DECISIONS OF THE BOARDS OF APPEAL

Decision of Technical Board of Appeal 3.3.2 dated 11 February 1997

T 655/92 - 3.3.2*

(Language of the proceedings)

Composition of the board:

Chairman: P. A. M. Lançon

Members: C. Germinario

R. E. Teschemacher

Patent proprietor/Appellant: NYCOMED AS

Opponent/Respondent: Advanced Magnetics Inc.

Headword: Contrast agent for NMR imaging/NYCOMED

Article: 52(4), 54, 56, 84 EPC

Keyword: "Clarity - (yes)" - "Diagnostic method within the meaning of Article 52(4) - (yes)" - "Novelty - (yes)" - "Inventive step - (yes)"

Headnote

I. The use of a substance or composition for the manufacture of a preparation to be used in a specific method may derive its novelty from the subsequent use of the

preparation in this specific method only if said method is one of those excluded from patentability by virtue of Article 52(4) EPC (see G 5/83, OJ EPO 1985, 64).

II. Methods for determining chemical or physical conditions which do not include any stages or measures requiring a doctor to carry them out but rather a technician in order to provide a basis for the doctor's subsequent activity of diagnosis may not necessarily fall within the exclusion of Article 52(4) EPC (see eg T 385/86, OJ EPO 1988, 308).

III. However, the diagnostic character of a process, within the meaning of Article 52(4) EPC, may be recognised in that such a process for which protection is sought does include essential steps which are to be implemented by medical staff or under the responsibility of a doctor (see reasons point 5.2).

Summary of Facts and Submissions

I. European patent No. 0 166 755 was granted in response to European patent application No. 85900253.7, claiming the priority date of 21 December 1983.

II. Notice of opposition was filed by the respondents, requesting revocation of the patent in its entirety on the grounds of lack of novelty, lack of inventive step and insufficiency of disclosure (Articles 52, 54, 56, 83, 100(a) and (b) EPC).

The patent was revoked by the opposition division, mainly on the basis of the following documents:

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III. The decision was taken on the basis of the granted claims, as the main request, and two auxiliary requests.

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IV. The appellants (patentees) lodged an appeal against this decision.

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V. The appellants' position can be summarised as follows.

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VI. The respondents (opponents) did not reply to the statement setting out the grounds of appeal and declared that they were withdrawing from the appeal proceedings.

VII. As a reaction to the communications issued by the board, in which inter alia the latter expressed doubts concerning the medical nature of the NMR imaging method set out in the invention, an amended form of claim 1 according to the main request was filed on 22 April 1996. The claim reads:

"Use of a magnetically responsive material for the manufacture of a diagnostic contrast agent for use in a method of in vivo nuclear magnetic resonance imaging of a subject, said agent comprising particles of a matrix material having a diameter of up to 10 micrometres and having enclosed therein a said magnetically responsive material the magnetic responsiveness of which is such that said particles are magnetically localisable and such that said particles in said nuclear resonance

imaging of said subject cause relaxation time changes resulting in a visualisable 'black hole' contrast effect".

VIII. The appellants requested maintenance of the patent in the amended form of 22 April 1996, as their main request, or in the form of one of the two auxiliary requests enclosed in the statement setting out the grounds of appeal.

Reasons for the Decision

1. The appeal is admissible.

2.1 Article 123(2) EPC

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2.2 Article 123(3) EPC

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3. Article 84 EPC

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4. Article 83 EPC

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5. Article 52(4) EPC

5.1 As acknowledged in the patent description, the agent of claim 1, which comprises particles of a matrix material having a diameter of up to 10 microns and having enclosed therein a magnetically responsive material, have been known in the prior art as a haematopoietic medicament for intravenous or intramuscular injection in the treatment of iron deficiency since about 1965.

More specifically, document (35) discloses the use of dextran-magnetite (triiron tetroxide) particles, having a diameter of 5 to 20nm. The compound is said to be related to the iron-dextran complex (1) utilised as a haematopoietic and made by adding dextran to a suspension of triiron tetroxide (cf. first paragraph). Reference (1) (Ricketts, Cox et al. Nature 208, 237, 1965) apparently represents one of the first reports on this complex.

Also (2) describes an iron-dextran complex designated as "Imferon" (see footnote on page 513). As is evident from the quotation from the aforementioned Ricketts, Cox et al. (cf. page 513, line 12), "Imferon" is the same complex as that disclosed in (35).

Finally, document (46) refers again to "Imferon", ie Iron Dextran Injection U.S.P. as the parenteral preparation in general use in the United States at the present time. (cf. page 1325).

The board can therefore conclude that all three prior documents relate to the same particles according to claim 1 and their first therapeutic application.

5.2 For this reason, during the proceedings before the examining division, claim 1 was drafted in the form for the protection of the "second medical indication" of a medicament, according to the decisions G 1/83 (OJ EPO, 1985, 60), G 5/83 (OJ EPO, 1985, 64) and G 6/83 (OJ EPO, 1985, 67).

Whether or not the use of a substance for the manufacture of a "preparation" may derive its novelty from the subsequent use of said "preparation" in a specific method, depends on the nature of the method itself. The answer is in the affirmative only if said method is one of those excluded from patentability by virtue of Article 52(4) (cf. G 5/83 (supra), point 21, last paragraph). Therefore, in order to assess the novelty of the subject-matter of claim 1, it first has to be established whether the present claim 1 refers to one of those methods or, alternatively, to a technical method susceptible of patent protection.

The policy behind the exclusion of the methods defined in Article 52(4) EPC was to ensure that those who carry out such methods as part of the medical treatment of humans or the veterinary treatment of animals should not be hampered by patents (T 385/86, OJ EPO 1988, 308, point 3.2). The intention was only to prevent non-industrial medical and veterinary activities from being restrained by patent rights (G 5/83, supra, point 22). When Article 52(4) EPC is being interpreted, this purpose has to be taken in consideration.

With regard to methods for obtaining chemical/physical data from inside the living body by means of diagnostic apparatus registering these data or reproducing images, the boards have ruled that these do not fall within the exclusion of Article 52(4) EPC and that only such methods are excluded which provide results immediately enabling a decision to be taken on a particular line of medical treatment (T 385/86, supra, and the other decisions cited in Case Law of the Boards of Appeal, 2nd edition, 1996, I.A. 2.5). This ruling was based on the consideration that in such methods the step sequence for which protection is sought does not include any stage having the character of medical diagnostic activity or medical treatment or any measure requiring a doctor to carry them out. Rather the method therein claimed could be carried out by a technician in order to provide a basis for the doctor's subsequent activity of diagnosis (T 385/86, supra, points 3.5.1 and 3.5.2).

5.3 The nature of the process according to claim 1 of the patent at issue is quite different. The method is an in vivo NMR imaging technique using contrast agents. Unlike the technique envisaged in T 385/86, supra, the method of the present invention is characterised by the parenteral administration (iv) of the contrast agent of claim 1, which transforms the NMR imaging from a non-invasive to an invasive technique. Additionally the intravenous injection of dextran-magnetite, ie Imferon (see point 5.1 of the decision), is not devoid of any risk of side-effects, some severe, as is well documented by (46) which reports at page 1326, right-hand column, that:

Reactions to intravenous iron include headache, malaise, fever, generalised lymphadenopathy, arthralgias, urticaria and in some patients with rheumatoid arthritis, an exacerbation of the disease. Of greatest concern, however, is the rare anaphylactic reaction, which may be fatal in spite of treatment. While only a few such deaths have been reported, it remains a deterrent to the use of iron dextran.

In consideration of the risk inherent in the treatment, it is further suggested that:

The technique of intravenous administration involves first the injection of 1 or 2 drops of iron dextran over a period of 5 minutes to determine whether any signs or symptoms of anaphylaxis appear. If not, 500 mg of iron may then be injected over a period of 5 to 10 minutes.

It is indisputable that the task of "determining whether any signs or symptoms of anaphylaxis appear" can only be the responsibility of medical staff who have to recognise the earliest symptoms of anaphylaxis or any other undesired reaction and accordingly either have to adapt the treatment to the specific situation, or interrupt the administration or even undertake without delay all those measures necessary to control and minimise the side-effects already evident.

Therefore, unlike the processes of the previous cases, the present diagnostic process, when considered in its totality, comprises at least one step essential for the desired diagnostic result, which cannot fall under the exclusive responsibility of the technician skilled in NMR technology. While for a process whose steps as a whole are non-medical but technical it is legitimate not to derive the in vivo diagnostic character from its final diagnostic purpose, this does not apply to a process for a diagnostic purpose which is to be implemented in its essential steps by medical staff or under the responsibility of a doctor. A different interpretation would be in clear conflict with the spirit of Article 52(4) EPC.

Finally it is recognised that, in the present case, the skilled person, namely the competent medical staff, is not necessarily represented by one single specialist. In fact, it may well be the case that the doctor competent for the final diagnostic activity is not the specialist competent for carrying out and controlling the medical part of the diagnostic method, that is, injecting the contrast agent and undertaking all the subsequent therapeutical measures, should they prove necessary. This situation does not modify the medical nature of the diagnostic process of claim 1. On the contrary, it shows that, being the activity of the specialist administering the contrast agent independent from the activity of the specialist making the final diagnosis, the diagnostic character, within the meaning of Article 52(4) EPC, can also be recognised in consideration of the medical character of some steps of the said method and independently from the final diagnostic activity which, indeed, is not part of the claimed process.

In conclusion, the process according to claim 1 is, in the board's judgment, a diagnostic method within the meaning of Article 52(4) EPC.

6. Article 54 EPC

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7. Article 56 EPC

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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 with the following claims and a description to be adapted:

Claims 1 to 10 of the main request filed with the letter of 22 April 1996.

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* This is an abridged version of the decision. A copy of the full text in the language of proceedings may be obtained from the EPO Information Office in Munich on payment of a photocopying fee of DEM 1.30 per page.