Interlocutory Decision of Technical Board of Appeal 3.4.01 dated 20 October 2006

T 992/03 - 3.4.01

(Language of the proceedings)

Composition of the board:

Chairman: B. Schachenmann

Members: G. Assi

H. Wolfrum

Applicant: Medi-Physics, Inc.

Headword: Treatment by surgery/MEDI-PHYSICS

Article: 52(1), 52(4), 112(1)a EPC

Keyword: "Physical intervention on the body intended for data collection - method for data collection in connection with treatment by surgery - exclusion from patent protection under Article 52(4) EPC - referral to the Enlarged Board"

Headnote

The following questions are referred to the Enlarged Board of Appeal:

I. Is a claimed imaging method for a diagnostic purpose (examination phase within the meaning given in G 1/04), which comprises or encompasses a step consisting in a physical intervention practised on the human or animal body (in the present case, an injection of a contrast agent into the heart), to be excluded from patent protection as a "method for treatment of the human or animal body by surgery" pursuant to Article 52(4) EPC if such step does not per se aim at maintaining life and health?

II. If the answer to question 1 is in the affirmative, could the exclusion from patent protection be avoided by amending the wording of the claim so as to omit the step at issue, or disclaim it, or let the claim encompass it without being limited to it?

III. Is a claimed imaging method for a diagnostic purpose (examination phase within the meaning given in G 1/04) to be considered as being a constitutive step of a "treatment of the human or animal body by surgery" pursuant to Article 52(4) EPC if the data obtained by the method immediately allow a surgeon to decide on the course of action to be taken during a surgical intervention?

Summary of facts and submissions

I. The appellant (applicant) lodged an appeal, received on 3 June 2003, against the decision of the examining division, despatched on 17 April 2003, refusing European patent application No. 99918429.4 (publication number 1 066 537). The fee for the appeal was paid on 3 June 2003. The statement setting out the grounds of appeal was received on 15 August 2003.

II. The application relates to magnetic resonance methods for imaging the pulmonary and/or cardiac vasculature and evaluating blood flow using dissolved polarised ^{129}Xe. In the contested decision, the examining division held that the claimed methods according to the requests then on file constituted diagnostic methods practised on the human or animal body and thus were excluded from patent protection pursuant to Article 52(4) EPC (Reasons, No. 5.1, second paragraph).

Moreover, the examining division noted that the claimed methods comprised the step of administering polarized ^{129}Xe as an imaging agent to a subject, either by inhalation or by injection (Reasons, No. 5.2). The examining division thus held that, insofar as the delivery of the imaging agent was done by injection, the claimed methods were excluded from patent protection pursuant to Article 52(4) EPC as involving a surgical step (Reasons, No. 5.3).

III. Oral proceedings before the Board were held on 20 October 2006.

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:

Nos. 1-22 filed in the oral proceedings on 20 October 2006,

Description:

Pages 1-3, 8-10, 12-21, 25, 28, 29, 32, 33, 35 of the published application,

Pages 4-7, 11, 22-24, 26, 27, 30, 31, 34 filed in the oral proceedings on 20 October 2006,

Drawings:

Sheets 1/4-4/4 of the published application.

V. The wording of claims 1, 6, 8, 11, 14, 17, 18 and 22 reads as follows:

"1. A method for MRI imaging the pulmonary and/or cardiac vasculature using dissolved-phase polarized ^{129}Xe, comprising the steps of:

positioning a patient in an MRI apparatus having a magnetic field associated therewith;

delivering polarized ^{129}Xe gas to a predetermined region of the patient's body, the polarized gas having a dissolved imaging phase associated therewith;

exciting a predetermined region of the patient's body, having a portion of the dissolved phase polarized gas therein with at least one large flip angle RF excitation pulse; and

acquiring at least one MR image associated with the dissolved phase polarized gas after said exciting step."

"6. A method according to any of Claims 1 to 5, wherein said delivering step includes having the patient inhale the polarized ^{129}Xe gas into the lungs, the ^{129}Xe having a gas phase resonance which is higher than the dissolved-phase resonance, and wherein at least a portion of the ^{129}Xe gas enters into the pulmonary vasculature in a dissolved-phase, and wherein at least a portion of the dissolved-phase ^{129}Xe then enters the blood stream with an associated perfusion rate."

"8. A method according to Claim 6 or Claim 7, wherein said method further comprises the step of delivering via inhalation a quantity of polarized ^{3}He gas, and wherein an MRI differential image is obtained which includes information corresponding to the polarized gas ^{3}He in the lungs in addition to the information corresponding to the dissolved-phase polarized ^{129}Xe."

"11. A method for deriving a spectroscopic signal representative of a blood volume or a blood flow rate of a patient, comprising the steps of:

positioning a subject in an MR spectroscopy system capable of detecting spectroscopic signals in a subject having a pulmonary vasculature;

delivering gaseous polarized ^{129}Xe to the subject;

dissolving a portion of the gaseous polarized ^{129}Xe into the pulmonary vasculature having an associated blood flow path;

exciting the dissolved portion of the ^{129}Xe with an MR spectroscopy RF excitation pulse; and

deriving a spectroscopic signal associated with the dissolved phase ^{129}Xe representing a blood volume or blood flow rate."

"14. A method according to Claim 13, wherein said large angle pulse is above about a 90 degree flip angle pulse, and wherein said delivering step is performed by the subject inhaling a quantity of gaseous polarized ^{129}Xe."

"17. A cardiac imaging method, comprising the steps of:

positioning a subject having a cardiac blood flow path in an MRI system;

delivering polarized ^{129}Xe to the subject;

dissolving at least a portion of the polarized ^{129}Xe into the subject's cardiac blood flow path;

exciting dissolved polarized ^{129}Xe in a target region along the blood flow path with at least one large angle RF excitation pulse; and

generating an MR image associated with the excited dissolved polarized ^{129}Xe."

"18.A method according to Claim 17, wherein said delivering step is performed by the subject inhaling a quantity of gaseous ^{129}Xe."

"22.Use of ^{129}Xe for the preparation of a hyperpolarized imaging agent for use in methods of treatment or diagnosis involving performance of the method as described in any one of claims 1 to 21."

VI. In a communication dated 29 August 2006, the Board considered inter alia the fact that, according to an embodiment of the invention, polarized ^{129}Xe may be delivered directly to a region of the heart "via injection and the like". As the Enlarged Board of Appeal in its opinion G 1/04 (OJ EPO 2006, 334, No. 6.2.1) took the view that a claim including the feature of "performing a lumbar puncture to deliver epidural injections" was to be considered to relate to a method of surgery, the Board raised the question whether the claimed imaging methods, insofar as they encompassed the step of delivering polarized ^{129}Xe via injection, might be considered as treatments by surgery excluded from patent protection under Article 52(4) EPC. Furthermore, the Board drew attention to statements made in the description of the present application according to which the imaging methods of the invention provided real-time feedback during surgery to verify success of treatment. This observation led to the question whether, in these circumstances, the claimed methods as a whole should be regarded as constituting an element of treatment by surgery.

VII. In a response to this communication, dated 20 September 2006, the appellant made reference to decision T 383/03 (OJ EPO 2005, 159), in which the board stated that "the intention of the legislator was that only those treatments by therapy or surgery are excluded from patentability which are suitable for or potentially suitable for maintaining or restoring the health, the physical integrity and the physical well-being of a human being or an animal or to prevent diseases" (Reasons, No. 3.2). The appellant took the view that this definition was not inconsistent with that given in opinion G 1/04 (loc. cit.) according to which "methods of surgery within the meaning of Article 52(4) EPC include any physical interventions on the human or animal body in which maintaining the life and health of the subject is of paramount importance" (Reasons, No. 6.2.1). In the present case, the methods of independent claims 1, 11 and 17 did not maintain or restore the health or prevent diseases but concerned in vivo imaging. The methods were intended for obtaining intermediate results which, according to opinion G 1/04 (loc. cit.), did not constitute a sufficient basis for denying patent protection by virtue of Article 52(4) EPC. Anyhow, even if the claimed methods implied steps involving a substantial physical intervention on the body, such steps were performed solely with the aim of collecting data and thus should not be regarded as being surgical. Moreover, although the claimed methods might find application in conjunction with methods of surgery and/or therapy, for example as real-time imaging methods during surgery or for monitoring the progress or success of therapy, they were not in themselves methods having any surgical or therapeutic character. Without any subsequent steps, like using the image information obtained for diagnosis of a disease or for therapy, the methods were not suitable to maintain or restore the health or to prevent a disease. In fact, in the light of opinion G 1/04 (loc. cit.) applicants in the field of diagnostics should be provided with comprehensive patent protection. In the field of in vivo imaging there were procedures where no

contrast agent was required, for example x-ray imaging of the skeleton. There were conversely other procedures where a useful image could only be obtained with a contrast agent administered by injection, for example x-ray imaging of the vasculature. It did not seem reasonable that a method related to in vivo imaging of one part of the body should be patentable and another similar method related to a different part of the body should be excluded from patent protection.

Reasons for the decision

1. The appeal is admissible.

2. During the first-instance procedure, the examining division only addressed the issue of exclusion from patent protection pursuant to Article 52(4) EPC. Hence, if the appeal is allowed, it would be appropriate to remit the case to the examining division for further prosecution (Article 111(1) EPC, second sentence, second alternative).

3. Diagnostic method

The Board holds in the light of G 1/04 (loc. cit.) (Reasons, No. 5. and 6.2.1) that the method claims on file do not relate to diagnostic methods practised on the human or animal body falling under the prohibition of Article 52(4) EPC. The claimed methods lead to the acquisition of data in the form of an image or a spectroscopic signal, which may then be used for making a diagnosis. Thus, they relate to the examination phase but lack the steps of comparing the acquired data with standard values, finding any significant deviation, and attributing such deviation to a particular clinical picture, which are steps considered constitutive for making a diagnosis.

4. Method for treatment by surgery

4.1 The present invention relates to a method for magnetic resonance imaging the pulmonary and/or cardiac vasculature of a subject (claim 1), a method for deriving a spectroscopic signal representative of a blood volume or a blood flow rate of a subject (independent claim 11) and a cardiac imaging method (independent claim 17). All these methods comprise the step of delivering polarized ^{129}Xe to the subject, in particular via inhalation (claims 6, 8, 14 and 18; published application, page 9, lines 24-30; page 23, lines 7-25; page 27, lines 7-10). In the context of the cardiac imaging method, an embodiment, which falls under the wording of claim 17, relies on directly delivering polarized ^{129}Xe to a region of the heart such as via injection and the like into the left ventricle. Delivery directly into the right atrium or ventricle is also envisaged. In any event, the polarized ^{129}Xe delivery can be via injection of various phases such as but not limited to gaseous, dissolved or liquid phase (published application, page 26, lines 8-13).

The imaging methods of the present invention may precede surgery or a drug therapy for treating pulmonary or cardiac vasculature problems. During surgery, they may provide real-time feedback for verifying success, for example surgically induced variations in blood perfusion. During a drug therapy, they may allow the effects of the drug to be determined (published application, page 26, line 29 to page 27, line 3; page 31, line 27 to page 32, line 2; page 34, lines 4 to 31).

4.2 An injection of polarized ^{129}Xe into the heart, as envisaged in the description of the present application, represents a substantial physical intervention on the body which entails a health risk and requires professional medical expertise to be carried out. Such an injection, which is encompassed by the wording of claims 1, 11 and 17 on file, could be regarded as a method for treatment of the human or animal body by surgery within the meaning of Article 52(4) EPC, although, in the context of the claimed imaging methods, the physical intervention on the body does not aim in itself at maintaining life and health but constitutes a prerequisite for the collection of data in the course of an examination phase of a medical diagnosis. Thus, the question arises whether the claimed imaging methods comprising or encompassing such a step would fall under the prohibition of Article 52(4) EPC, although they do not in themselves provide any curative effect.

4.3 Another circumstance which has to be taken into consideration is that the description of the present application repeatedly refers to the usefulness of the inventive imaging methods during a surgical intervention. As a matter of fact, the claimed methods rather than being concerned with the task of how image data are obtained merely require

that such data are generated. Certainly, the steps of monitoring and evaluating the progress of a surgical intervention do not constitute activities which serve the purpose of finding a symptom and attributing it to a particular clinical picture since these steps presume an already established diagnosis within the meaning of the definition given in G 1/04 (loc. cit.). Nevertheless, when used in the described manner, the claimed methods apparently produce images which directly, i.e. in real time and without undertaking any further steps except for purely mental acts, enable a surgeon to decide on the course of action to be taken. Therefore, the question arises of whether methods providing information of diagnostic value, when used during a treatment by surgery, should as a whole be considered a constitutive element or step of such treatment.

4.4 Definitions of surgery

In decision T 182/90 (OJ EPO 1994, 641) concerning a method for measuring blood flow to a specific tissue of an animal which comprised the step of sacrificing the animal, a comprehensive analysis of the expression "treatment by surgery" was made on the basis of definitions of the term "surgery" given in the literature and in encyclopaedias (Reasons, No. 2.3). The board found that the reference to healing in some of these definitions appeared to be inconsistent with the fact that, in today's medical and legal linguistic usage, apparently non-curative treatments were nevertheless regarded as surgical treatments, for example cosmetic treatments, 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 (Reasons, No. 2.2). In view of this, the board noted that the term "treatment by surgery" had apparently undergone a change in meaning insofar as it nowadays might also comprise particular treatments which were not directed to restoring or maintaining the health of the human or animal body (Reasons, No. 2.4). However, the semantic change in the terminology mentioned above could not extend so far that "surgical treatment" included any kind of manual or instrumental intervention by one human being on another or on an animal. In particular, methods consciously ending in the animal's death were not in their nature methods of surgical treatment, even if some of the steps they involved might have a surgical character (Headnote, second paragraph).

The reasoning of decision T 182/90 was confirmed in case T 35/99 (OJ EPO 2000, 447) concerning a method for transvenously accessing the pericardial space. The method comprised the steps of guiding a catheter downstream through the vena cava to the right atrium, guiding the catheter through the right atrium and into the right auricle, and accessing the pericardial space with said catheter by penetrating through the wall of the right auricle. The safe and reliable introduction of a catheter and/or electrodes into the pericardial space permitted the delivery of electricity to the heart muscle and/or the administration of pharmacologic agents directly into the pericardial space (Reasons, No. 9). The board held that all the claimed methods involved catheterisation as part of a medical process and therefore qualified as methods for the treatment of the human or animal body by surgery (Reasons, No. 10). In drawing this conclusion, the board relied on the idea that one had to distinguish between two categories of physical intervention on the human or animal body. The first category embraced those interventions which, whatever their purpose, be it for healing or cosmetic purposes, gave priority to maintaining the life or health of the body on which they are performed. These were "in their nature" methods for treatment by surgery within the meaning of Article 52(4) EPC. The second category comprised all those procedures whose end result was the death of living beings as, for example, methods for slaughtering animals or methods ending in the laboratory animal's death. These "lethal" procedures were, in the board's view, subject to ethical considerations (Article 53(a) EPC) and specific legal restrictions (e.g. criminal penalties for causing death) (Reasons, No. 4).

Decision T 383/03 (OJ EPO 2005, 159) concerned a cosmetic method for the simultaneous removal of a plurality of hairs from a skin region, the method comprising the step of applying optical radiation to the skin region. The application of optical radiation aimed at damaging the hairs without causing significant damage to the surrounding tissue. As already acknowledged in T 182/90, the board observed that in medical linguistic usage the term "treatment by surgery" nowadays also comprised treatments which were not directed to the health of human beings or animals (Reasons, No. 3.3). However, treatments by surgery which were clearly neither suitable nor potentially suitable for maintaining or restoring the health, the physical integrity or the physical well-being of human beings or animals did not fall within the exclusion from patent protection of Article 52(4) EPC (Reasons, No. 3.4). In the light of this approach, the board found that the claimed cosmetic method, although it involved an intentional physical intervention on the body which was to be regarded as a surgical operation, was not excluded from patent protection as it was clearly not potentially suitable for maintaining or restoring health, physical integrity or physical well-being (Reasons, No. 4.2).

The same line was continued in decisions T 1102/02 (Reasons, No. 3, fourth paragraph) and T 9/04 (Reasons, No. 6, second paragraph) in which it was found that a method for treatment of the human or animal body by surgery within the meaning of Article 52(4) EPC had to be suitable or at least potentially suitable for maintaining or restoring the health, the physical integrity or the physical well-being of a human being or animal.

In its opinion G 1/04 (loc. cit.) the Enlarged Board of Appeal held, as an obiter dictum, that methods of surgery within the meaning of Article 52(4) EPC included any physical interventions on the human or animal body in which maintaining the life and health of the subject was of paramount importance (Reasons, No. 6.2.1, first sentence). Moreover, the Enlarged Board pointed to the established jurisprudence of the boards of appeal, according to which a method claim fell under the prohibition of Article 52(4) EPC if it included at least one feature defining a physical activity or action that constituted a method step for treatment of the human or animal body by surgery or therapy (Reasons, No. 6.2.1, third sentence).

4.5 Consequences of the definitions

The cited jurisprudence identifies two aspects in the definition of surgery, namely the nature of the physical intervention on the one hand and its purpose on the other hand.

The boards of appeal have drawn different conclusions in respect of the exclusion under Article 52(4) EPC depending on whether the emphasis was put on the former or the latter aspect.

4.5.1 Nature and purpose of the physical intervention

In the Guidelines for Examination in the European Patent Office (June 2005) it is stated that "surgery defines the nature of the treatment rather than the purpose" (No. C-IV, 4.2.1).

This approach corresponds to that adopted in decisions T 182/90 (loc. cit.) and T 35/99 (loc. cit.). In agreement with T 182/90 (loc. cit.), the board held in case T 329/94 (OJ EPO 1998, 241) that withdrawal of blood would fall under the exclusion of Article 52(4) EPC if it could be regarded inter alia "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" (Reasons, No. 4).

On the other hand, in case T 383/03 (loc. cit.) the fact that the claimed method did not aim at maintaining or restoring the health, the physical integrity or the physical well-being of a person or animal played a decisive role in determining which inventions were excluded from patent protection under Article 52(4) EPC. The nature of the physical intervention on the body, i.e. optical irradiation of the skin, was secondary.

The jurisprudence of the boards of appeal concerning the interpretation of "methods for treatment of the human or animal body by surgery" in Article 52(4) EPC does not appear to be consistent. Whereas one approach is based on an assessment of the nature of the physical intervention on the body, the other concentrates on whether the physical intervention is suitable for maintaining or restoring the health, the physical integrity or the physical well-being of a person or an animal. The definition in G 1/04 (loc. cit.) according to which "methods of surgery within the meaning of Article 52(4) EPC include any physical interventions on the human or animal body in which maintaining the life and health of the subject is of paramount importance" appears to emphasise the purpose of the intervention rather than its nature (Reasons, No. 6.2.1).

In the Board's view, the approach based on the purpose may give rise to opposing judgements as to the exclusion from patent protection of one and the same physical intervention. For example, an injection of a medicament for treating a disease would be excluded but an injection of a substance reducing wrinkles for cosmetic purposes might not be considered to constitute a treatment by surgery within the meaning of Article 52(4) EPC because it is not suitable for maintaining or restoring health. In both cases, the physical intervention on the body would be substantially the same, i.e. an injection.

4.5.2 Other approaches

Besides the nature and the purpose of the physical intervention other approaches are conceivable.

An approach may be related to the medical risk involved in the physical intervention. This risk is linked to the further issue of whether a medical or veterinary practitioner should be responsible for carrying out the method steps. In this context, the approach based on the nature of the physical intervention appears to be more suitable than that based

on its purpose, at least for those methods whose execution would require professional medical expertise and would thus fall under the competence of a medical or veterinary practitioner. The Enlarged Board, however, found in G 1/04 (loc. cit.) that it was difficult to give a definition of the medical or veterinary practitioner on a European level and, therefore, concluded that, for reasons of legal certainty, the European patent grant procedure should not be rendered dependent on the involvement of such practitioners (Reasons, No. 6.1). Apart from this objective difficulty, in the present case it is reasonable to assume that an injection into the heart should be carried out by a medical or veterinary practitioner.

Other approaches may be related to factors like the degree of invasiveness or the operative complexity of the physical intervention. The Board, however, is aware of the difficulty of defining interpretative criteria for the exclusion under Article 52(4) EPC on the basis of such factors.

5. Form of admissible claims

5.1 For the sake of argument, assuming that the step of injecting a contrast agent in the context of an imaging method would indeed exclude such a method from patent protection under Article 52(4) EPC, the question arises of whether such an exclusion might be avoided by either omitting this step from the claim wording or by disclaiming it, for instance by making it clear that the step precedes but does not form part of the claimed imaging method. Expressions like "pre-delivered contrast agent" are conceivable.

In this respect, the appellant referred to decision G 1/03 (OJ EPO 2004, 413) of the Enlarged Board of Appeal according to which it was deemed allowable to make a disclaimer to disclaim subject-matter which under Articles 52 to 57 EPC was excluded from patent protection for non-technical reasons. On the other hand, the Board notes that, according to G 1/04 (loc. cit.), if a feature like, in the present case, the administration of the contrast agent "is to be regarded as constitutive for defining the invention", it must be included as an essential feature in the claim under Article 84 EPC (Reasons, No. 6.2.4).

5.2 Furthermore, the appellant referred to the principles set out by the Enlarged Board of Appeal in decision G 1/98 (OJ EPO 2000, 111). On this basis, the appellant argued that a claim of a higher level of abstraction embracing subject-matter excluded from patent protection without explicitly claiming it should be allowed. Thus, a claim including the step of "administering a contrast agent", thereby leaving open in which way the administration step was to be performed, should be allowed at least if uncritical methods for administration of the contrast agent, as by inhalation or orally, were disclosed or available.

6. Referral to the Enlarged Board of Appeal

Pursuant to Article 112(1)(a) EPC, a board of appeal shall, during proceedings on a case and of its own motion, refer any question to the Enlarged Board of Appeal if it considers that a decision is required in order to ensure uniform application of the law or if an important point of law arises.

Different definitions of the term "surgery" have been identified in the jurisprudence of the boards of appeal. The application of the approach based on the nature of the physical intervention on the one hand or on its purpose on the other hand might result in different conclusions on patentability under Article 52(4) EPC. The application of other approaches may not be excluded. Therefore, it is necessary in deciding on the present case, to clarify how the term "treatment by surgery" within the meaning of Article 52(4) EPC is to be interpreted.

The issue of which interpretation to take is an important point of law. It is commonly accepted that the purpose of the exclusion from patentability under Article 52(4) EPC is to deny patent protection to methods which serve medical purposes, so that no one can be hampered in the practice of medicine by patent legislation. Hence, the scope of this exclusion is materially dependent upon the interpretation of the expression "treatment by surgery" as used in Article 52(4) EPC, which determines the extent of an area of activities exempt from patent protection.

In addition to the above issue, the question arises in the present case of whether an imaging method providing information of diagnostic value, albeit concerning an examination phase in the light of G 1/04 (loc. cit.), should be considered as being a constitutive step of a treatment by surgery within the meaning of Article 52(4) EPC if it is

established that in certain cases the immediate results, i.e. the image data produced, allow a surgeon, by merely taking note of said data, to decide on the course of action to be taken during a surgical intervention.

Order

For these reasons it is decided that:

The following questions are referred to the Enlarged Board of Appeal:

1. Is a claimed imaging method for a diagnostic purpose (examination phase within the meaning given in G 1/04), which comprises or encompasses a step consisting in a physical intervention practised on the human or animal body (in the present case, an injection of a contrast agent into the heart), to be excluded from patent protection as a "method for treatment of the human or animal body by surgery" pursuant to Article 52(4) EPC if such step does not per se aim at maintaining life and health?

2. If the answer to question 1 is in the affirmative, could the exclusion from patent protection be avoided by amending the wording of the claim so as to omit the step at issue, or disclaim it, or let the claim encompass it without being limited to it?

3. Is a claimed imaging method for a diagnostic purpose (examination phase within the meaning given in G 1/04) to be considered as being a constitutive step of a "treatment of the human or animal body by surgery" pursuant to Article 52(4) EPC if the data obtained by the method immediately allow a surgeon to decide on the course of action to be taken during a surgical intervention?