edn., Georg Thieme Verlag Stuttgart-New York 1989, pages 131 and 132), defines an operation as direct or indirect treatment of

any kind performed on the structure of an organism - including endoscopy, puncture, injection, excision, and opening of the bodily cavities. Catheter insertion is also considered as an intensive surgical technique (cf. page 170).

This inclusion of endoscopy, puncture, injection, excision and catheterisation in the definition of "surgical interventions" is also consistent with the definition of "chirurgie" given in the French dictionary "Le Grand Robert de la Langue Française", Vol. II, 1985, pages 577 and 578.

2.4 The term "treatment by surgery" or "surgical treatment"

The reference to healing in some of the preceding definitions of the term "surgery" appears to be inconsistent with the fact that, in today's medical and legal linguistic usage, the non-curative treatments mentioned at the end of paragraph 2.2 above are, if carried out by surgery, regarded as surgical treatments. Some of these treatments were considered in national case law and led to their exclusion from patentability (cf. R. Moufang, "Medizinische Verfahren im Patentrecht", GRUR Int. 1992, pages 10 to 24, in particular page 19; English version published in IIC, Vol. 24, No. 1/1993, pages 18 to 49). Apparently, the term "treatment by surgery" has undergone a change in meaning insofar as it nowadays may also comprise particular treatments which are not directed to the health of the human or animal body.

2.5 The present application

2.5.1 Claim 1 of the present application relates to a method for measuring blood flow to a specific tissue of an experimental animal, i.e. to a medical treatment for experimental purposes. The feature of Claim 1, whereby microspheres are introduced into the blood stream of the experimental animal, involves injecting labelled microspheres into the left atrium of the animal (cf. page 6, second paragraph and page 15, fourth paragraph of the description) and inserting a femoral artery catheter (cf. page 26, Example 9 of the description).

In the light of points 2.2 and 2.3 above, these steps represent a surgical treatment. Normally, the presence of a surgical step in a multi-step method for treatment of the human or animal body confers a surgical character on that method.

2.5.2 However, in the present case, the claimed method, when considered in its entirety, cannot be regarded as a method for treatment of an animal by surgery for the following reason.

Although the term "surgical treatment" is not restricted to a treatment serving a curative purpose (cf. points 2.2 to 2.4 above), the distinction between surgical and non-surgical procedures cannot be so broadly drawn that "surgical treatment" includes any kind of manual or instrumental intervention by one human being on another, or on an animal. Clearly, the guillotining of people, or the slaughter of animals, is not a form of surgical treatment (indeed, methods for the slaughter of animals have traditionally been considered patentable). In the Board's view, methods consciously ending in the laboratory animal's death

(cf. feature (c) of Claim 1) are not in their nature methods of surgical treatment, even if some of the steps they involve may have a surgical character.

In other words, the semantic change in the terminology mentioned in point 2.4 above cannot extend so far that the opposite of the original meaning falls within its scope, i.e. that a method involving the deliberate killing of the laboratory animal should represent a surgical treatment.

It appears that the matter of such and similar destructive purposes was discussed in the preparatory stage of the European Patent Convention (cf. document BR/177/72 dated 13 April 1972, page 6, point 9d), published in "Historical Documentation (Travaux préparatoires) relating to the European Patent Convention", Vol. 13D, Munich 1982). It was agreed that these methods were not to be excluded from patentability and that, however, there was no need to expressly mention this in the Article.

Hence, a method which includes a surgical step practised on a living laboratory animal and, in addition, a step of sacrificing said animal, which step is also necessary to carry out the method, cannot be regarded in its entirety as a method for treatment of the animal by surgery in the sense of Article 52(4) EPC.

- 2.6 For the same reason, the claimed method does not constitute a diagnostic method either, since the animal body on which it is practised does not survive. Again the purpose of diagnosis as a method cannot be the

killing of the animal involved. This is also in line with the general impression that the non-industrial character of the various kinds of medical treatments covered in Article 52(4) EPC was intended to reflect the fact that the primary purpose was to achieve an improved state of the health of the human or animal body and not the destruction of the organism.

2.7 The method according to Claim 1 therefore does not belong to those methods excluded from patent protection under Article 52(4) EPC.

3. Other considerations

Since Claims 2 to 8 are dependent on Claim 1, no objection under Article 82 EPC arises against these claims. However, the expression "for preparing microspheres of claims 6 or 7" in Claim 8, second and third line, is to be deleted.

The present set of claims no longer comprises a claim which relates to microspheres as such and which was considered not novel by the first instance.

It appears from the content of the file that no search has yet been carried out on the subject-matter of Claim 1, since no document was cited which discloses the prior art mentioned on pages 3 and 4 of the description of the application. The case is therefore remitted to the first instance for further prosecution (Article 111 EPC).

4. *Reimbursement*

As to the Appellant's request for reimbursement of the appeal fee, the Board takes the following position.

The Appellant did not request oral proceedings before the Examining Division but instead asked only for an interview. Therefore, no contravention of Article 116(1) EPC as alleged by the Appellant can be recognised.

Furthermore, the decision to refuse the application was based on the ground of Article 52(4) EPC (cf. point II.1 of the refusal) on which the Appellant had an opportunity to present its comments. The additional objections under Articles 82 and 52(1) EPC concerning lack of unity and novelty were raised in the decision in order to draw the Appellant's attention to the fact that, as a further point, the application might not meet the requirements of the Convention in these respects. The decision thus does not contravene Article 113(1) EPC either.

Hence, in the absence of a substantial procedural violation, reimbursement of the appeal fee cannot be ordered (cf. Rule 67 EPC).

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 the claims filed on 13 July 1993.
3. The request for reimbursement of the appeal fee is rejected.

The Registrar:

The Chairman:

S. Fabiani

G. Szabo