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**Datasheet for the decision
of 4 November 2010**

Case Number: T 0992/03 - 3.4.01

Application Number: 99918429.4

Publication Number: 1066537

IPC: G01R 33/28

Language of the proceedings: EN

Title of invention:

MR methods for imaging pulmonary and cardiac vasculature and evaluating blood flow using dissolved polarized ^{129}Xe

Applicant:

Medi-Physics, Inc.

Headword:

-

Relevant legal provisions:

EPC Art. 53(c), 123(2)

Relevant legal provisions (EPC 1973):

EPC Art. 84, 111(1)(2)

Keyword:

-

Decisions cited:

T 0992/03 (interlocutory decision), G 0001/04, G 0001/07

Catchword:

Application of the decision G 0001/07 to case T 0992/03 for which questions were referred to the Enlarged Board of Appeal



Case Number: T 0992/03 - 3.4.01

D E C I S I O N
of the Technical Board of Appeal 3.4.01
of 4 November 2010

Appellant: Medi-Physics, Inc.
101 Carnegie Center
Princeton, NJ 08540 (US)

Representative: Canning, Lewis R.
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Decision under appeal: Decision of the Examining Division of the
European Patent Office posted 17 April 2003
refusing European application No. 99918429.4
pursuant to Article 97(1) EPC 1973.

Composition of the Board:

Chairman: B. Schachenmann
Members: G. Assi
H. Wolfrum

Summary of Facts and Submissions

- I. The European patent application No. 99918429.4 (European publication No. 1 066 537; International publication No. WO 99/47940) was refused by the examining division with a decision dispatched on 17 April 2003.

The International application as published (hereinafter application as filed) relates to magnetic resonance (MR) methods for imaging the pulmonary and/or cardiac vasculature and evaluating blood flow using dissolved polarized ^{129}Xe .

- II. In its 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 1973 (Reasons, 5.1, second paragraph).

Moreover, the examining division noted that the claimed methods comprised the step of administering polarized ^{129}Xe as a contrast agent to a subject, either by inhalation or by injection (Reasons, 5.2). The examining division thus held that, insofar as the delivery of the contrast agent was done by injection, the claimed methods were excluded from patent protection pursuant to Article 52(4) EPC 1973 as involving a surgical step (Reasons, 5.3).

- III. The applicant (appellant) lodged an appeal, received on 3 June 2003, against the decision to refuse the application. 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.

- IV. After a procedure in writing, oral proceedings before the Board were held on 20 October 2006. At the end of the oral proceedings, the Board declared that it intended to issue an interlocutory decision referring ex officio to the Enlarged Board of Appeal a point of law concerning the presence of a step of potentially surgical nature in the context of a method of data collection for diagnostic purposes.
- V. In its interlocutory decision T 0992/03 of 20 October 2006 (Reasons, 3), the Board held in the light of G 1/04 (OJ EPO 2006, 334; Reasons, 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 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."*

Moreover, the Board referred the following questions 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?"*

VI. The referred questions were answered in G 0001/07 (to be published; Headnote) as follows:

- "1. A claimed imaging method, in which, when carried out, maintaining the life and health of the subject is important and which comprises or encompasses an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the

required professional care and expertise, is excluded from patentability as a method for treatment of the human or animal body by surgery pursuant to Article 53(c) EPC.

- 2a. A claim which comprises a step encompassing an embodiment which is a "method for treatment of the human or animal body by surgery" within the meaning of Article 53(c) EPC cannot be left to encompass that embodiment.*
- 2b. The exclusion from patentability under Article 53(c) EPC can be avoided by disclaiming the embodiment, it being understood that in order to be patentable the claim including the disclaimer must fulfil all the requirements of the EPC and, where applicable, the requirements for a disclaimer to be allowable as defined in decisions G 1/03 and G 2/03 of the Enlarged Board of Appeal.*
- 2c. Whether or not the wording of the claim can be amended so as to omit the surgical step without offending against the EPC must be assessed on the basis of the overall circumstances of the individual case under consideration.*
- 3. A claimed imaging method is not to be considered as being a "treatment of the human or animal body by surgery" within the meaning of Article 53(c) EPC merely because during a surgical intervention the data obtained by the use of the method immediately allow a surgeon to decide on the course of action to be taken during a surgical intervention."*

VII. The proceedings were resumed with a Board's communication of 10 March 2010.

With a letter of 20 May 2010 (page 4, first paragraph) the appellant, on the basis of the reasoning provided in G 0001/07, concluded inter alia that "*the embodiment of the methods of previous claims 1, 11 and 17 wherein delivery of ^{129}Xe is carried out by directly delivering to a region of the heart is excluded from patentability as a method for treatment of the human or animal body by surgery pursuant to Article 53(c) EPC.*".

VIII. After a procedure in writing, oral proceedings before the Board were held on 4 November 2010.

The appellant requested that the decision under appeal be set aside, that the Board decide that the amended independent claims 1 and 22 filed at the oral proceedings meet the requirement of Articles 53(c) EPC, 84 EPC 1973 and 123(2) EPC, and that the case be remitted to the examining division for further prosecution, with claims 2-21 and 23-31 of the application as filed to be adapted to the amended claims 1 and 22 filed at the oral proceedings.

IX. The wording of claim 1 on file reads as follows:

"A method for MR imaging the pulmonary and/or cardiac vasculature of a subject, using dissolved-phase polarized ^{129}Xe gas comprising the steps of: exciting dissolved-phase polarized ^{129}Xe gas with at least one large flip angle RF excitation pulse; and

acquiring at least one MR image associated with the dissolved-phase polarized ^{129}Xe gas after said exciting step."

The wording of independent claim 22 on file reads as follows:

"A method for evaluating the blood flow of a subject, using dissolved-phase polarized ^{129}Xe gas, comprising the steps of:

exciting dissolved-phase polarized ^{129}Xe gas in the pulmonary vasculature having an associated blood flow path with an MR spectroscopy large flip angle RF excitation pulse; and

evaluating blood flow of the subject based on a spectroscopic signal corresponding to the dissolved-phase polarized ^{129}Xe gas."

Claims 2-21 of the application as filed depend on claim 1 on file, claims 23-31 of the application as filed on independent claim 22 on file.

- X. The revised version of the European Patent Convention or EPC 2000 entered into force on 13 December 2007. In the present decision, reference is made to "EPC 1973" or "EPC" for EPC 2000 (EPC, Citation practice, pages 4-6) depending on the version to be applied according to Article 7(1) of the Revision Act dated 29 November 2000 (Special Edition No. 1 OJ EPO 2007, 196) and the decisions of the Administrative Council dated 28 June 2001 (Special Edition No. 1 OJ EPO 2007, 197) and 7 December 2006 (Special Edition No. 1 OJ EPO 2007, 89).

Reasons for the Decision

1. The appeal is admissible.
2. Res judicata concerning diagnostic methods (Article 53(c) 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 steps are considered constitutive for making a diagnosis.

Therefore, in the light of G 1/04 (Reasons, 5 and 6.2.1) present claims 1 and 22 do not relate to diagnostic methods practised on the human or animal body falling under the prohibition of Article 53(c) EPC, as the Board already decided in its interlocutory decision T 0992/03 of 20 October 2006 (Reasons, 3).

3. Appellant's submissions
 - 3.1 The appellant submitted that the claimed methods 1 and 22 on file clearly required the presence of a dissolved-phase polarized ^{129}Xe gas. However, the invention did not concern when and how ^{129}Xe gas had to be delivered. Such a delivery step was indeed conventional and did not belong to the features by which the methods at issue were claimed to differ from the prior art. The technical contribution of the

invention to the art simply consisted in the step of exciting the dissolved-phase polarized ^{129}Xe gas with RF excitation pulses characterised by a large flip angle, this step being considered to be essential and recited by claims 1 and 22. With this understanding, which was consistent with the disclosure of the application as filed, the delivery step did not form part of the claimed methods which, therefore, could not be considered as having a surgical character. Moreover, the performed amendments did not introduce new subject-matter and claims 1 and 22 as amended were clear.

4. Invention according to the application as filed

In order to evaluate the appellant's submissions, it is necessary to consider how the application as filed defines the invention in its broadest form.

4.1 The field of the invention is MR imaging and MR spectroscopy using dissolved-phase hyperpolarized noble gases (application as filed, page 1, lines 5-8).

4.2 Conventionally, MR imaging was used to produce images by exciting the nuclei of hydrogen molecules in the human body. Then, it has been discovered that polarized noble gases can produce improved images of certain areas and regions of the body which beforehand produced less than satisfactory images in this modality. Polarized ^3He and ^{129}Xe gases have been found to be particularly suited for this purpose. Such polarized gases are produced and accumulated by using hyperpolarizers that are well-known in the art

(application as filed, page 1, line 11 to page 3, line 3).

Conventionally, gas-phase imaging has been possible using both ^3He and ^{129}Xe gases, and has been particularly useful in producing ventilation-driven images of the lungs, a region where proton images have produced signal voids. However, in contrast to gas-phase imaging, dissolved-phase imaging has proven to be problematic. Dissolved-phase imaging uses the solubility characteristic of ^{129}Xe in tissue which is rich in blood and lipid. The gas-phase is thus dissolved into surrounding tissue or blood vessels and may allow perfusion imaging of the brain, lung, or other regions. Unfortunately, once the polarized gas has been dissolved, it has proven difficult to generate clinically useful images using the dissolved-phase gas. Conventionally, dissolved-phase imaging is attempted by performing a gas-based "regular" image and then looking for a spatially shifted dissolved-phase image. However, the small flip angles typically associated with the "regular" image excitation pulses generally fail to produce sufficient detectable signal spectra in the dissolved-phase, thus generating relatively inadequate dissolved-phase images (application as filed, page 3, lines 4-20).

In addition, conventional imaging with MR imaging units generally requires relatively large magnetic fields (1.5 Tesla). Further, the MR imaging units must typically shim or control the magnetic field in order to produce magnet homogeneity which is suitable for imaging. Unfortunately and disadvantageously, both the high field strength magnet and the relatively high

homogeneity requirements increase the costs (application as filed, page 3, line 28 to page 4, line 4).

- 4.3 In view of this technical background, an object of the present invention consists in detecting and/or manipulating dissolved-phase ^{129}Xe signals so as to yield clinically useful images. Another object consists in the provision of a MR imaging method using dissolved-phase polarized ^{129}Xe gas for obtaining clinically useful images of the pulmonary and/or cardiac vasculature. A further object of the present invention consists in the provision of a MR spectroscopy method using dissolved-phase polarized ^{129}Xe gas for obtaining real-time blood flow path information. Yet another object of the present invention consists in the provision of a method for obtaining useful information and/or images of dissolved-phase polarized ^{129}Xe gas, which method does not require high magnetic field strength and/or high magnetic field homogeneity (application as filed, page 4, lines 5-23).
- 4.4 According to the application as filed (page 4, lines 24-26), *"These and other objects are satisfied by the present invention, which uses large flip angle (such as 90°) RF excitation pulses to excite dissolved phase gas in the pulmonary vasculature and MR data image acquisition techniques"*. In other words, in its broadest definition, the invention concerns a method for MR imaging the pulmonary vasculature, the method using dissolved-phase polarized gas excited with large flip angle RF excitation pulses and relying on MR data image acquisition techniques. The contribution of the

invention to the art would thus consist in the use of large flip angle RF excitation pulses to excite dissolved-phase polarized gas. As regards the further mentioned "*MR data image acquisition techniques*", they are not otherwise specified so that it may be concluded that they are conventional, this conclusion not contradicting the remainder of the disclosure of the application as filed.

In particular, the disclosure on page 4, line 26 to page 6, line 2 of the application as filed concerns some further aspects of the present invention. Although these aspects are described in greater detail by mentioning the steps of positioning a subject in the MR system, delivering polarized ^{129}Xe gas to the subject and generating an MR image or evaluating an MR spectroscopic signal, they should not be understood as implying that the positioning and delivering steps also form part of the contribution of the invention to the art. Indeed, such an understanding would be in contradiction with the above cited sentence on page 4, lines 24-26 of the application as filed. Rather, they are descriptions of particular aspects of the invention at a higher level of detail that is further increased in the rest of the description (page 7, line 11 to page 35, line 18).

- 4.5 As regards the advantages achieved by the present invention, unlike imaging the gas-phase ^{129}Xe in the lung where conventionally small flip angles are used to avoid destroying the available ^{129}Xe magnetization, there is minimal or no penalty for using a large flip angle excitation of the dissolved-phase ^{129}Xe gas because it will otherwise flow out of the chest region

unimaged. Indeed, a rapid large angle pulse imaging sequence makes optimal use of the dissolved magnetization. Such an imaging method can provide useful dissolved-phase images of the pulmonary and cardiac vasculature, for example (application as filed, page 6, lines 3-13).

Further advantageously, blood flow rate evaluation spectroscopic methods according to the present invention can be used in MR imaging systems with reduced magnetic fields, such as 0.15 Tesla, and less restrictive homogeneity requirements. It should be noted that the use of large flip angle RF excitation pulses to excite dissolved-phase ^{129}Xe gas is expressly envisaged for these spectroscopic methods too (original claim 26).

4.6 In summary, the description of the application as filed consistently presents the contribution of the present invention to the art as consisting only in the use of large flip angle RF excitation pulses to excite dissolved-phase gas. For this reason, it is allowed to amend the independent claims 1 and 22 as originally filed by deleting the positioning and delivering steps, whereby present claim 1 corresponds to original claim 1 and present claim 22 corresponds to original claim 26.

5. Conclusions

The technical understanding of the invention as discussed above has the following legal consequences.

5.1 Methods for treatment by surgery (Article 53(c) EPC)

5.1.1 Present claim 1 concerns a method for MR imaging the pulmonary and/or cardiac vasculature of a subject, using dissolved-phase polarized ^{129}Xe gas. This method "comprises" the steps of exciting dissolved-phase polarized ^{129}Xe gas with at least one large flip angle RF excitation pulse and then acquiring at least one MR image associated with the dissolved-phase polarized ^{129}Xe gas. The use of the verb "comprise", according to a commonly accepted understanding in the EPO, implies that the claimed imaging method also includes steps other than the recited excitation and acquisition. Indeed, a skilled person knows that a MR imaging method is in reality a rather complex procedure requiring inter alia preparatory steps like positioning of a subject in the MR system, delivering polarized ^{129}Xe gas to the subject and initialising the MR system. Such preparatory steps, however, do not form part of the contribution of the invention to the art, as the appellant convincingly submitted.

5.1.2 With the understanding of the invention as mentioned above, present method claims 1 and 22 do not comprise "*an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise*" (G 0001/07, Headnote, 1).

Rather, the contribution of the invention to the art, for which protection is sought, is limited to the technical feature pertaining to the excitation of the

dissolved-phase polarized ^{129}Xe gas with at least one MR imaging large flip angle RF excitation pulse or with an MR spectroscopy large flip angle RF excitation pulse. Thus, the amended method claims are not left to encompass the step of delivering polarised ^{129}Xe gas to a subject, which step may have a surgical character at least if it is carried out by an injection and the like, as described on page 26 (lines 8-17) of the application as filed (G 0001/07, Headnote, 2a).

5.1.3 It is well-known that ^{129}Xe can be used as an anaesthetic. Anaesthesia, however, may reasonably be considered as a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a substantial health risk even when carried out with the required professional care and expertise. Thus, the question arises as to whether the methods according to claims 1 and 22 on file, which are based on the presence of ^{129}Xe gas in the body, would possess surgical character for this reason.

In this respect, the Enlarged Board of Appeal clarified in G 0001/07 (Reasons, 3.4.2.3, third paragraph) that *"there is an exclusion from patentability as a surgical method only if the health risk is associated with the mode of administration and not solely with the agent as such."* Therefore, any anaesthetic effect of the ^{129}Xe gas is irrelevant for the issue of assessing whether the claimed methods should be excluded from patentability under Article 53(c) EPC.

5.1.4 Furthermore, according to G 0001/07 (Headnote, 3), *"A claimed imaging method is not to be considered as being*

a "treatment of the human or animal body by surgery" within the meaning of Article 53(c) EPC merely because during a surgical intervention the data obtained by the use of the method immediately allow a surgeon to decide on the course of action to be taken during a surgical intervention."

In view of this answer, it is irrelevant whether the present claimed methods provide information allowing a surgeon to decide on the course of action to be taken during a surgical intervention.

5.1.5 It results from the foregoing that the claimed methods according to claims 1 and 22 on file do not relate to methods for treatment of the human or animal body by surgery falling under the prohibition of Article 53(c) EPC. This conclusion is consistent with the answers given by the Enlarged Board of Appeal in G 0001/07.

5.2 Article 84 EPC 1973

5.2.1 The wording of present claims 1 and 22 is meaningful for the skilled person who reads them even in isolation from the context of the whole application.

5.2.2 With the understanding of the invention as mentioned above, the preparatory steps of positioning of a subject in the MR system and delivering polarized ^{129}Xe gas to the subject are conventional. They do not contribute to the solution of the technical problem with which the invention is concerned and thus are not essential for performing the invention. For this reason, present claims 1 and 22 as amended by omission of these steps meet the requirement of Article 84 EPC 1973 in

connection with Rule 29(3) EPC 1973 that a claim shall state the essential features of an invention.

- 5.2.3 According to G 0001/07 (Headnote, 2c), *"Whether or not the wording of the claim can be amended so as to omit the surgical step without offending against the EPC must be assessed on the basis of the overall circumstances of the individual case under consideration."*

In the present case, the application as filed provides a clear basis for the mentioned omission of the allegedly surgical step of delivering polarised ^{129}Xe gas to a subject.

- 5.2.4 Moreover, present claims 1 and 22 and the definition of the invention as derivable from the description of the application as filed are consistent with each other. In particular, the claims recite the use of large flip angle RF excitation pulses to excite dissolved-phase ^{129}Xe gas, which is the only essential feature of the invention.

- 5.2.5 No doubt exists as to conciseness of present claims 1 and 22.

- 5.2.6 Therefore, present claims 1 and 22 meet the requirements of Article 84 1973 because they are clear, concise and supported by the description.

5.3 Article 123(2) EPC

- 5.3.1 Present claim 1 corresponds to original claim 1 with amendments which are based on the application as filed

(page 4, lines 9-11 and 24-26; page 5, lines 1-11), as the appellant submitted.

Present claim 22 corresponds to original claim 26 with amendments which are also based on the application as filed (page 4, lines 18-20 and 24-26; page 11, lines 26-28; page 26, line 19 to page 27, line 6), as the appellant submitted.

- 5.3.2 As no doubt exists that the omission of the preparatory steps mentioned above is justified on the basis of the original disclosure, present claims 1 and 22 have not be amended in such a way that they contain subject-matter which extends beyond the content of the application as filed.

Therefore, present claims 1 and 22 meet the requirement of Article 123(2) EPC.

6. Remittal of the case for further prosecution

- 6.1 The issues of novelty and inventive step of present claims 1 and 22 still remain to be elucidated. Moreover, dependent claims 2-21 and 23-31 as well as the description of the application as filed would have to be adapted to present claims 1 and 22.

- 6.2 The appellant requested that the case be remitted to the examining division for further prosecution (Article 111(1) EPC 1973). The Board has no reason to refuse this request. The appellant would thus not be deprived of the possibility to further present its case in two instances, if necessary.

In conclusion, the examining division shall be bound by the ratio decidendi of the Board, i.e. the assessment mentioned above of present claims 1 and 22 under Articles 53(c) EPC, 84 EPC 1973 and 123(2) EPC, in so far as the facts are the same (Article 111(2) EPC 1973).

Order

For these reasons, it is decided that:

1. The decision under appeal is set aside.
2. The case is remitted to the examining division for further prosecution on the basis of
 - the independent claims 1 and 22 filed at the oral proceedings on 4 November 2010,
 - the dependent claims 2-21 and 23-31 of the application as filed to be adapted, and
 - the description of the application as filed to be adapted.

The Registrar

The Chairman:

R. Schumacher

B. Schachenmann