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**Datasheet for the decision
of 15 February 2010**

Case Number: G 0001/07
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.

Opponent:

-

Headword:

Treatment by surgery/MEDI-PHYSICS

Relevant legal provisions:

Vienna Convention on the Law of Treaties

Art. 31,32

TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights): Art. 27.3(a)

European Union

Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions

Art. 6(2)

Recital 35

Transitional Provisions:

Decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the EPC

Art.1

Act revising the Convention on the Grant of European Patents

Art. 3(1), 7(1)

EPC Art. 4(3), 53(c), 53(b), 56, 83, 84, 123(2)(3)

Rule 43

PCT Rule 39.1, 67.1,

Swiss PatG

Art. 2(2)

German PatG

§ 5(2)

UK Patents Act 1977

Section 4(2)

EPC 1973:

EPC Art. 52-57, 52(2)(3)(4), 53(b), 84, 112(1), 177(1)

Keyword:

Applicable provisions - Art. 112(1) EPC 1973 - Art. 53(c) EPC"
"Admissibility of the referral - yes"
"The Vienna Convention - principle of narrow interpretation of
exclusions - no"
"One surgical step in a multi-step method - excluded from
patentability - yes"
"Limited to surgery for a therapeutic purpose - no"
"Meaning of the wording of the exclusion - legal history -
impact of jurisprudence and practice - ratio legis"
"Nature of interventions - involvement of a practitioner - no"
"Medical skills and health risks - further criteria"
"Claim left to encompass a surgical step - no"
"Disclaimer under Article 53(c) EPC - yes - subject to
remaining requirements of EPC"
"Omission - methods only concerning the internal operation of
a device - yes - subject to remaining requirements of the EPC"
"Possible use of non-surgical method in a surgical method -
irrelevant, if non-surgical method complete teaching in
itself"

Decisions cited:

G 0005/83, G 0001/98, G 0001/03, G 0002/03, G 0001/04,
G 0002/06, J 0010/07, T 0004/80, T 0144/83, T 0245/87,
T 0182/90, T 0820/92, T 0082/93, T 0329/94, T 0789/96,
T 1054/96, T 0035/99, T 1102/02, T 0383/03, T 0992/03,
T 1172/03, T 0005/04, T 0009/04, T 0924/05, T 0542/06,
T 0810/06, T 1107/06

Headnote:

The questions referred to the Enlarged Board of Appeal are answered 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.



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Case Number: G 0001/07

D E C I S I O N
of the Enlarged Board of Appeal
of 15 February 2010

Appellant: Medi-Physics, Inc. 100 Abbott Park Road
(Applicant) 101 Carnegie Center
Princeton, NJ 08540 (US)

Representative: Canning, Lewis R.
GE Healthcare Limited
Amersham Place
Little Chalfont
Buckinghamshire HP7 9NA (GB)

Decision under appeal: Interlocutory decision of the Technical Board
of Appeal 3.4.01 dated 20 October 2006.

Composition of the Board:

Chairman: P. Messerli
Members: B. Günzel
P. Alting van Geusau
U. Kinkeldey
S. Perryman
A. Pézard
J.- P. Seitz

Summary of Facts and Submissions

I. The referred questions

By an interlocutory decision T 992/03 dated 20 October 2006, in its version as corrected by the Board's decision dated 20 August 2007, Technical Board of Appeal 3.4.01 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?**

II. The appealed decision of the Examining Division

The appeal proceedings before the referring Board concern the appellant's appeal against the decision of the Examining Division of 17 April 2003 refusing European patent application No. 99918429.4. The Examining Division decided 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. Furthermore, the claimed methods comprised the step of administering polarized ^{129}Xe as an imaging agent to a subject, either by inhalation or by injection. 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 1973 as involving a surgical step.

III. The claims underlying the referring decision

The application relates to magnetic resonance methods for imaging the pulmonary and/or cardiac vasculature and evaluating blood flow using dissolved polarized ^{129}Xe .

The wording of claims 1, 11 and 17, underlying the referring decision 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."

"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."

"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 ."

IV. The referring decision

1. Technical background

All claimed methods comprise the step of delivering polarized ^{129}Xe to the subject, in particular via inhalation. However, an injection of polarized ^{129}Xe into the heart, as envisaged in the description, is encompassed by the wording of claims 1, 11 and 17 on file (point 4.2 of the reasons).

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. The polarized ^{129}Xe delivery can be via injection of various phases such as but not limited to gaseous, dissolved or liquid phase.

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.

2. Diagnostic method

The referring decision holds that in the light of opinion G 1/04, (Reasons, No. 5 and 6.2.1) 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 1973. 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 (point 3 of the Reasons).

3. Method for treatment by surgery

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 1973, 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, in the view of the referring Board the question arises whether the claimed imaging methods comprising or encompassing such a step would fall under the prohibition of Article 52(4) EPC 1973, although they do not in themselves provide any curative effect (point 4.2 of the Reasons).

Furthermore, 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. 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. Definitions of surgery

In past jurisprudence different definitions of the expression "treatment by surgery" have been given.

In decision T 182/90 (OJ EPO 1994, 641) the board found that, in today's medical and legal linguistic usage 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. The reasoning of decision T 182/90 was confirmed in case T 35/99 (OJ EPO 2000, 447).

In decision T 383/03 (OJ EPO 2005, 159) the board observed that while 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), 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 1973 (Reasons, No. 3.4). 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 1973 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 1973 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 1973 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).

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.

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" (C-IV, 4.2.1).

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 1973 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 opinion G 1/04 (loc. cit.) according to which "methods of surgery within the meaning of Article 52(4) EPC 1973 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.

The approach based on the purpose may give rise to opposing judgments 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 1973 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.

6. 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 opinion 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.

7. Form of admissible claims

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 1973, the question would arise 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.

With respect 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, the Board notes that, according to opinion G 1/04, 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).

Furthermore, the referring Board refers to the appellant's submissions with regard to decision G 1/98 (OJ EPO 2000, 111). On this basis, the appellant had argued that a claim of a higher level of abstraction embracing subject-matter excluded from patent protection without explicitly claiming it should be allowed. According to the appellant, 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.

8. Referral to the Enlarged Board of Appeal

Different definitions of the term "surgery" have been identified in the jurisprudence of the boards of appeal. The issue of which interpretation to take is an important point of law. In addition, the question arises in the present case whether an imaging method providing information of diagnostic value should be considered as being a constitutive step of a treatment by surgery within the meaning of Article 52(4) EPC 1973 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.

V. The course of the proceedings before the Enlarged Board

By decision of 25 May 2007 the Enlarged Board invited the President of the EPO to comment in writing on the points of law referred to the Enlarged Board and also issued an invitation for third parties to file comments. The President of the EPO and numerous third parties submitted comments in writing. On 16 June 2009 the Enlarged Board sent a summons to attend oral proceedings and thereafter, on 16 September 2009, a communication drawing attention to a number of issues that appeared of significance for discussion in the oral proceedings. Oral proceedings were held on 17 November 2009. At the end of the oral proceedings the Chairman announced that the Enlarged Board would give its decision in writing.

VI. The appellant's submissions

The submissions of the appellant may be summarised as follows:

1. The applicable law

Article 53(c) EPC applies to the answers to be given by the Enlarged Board. However, the views expressed by the appellant apply with equal validity under Article 52(4) EPC 1973 and under Article 53(c) EPC.

2. The construction of Article 52(4) EPC 1973

a) The historical legal background

It is consistent with the legislative purpose that the surgical treatment exclusion should be confined to procedures having a therapeutic purpose in their own right.

The exclusion of medical methods from patentability was not contained in the earliest draft versions of the EPC, the exclusion of methods of therapy and diagnostic methods being introduced in 1965, first by exclusion from the meaning of "invention" and eventually by inclusion of the legal fiction of lack of industrial applicability in the then Article 50(4) draft EPC 1973. The exclusion of surgical methods first appeared in a draft of 1969, echoing the wording of Rule 39.1(iv) of the then draft PCT, which was however only concerned with subject-matter for which the International Searching Authority might not be required to conduct a preliminary search. The explanation given by the Working Party in response to a question reported in Historical Documentation BR/177d/72 nan/JF/prk, page 6, 9d, that a surgical treatment of animals for destructive purposes was not intended to be included in this provision, indicates that it is consistent with a broader intention of the legislator that the exclusion should not extend to procedures with a non-therapeutic purpose. When drafting the EPC 2000 the justification for the exclusion has been restated as being the interests of public health. In other words, as has also been stated in past case law of the boards of appeal, the supposed

freedom of a medical or veterinary practitioner from being hampered by patents and thus, social-ethical considerations, have emerged as the policy underpinning Article 52(4) EPC 1973. Whereas the wording of the exclusions specifically focuses on certain acts, whether those acts fall within the exclusion from patentability in respect of any specific invention must reflect the purpose of the policy of the exclusion itself and should not be construed in a manner that would expand the scope of the exclusion beyond that which was intended.

b) *The principle of narrow construction of exceptions in accordance with the Vienna Convention*

Authority for the principle that exclusions to patentability must be construed narrowly is found in Articles 31 and 32 of the Vienna Convention on the Law of Treaties (hereinafter: Vienna Convention). The case law of the boards of appeal has stressed that repeatedly, also in relation with Article 52(4) EPC 1973, including the Enlarged Board of Appeal in decision G 5/83. Even if in its opinion G 1/04 the Enlarged Board stated *obiter* that the principle of narrow construction of exclusions does not apply without exception, in the case in point the Enlarged Board did apply the diagnostic methods exclusion narrowly.

c) *The boards of appeals' approach to Article 52(4) EPC 1973*

As regards the definition of the term "surgical" decision T 182/90 was wrong. The sharp distinction drawn between the terms "therapy" and "surgery" while explainable historically, appears inappropriate, since it is not as much representative of a purposive legislative distinction but rather the adaptation in legal terms of the historical distinction in the medical field, where traditional medical treatments were generally not inclusive of specific means of treatment by way of surgery. On this basis the term "therapy"

may be regarded as indicating medical treatments that are procured by means of traditional medical practice, while surgery relates to a specific subset of therapy that requires invasive methods.

d) *The breadth of the definition given in decision T 182/90*

The breadth of the definition adopted in decision T 182/90 may also be criticised on the basis that it would include within the term "treatment by surgery" activities that people would not as a matter of common sense remotely consider surgical. A routine injection of a therapeutic or prophylactic agent would be "treatment by surgery", for instance administration of an influenza vaccine. A procedure ought not to be considered as being "treatment by surgery" if it is simply the means to administer a therapeutic agent: the intervention needs to be the purpose of the procedure before it is truly "surgical". Likewise taking a single drop of blood for a diagnostic test is not surgical at all, puncturing the skin is not the sure determinate of what constitutes surgery. Still less "surgical" is the non-invasive administration of a therapeutic agent, such as by swallowing a pill or by inhaling a preparation. Yet all these procedures and more are supposedly "surgical" according to the board in decision T 182/90. Furthermore, the policy consideration being the "interest of public health", that also would have had to lead the board to a meaning of the term "treatment by surgery" restricted to curative purposes.

e) *The presence of one surgical step in a multistep method*

The statement in decision T 182/90 that normally the presence of a surgical step in a multistep method for treatment of the human or animal body confers a surgical character on that method, was also wrong as going against the natural meaning of the words in Article 52(4) EPC 1973, according to which methods of treatment by surgery are not to be regarded as inventions capable of industrial

application, and are on that basis excluded from patentability. There is thus a matching of a method of treatment by surgery with what is defined by a claim. As in the consideration of novelty the claimed subject-matter as a whole must be assessed as to whether it is a method of surgery and therefore excluded from patentability. The board's decision in case T 182/90 was not necessary to give effect to the stated underlying policy of a medical practitioner's and specifically, in this context, a surgeon's freedom to practice. If a surgeon carries out only one surgical step of a multistep method he or she will not be practising the claim as a whole so there is no need for any protectiveness exclusion. On the other hand, if the surgeon is carrying out all the steps of the claim, then he or she is doing more than mere surgery, and the justification for the exclusion is removed.

f) The right approach

The right approach to be followed for the interpretation of the surgical treatment exclusion is the view taken by the decisions T 383/03, T 1102/02 and T 9/04, also cited by the referring board, namely its purpose-driven construction.

The Enlarged Board's statement in point 6.2.1 of the Reasons for its opinion G 1/04 that the surgical or therapeutic nature of a method claim can perfectly be established by a single method step without contravening Article 84 EPC, was essentially *obiter* and based on decision T 182/90 which fell into error on this point. The Enlarged Board simply used the point as part of its *rationale* for treating methods of treatment by therapy or surgery as an essentially one step method, in contra distinction to the inherently multi-step nature of a diagnostic method.

The wording of the statement relating to methods of surgery in point 6.2.1 of the Reasons of the Enlarged Board's opinion G 1/04

that said methods include any physical interventions on the human or animal body in which maintaining the life and health of the subject is of paramount importance, echoes that in decision T 35/99. However, this can only embrace the cases in which maintaining life and health is the purpose of the procedure. Otherwise, the exclusion is vastly, and improperly, broadened. Where the maintenance of life or health, while being important (as it always is in human activity), is only incidental to a different purpose, then the exclusion should not apply.

Summarising the conclusions on construction, the surgical treatment exclusion does not apply when the purpose of the procedure is not itself therapeutic but is something else (such as a cosmetic purpose in decision T 383/03, or for the purposes of acquiring a diagnostically useful image in decision T 9/04 or for collecting an analyte in decision T 924/05).

g) *Socio-ethical and business considerations*

It is an ethical imperative of the patent system to encourage the development of inventions which benefit the human condition; chief among these are inventions relating to medicine whether for therapy or - as in the present case - diagnosis. The patent system is needed to protect the considerable investments made in the field of medical diagnosis. Examples include magnetic resonance imaging (MRI), computed tomography (CT) and X-ray procedures. Advances in medical diagnosis are of paramount importance for society.

The ethically-based exclusion for medically-related methods in Article 52(4) EPC 1973 does not in fact achieve its aim, since product protection also hampering the medical practitioners' freedom to operate is available. It is therefore at least difficult to establish what the extent of the policy is. In its opinion G 1/04 the Enlarged Board provided welcome confirmation that

patents on methods relating to (but not consisting of) diagnoses, are not prohibited by the diagnostic method exclusion in Article 52(4) EPC 1973. Diagnostic agents are important for the enhancement of diagnostic procedures and they must be administered to the patient which will sometimes be by parenteral delivery, such as by injection either locally or systemically. If specifying the delivery of a diagnostic agent, in particular in the most interventionist form discussed in the application (injection) meant that such an examination phase invention is not patentable, then opinion G 1/04 is effectively neutered for an important sub-group of such inventions involving the use of a diagnostic agent. Furthermore, in analogy to the interpretation given by the Enlarged Board to the exclusion under Article 53(b) EPC 1973 in its decision G 1/98 with respect to plant varieties, the fact that the delivery step may encompass a "surgical step" should not mean that the step as a whole, in the higher level of abstraction as claimed, and thereby directed to any appropriate means of delivery, is also surgical.

There are more satisfactory (and nationally based) measures for protecting practitioners' activities where necessary. The more logical place for such protection is in legislation dealing with patent infringement. For example, in the United States methods of treatment by surgery and therapy and methods of diagnosis have long been patentable but a court may not issue an injunction or award damages with respect to a medical practitioner's performance of a medical activity that constitutes an infringement.

In its opinion G 1/04, point 6.1 of the Reasons, the Enlarged Board has also recognised that comprehensive protection of medical and veterinary practitioners can be achieved by other means, if deemed necessary. Furthermore, therapeutics and diagnostics companies rarely if ever seek to enforce their patents over these customers.

3. Questions 2 and 3

In the event that question 2 is to be addressed, for the reasons addressed above the claim can be left to encompass excluded subject-matter without being limited to it. Furthermore, a step addressing the delivery of the diagnostic agent could legitimately be omitted by presenting it passively in the claim, said step thereby no longer being one of the active steps of the claim. In accordance with decision G 1/03 the embodiment of delivering the imaging agent by direct injection into the heart could also be disclaimed. This is, however, not a particularly satisfactory solution, since it not only deprives the applicant of valuable protection, it would also encourage applicants to write applications in such a way that embodiments which might have to be disclaimed are not mentioned.

If, however, question 2 is answered in the negative, it is vital for the appellant to be allowed protection in the form of a second medical use claim, the potential points of doubt being whether such claims are allowable for diagnostic agents as well as the level of detail required for the use specified in the claim. The appellant is aware that the present referral does not ask these questions but it would welcome the Enlarged Board's confirmation of the appellant's understanding.

Question 3 is to be answered in the negative. The fact that data obtained by a method of the invention can be used during surgery does not mean that the method is a constitutive step of a treatment of the human or animal body by surgery. Otherwise none of the technologies used by surgeons today like endoscopic cameras which may use all manner of inventive methodologies, such as image manipulation, signal modulation and data compression could be patented merely because they could be used by a surgeon in the course of a surgical procedure.

VII. The appellant's requests

The appellant requested that question 1 be answered in the negative. Since question 1 should be answered in the negative, question 2 should not need to be answered. However, if question 2 was to be addressed, it should be answered in the affirmative. Question 3 should be answered in the negative.

VIII. The comments made by the President of the EPO

1. Case law, issues involved, Travaux Préparatoires and EPC revision

The President, after having given an overview of the relevant case law with respect to the limitation of the term "treatment by surgery" to curative activities adopted in T 383/03, discusses in detail the issues involved in the approach to the definition as adopted in that decision and reports comprehensively on the legislative history and the conclusions to be drawn from the Travaux Préparatoires to the EPC 1973 as well as to the revision work on the EPC 2000. Since these points will be addressed in detail in the reasons for the decision, the President's submissions on these points will not be further set out here but reference is also made to the file, in this respect.

2. Terminological and systematic analysis

Under Article 31(1) of the Vienna Convention a treaty is to be interpreted in good faith in accordance with the ordinary meaning to be given to terms of the treaty in their context and in the light of its object and purpose. Linguistically, the term "treatment" as used in Article 52(4) EPC 1973 is not restricted to methods serving curative purposes. Moreover, Article 52(4) EPC 1973

contains three separate alternatives relating to surgery, therapy and diagnosis. If the scope of exclusion from patentability under Article 52(4) EPC 1973 in respect of methods for treatment by surgery were as proposed in decision T 383/03, eliminating from surgical treatments all those which do not serve curative purposes, what is now quite clearly an alternative would become a mere sub-category of therapeutic methods, and therefore redundant.

3. Ratio legis of Article 52(4) EPC 1973

The prevailing view has always been that medical practice must not be hindered by patent protection. The reasons for this can be classified in two main categories, namely (a) the consideration that medical practice cannot be regarded as a branch of industry and (b) the need to ensure medical care for the public but it may seem that with time the focus has moved from the first aspect to the latter. Nowadays, the exclusion of medical methods from patentability is rather based on the principle that the exercise of medical skills should not be restricted or hindered by patents for ethical and social reasons related to ensuring the provision of medical services to the public (opinion G 1/04 and further references are cited). Therefore, the purpose of Article 52(4) EPC 1973 is to remove any obstacle to the freedom to choose the best medical treatment to be applied to a patient and to avoid any delay in the application of such medical treatment. Hence, the exclusion of Article 52(4) EPC 1973 is intended to protect patients. The dissociation from the criterion of industrial applicability will also formally have been achieved with the entry into force of the EPC 2000, since the exclusion of medical methods from patentability will appear in the systematically correct place, i.e. among the exceptions to patentability listed in Article 53 EPC. The aim of safeguarding the freedom to choose the best medical treatment uninhibited by patent law restraints cannot be restricted to methods of surgery serving curative purposes. Indeed, the most

appropriate surgical method should be freely available in every case, an aspect which acquires special significance where the use of a surgical method involves health risks for the patient. Finally, it has to be borne in mind that the patient-doctor relationship is by nature a very confidential one. Any factor which could interfere with this, such as licence fee considerations, should therefore be carefully ruled out which might however prove difficult, if patents were granted on medical methods. This also holds true for surgical treatments, regardless of their purpose. It follows that associating the formulation "methods for treatment by surgery" with the nature of the treatment while not taking into consideration its purpose would be in conformity with the *ratio legis* of Article 52(4) EPC 1973.

4. International and national patent law and practice

This part of the President's submissions will be reported in some detail here, since it will for the most part be referred to in the reasons for the present decision. However, as regards further citations of legal norms, implementing texts and decisions contained in the President's submissions reference is made again to the President's comments on file.

The PCT Rules 39.1 and 67.1 which served as model for the provision corresponding to Article 52(4) EPC 1973 mention surgical, therapeutic and diagnostic methods as three separate alternatives. These PCT provisions have a different normative function, but the "surgery" alternative is also construed as not being limited to healing treatments. Methods for cosmetic surgery may thus be excluded from search or preliminary examination.

Article 27.3(a) of the Agreement on Trade Related Aspects of Intellectual Property (hereinafter: (TRIPS Agreement), according to which members may exclude from patentability diagnostic,

therapeutic and surgical methods for the treatment of humans or animals, was also based on the PCT model. In this context too, the term "surgical methods" does not seem to be restricted to curative activities. Before its wording was aligned with the PCT, the provision was meant to read "methods for [medical] treatment for humans [or animals]".

According to the Guidelines of the Swiss Federal Institute of Intellectual Property, the term "methods of surgery" within the meaning of Article 2(2) PatG is also construed regardless of its purpose, thus including methods for cosmetic purposes or for embryo transfers.

In Germany, too, the nature of the treatment is the relevant aspect for defining "methods for treatment by surgery" within the meaning of § 5(2), first sentence, PatG. For example, a method for implanting hair was considered as being excluded from patentability under § 5(2) PatG, since the method was performed on the body using surgical instruments and required medical knowledge. The question whether the method at issue served to cure a disease or was applied only for cosmetic purposes could be left unanswered.

In the United Kingdom, the exclusion of methods for treating the human or animal body by surgery within the meaning of Section 4(2) of the Patents Act 1977 is again not limited to therapeutic surgery. Accordingly, methods of surgery for cosmetic purposes, or other non-therapeutic ends such as sterilisation, are not patentable. This approach was based in particular on decisions T 182/90 and T 35/99, but also on the decisions *Unilever Ltd. (Davis's)* *Application* and *Occidental Petroleum Corporation's Application*. In the latter, a method of embryo implantation which required the intervention of a surgeon was held to be a surgical method excluded from patentability. The UK Examination Guidelines explicitly state

that the approach taken by T 383/03 is not being followed and that the practice of the Office remains unchanged.

5. Narrow construction of the expression "methods for treatment of the human or animal body by surgery"

Even if not limited to excluding surgery for a therapeutic purpose only, a narrow construction of the scope of Article 52(4) EPC 1973 could be achieved by applying the following criteria:

Firstly, a method for treatment of the human or animal body by surgery should only fall under the exclusion from patentability pursuant to Article 52(4) EPC 1973 if the application of the method does not result in death, i.e. it is not a destructive method.

Secondly, it could be considered whether methods comprising both surgical and non-surgical steps are to be excluded from patentability or whether a different approach should be adopted.

Thirdly, it could be argued that not every non-insignificant intervention on the human or animal body should be considered as treatment by surgery within the meaning of this provision.

For reasons of legal certainty, as stated in opinion G 1/04 in relation to diagnostic methods, the assessment should not depend on whether the method under consideration is carried out by a medical or veterinary practitioner.

The call for a narrow scope could however be based on consideration of why certain activities should be kept free from patent law restraints. Since Article 52(4) EPC 1973 is also intended to protect the subject on which the method is carried out, it could be relevant to ask whether the method concerned goes beyond a certain degree of invasiveness and/or involves harmful side-effects or

health risks for the subject. This approach could help to ensure that certain "superficial" methods are not contested as surgical despite being non-surgical in the everyday sense of that term. Examples are given by the President. On the other hand, methods for purely or mainly non-therapeutic purposes which comprise a substantial intervention ("Invasion") on the living body, e.g. sex-change operations, sterilisation, operative removal of wrinkles, breast enlargement or reduction, would continue to be excluded from patentability.

Methods involving subcutaneous, intramuscular or intravenous injection have been contestable under Article 52(4) EPC 1973 ever since decision T 182/90. The same applies to catheterisation. Such methods would presumably also involve a degree of invasiveness and therefore continue to be contestable as surgical methods under Article 52(4) EPC 1973. Admittedly, a clear line cannot be easily drawn, so that the exact definition of a criterion based on the degree of invasiveness might not be possible. However, under the current practice, there is no exact definition of what constitutes a "non-insignificant" intervention qualifying as "treatment". However, as this existing criterion is applied on a case-by-case basis with quite reasonable, broadly acceptable results, the same could equally be envisaged for a new criterion. Within such a framework, where a non-insignificant intervention also needs to be sufficiently invasive in order to be excluded from patentability, a method which comprised a step consisting in injecting a contrast agent into the heart would most probably fulfil both criteria and therefore be regarded as a treatment by surgery within the meaning of Article 52(4) EPC 1973.

6. Differentiation between human beings and animals?

The methods of treatment by surgery at issue were not yet in the text of then Article 52(4) EPC 1973 when the question of

maintaining or deleting the reference to the animal body was debated during the drafting of EPC 1973. Nonetheless, Article 52(4) EPC 1973 addresses the treatment of both the human and the animal body without distinction.

The first draft of the EC Directive of 1988 on the legal protection of biotechnological inventions contained a provision stating that the exclusion from patentability or from industrial applicability of methods practised on the animal body for the purpose of surgical treatment or diagnosis only apply if such methods are practised for therapeutic purposes. This "interpretation rule" was based on the consideration that the legislator had insufficiently foreseen the development of surgical methods that were not therapeutic in nature, but industrial. However, the provision was contained neither in the second draft of the Directive nor in the adopted version. The EPC legislators did not take up this issue when revising the EPC in November 2000, but left the substance of Article 52(4) EPC 1973 untouched. Their declared intention was to maintain the current practice while transferring the substance of the provision to the list of exceptions from patentability. For the term "treatment by surgery" to be interpreted differently in respect of animals and human beings, this would however have to be expressed somehow in the wording of Article 52(4) EPC 1973 - particularly since neither the history of the provision itself nor legal provisions in neighbouring fields (Biotechnology Directive) offer any hints in this respect.

7. Conclusions

Question 1: On the basis of the above considerations the proposed approach would result in the conclusion that the injection of a contrast agent into the heart of a living human being or animal should be considered as a treatment of the human or animal body by surgery within the meaning of Article 52(4) EPC 1973. A method comprising this step should be excluded from patentability.

Question 2: The principles of decision G 1/98 are not applicable to the present situation as Article 53(b) EPC is - only - based on the idea that European patents should not be granted for subject-matter for which the grant of patents was excluded under the ban on dual protection in the UPOV Convention of 1961. Allowing claims relating to methods of treatment as long as surgical steps are not explicitly claimed, would tend to cause more problems. An objection under Article 52(4) EPC 1973 would then be quite easily circumvented by simply using appropriately generalised terminology.

A positive limitation to the "uncritical" methods of administration disclosed in the description could be an appropriate solution in all three cases. If this were not feasible, a disclaimer as explicitly envisaged in decisions G 1/03 and G 2/03 could certainly be considered. It would then be necessary to decide whether a disclaimer using, for example, the terms "non-surgical" or "non-invasive" fulfils, in particular, the requirement of clarity under Article 84 EPC.

Amendments to the independent claim by omitting or deleting the surgical step must comply in particular with Article 84 and Article 123(2) EPC. Compliance can only be assessed individually in each case. In particular, where the surgical step is essential for a clear and complete definition of the invention, an omission or deletion would not be possible in view of Article 84 EPC.

Amendments designed to make clear that the surgical step precedes or follows the claimed method but does not form part of it (e.g. "pre-delivered", "pre-implanted" or "pre-inserted" instrument), should be judged according to the same criteria as the omission or deletion of the surgical step. Such a temporal limitation may undoubtedly be possible in certain clear-cut situations. If, however, a surgical step is only performed for the claimed (non-

surgical) method and is in close temporal, causal and functional association with it, such an amendment would seem to be problematic. Accordingly, a temporal limitation seems to be impossible in cases where the non-surgical steps of the method are interlinked with a number of surgical steps, for instance in iterative techniques, or when, after insertion, the instrument is further manipulated in the body, or when the position of a patient is continually adjusted during a surgical intervention.

Question 3: When a claimed method in itself cannot be regarded as a method of treatment of the body by surgery, the mere fact that the method is useful for a surgical treatment does not confer surgical character on the claimed method. The decisive factor is whether there is a functional link or a physical causality between the claimed method and the surgical intervention. A mere temporal concurrence of an imaging method with a surgical intervention does not seem to be sufficient. Accordingly, a diagnostic imaging method where the progress of a surgical intervention is monitored and evaluated, even if performed in real time and immediately allowing the surgeon to decide on the course of action to be taken but leaving him free in his decision about the treatment to be performed, should not be regarded as surgical as long as it remains a mere imaging method without itself causing any physical intervention on the patient.

On the other hand, "active" methods relating for example to the automated navigation of surgical tools ("robotic surgery"), in which the image information obtained is immediately used to control the motion of the tool within the human body, for instance by closed-loop feedback control, should be regarded as surgical, as there would be a functional link or a physical causality between the claimed method and the surgical intervention.

IX. The submissions of the Amici curiae

Amicus curiae briefs were received from the European Federation of Neurological Associations ("EFNA") and the European Parkinson's Disease Association ("EPDA"), the epi, "Universitäts-Klinikum Hamburg - Eppendorf" and "Bundesärztekammer", Philips Intellectual Property and Standards, "Deutsche Gesellschaft für Hals -, Nasen - und Ohrenheilkunde", the Institute for Scientific Policy Analysis ("SCIAN"), Roche Diagnostics, CIPA, IIPi, Dr. Martin Prince and European Patent Attorney Udo W. Altenburg.

1. Those in favour of a narrow construction of the exclusion basically argued along the lines of the submissions made by the appellant. The Enlarged Board was also asked to consider the questions more broadly than they have been worded, i.e. not limited to "imaging" methods but also considering other methods aimed at measuring physiological parameters which require physical intervention.

2. Those in favour of an interpretation not limiting the exclusion to surgical methods for a therapeutic purpose essentially argued:

There were numerous examples of methods which although not being directed to maintaining health and life were to be characterised as surgery in the medical sense (e.g. plastic surgery, organ removal and others). It was very important that with respect to such methods medical practitioners were not hindered by patents in their choice of appropriate methods for treatment. Therefore methods for surgical treatment ought to be excluded from patentability also where they were not directed to therapeutic purposes.

Any other interpretation would make the distinction between methods for surgical or therapeutic treatment redundant which however existed for very good reasons.

3. Comments on referred questions 2 and 3 were also made.

Reasons for the decision

1. *Applicable provisions*

1.1 *As regards the admissibility of the referral*

The present referral was made before the entry into force of EPC 2000. According to Article 7(1) of the Act revising the Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973, last revised on 17 December 1991, the "revised version of the Convention shall apply to all European patent applications filed after its entry into force.... It shall not apply to ... European patent applications pending at that time, unless otherwise decided by the Administrative Council of the European Patent Organisation". Since Article 112 is not mentioned in Article 1 of the decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 as a provision which would thereby apply to European patent applications pending at the time of entry into force of the revised EPC, Article 112 EPC 1973 continues to apply to European patent applications pending upon entry into force of the revised Convention. Hence, the admissibility of the present referral is to be determined on the basis of Article 112 EPC 1973.

This is also justified for reasons of legal certainty, which require that it be possible to determine the admissibility of a procedural act at the point in time when it is performed. This includes that it is the law applicable at that time which should apply (see also J 10/07, OJ EPO 2008, 567, point 1 of the Reasons, T 1366/04 of 16 April 2008, point 1.2 of the Reasons).

Article 112 EPC, although not having been amended in the revision process, was amended later by the Administrative Council, making use of the power entrusted to it under Article 3(1) of the Act revising the Convention on the Grant of European Patents to draw up a new text of the European Patent Convention, in which the wording of the provisions of the Convention shall be aligned, if necessary, in the three official languages. As regards Article 112, this "alignment" has resulted in the English version of Article 112(1) having been amended from reading "if an important point of law arises" to "if a point of law of fundamental importance arises". It does not appear *a priori* evident that this "alignment" of the English text is not associated with any change in the overall meaning to be given to Article 112(1), even when taking into account the equally authentic French and German texts of that Article, in accordance with Article 177(1) EPC 1973. Hence, it cannot be said to be totally irrelevant from the outset whether the old or the new version of Article 112 EPC applies. Therefore the Enlarged Board will examine the admissibility of the present referral on the basis of Article 112 EPC 1973.

1.2 As regards substantive law to be applied

The referring decision has raised issues in connection with the application of Article 52(4) EPC 1973. By the EPC revision the substance of Article 52(4) EPC 1973 was transferred to Article 53(c) EPC. According to Article 1, point 1 of the decision of the Administrative Council of 28 June 2001 on the transitional provisions under Article 7 of the Act revising the European Patent Convention of 29 November 2000 (OJ EPO 2001, Special edition No. 4, 139) Article 53 EPC shall apply to European patent applications pending at the time of its entry into force. Hence, since the referring Board will have to apply Article 53(c) EPC when deciding

the case before it the Enlarged Board will answer the questions referred to it on the basis of the EPC 2000.

2. Admissibility of the referral

Pursuant to Article 112(1)(a) EPC 1973 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.

The referring decision has identified different interpretations of the exclusion from patentability under Article 52(4) EPC 1973 of treatments by surgery in the jurisprudence of the boards of appeal leading to different results as regards the patentability of subject-matter potentially falling under that exclusion. The appellant has contested that there was a non-uniform application of the law in the cited jurisprudence.

The question of which interpretation of the term "treatment by surgery" in Article now 53(c) EPC is the right one is undoubtedly an important point of law. It is therefore not necessary to decide whether the decisions referred to reveal a non-uniform application of the law within the meaning of Article 112(1) EPC 1973 or whether, all these decisions having been given by Board 3.2.02, albeit in different compositions, they rather reflect a change of mind having taken place in the jurisprudence of that Board.

During the first-instance procedure, the examining division only addressed the issue of exclusion of the claimed invention from patentability pursuant to then Article 52(4) EPC 1973. The referring Board has taken the position that if the appeal was allowed, it would be appropriate to remit the case to the examining division for further prosecution. Hence, a decision on the

questions referred to the Enlarged Board is required before a decision on the appeal can be taken by the referring Board.

3. Question 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?

3.1 Narrow interpretation of exclusions - the Vienna Convention

The appellant, referring to case law of the boards of appeal (see the decisions cited by the appellant in point 46 of its submissions) and most of the *amici curiae* submit that on the basis of the Vienna Convention a principle of narrow interpretation of exclusions from patentability should apply, since according to Article 4(3) EPC it is the task of the Organisation to grant European patents.

It is established in the jurisprudence of the Enlarged Board of Appeal ever since decision G 5/83 (OJ EPO 1985, 64, points 3 et seq. of the Reasons) that the principles of interpretation of Articles 31 and 32 of the Vienna Convention are to be applied to the interpretation of the EPC even though its provisions do not apply to the EPC *ex lege*.

According to Article 31(1) of the Vienna Convention a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. Further means of

interpretation including in Article 32 the preparatory work of the treaty are then defined but there is no mention in the said provisions of any principle of narrow or broad interpretation, be it only of exclusions, and decision G 5/83 also does not say so.

Hence, no general principle of narrow interpretation of exclusions from patentability which would be applicable *a priori* to the interpretation of any such exclusions can be derived from the Vienna Convention. Rather, the general rule in Article 31, point 1 of the Vienna Convention that a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose must apply to the exclusion clauses contained in the EPC in the same manner as to any other provision, the latter including those positively defining the requirements for patentability.

If the interpretation of the provision concerned according to these principles of interpretation leads to the result that a narrow interpretation is the right approach then and only then such restrictive meaning is to be given to it.

Admittedly, when it comes to considering the impact of the context of a provision, the fact that a provision is an exclusion to a general rule is not without any bearing on its interpretation but this aspect is only one of the factors determining what the right interpretation of the provision concerned is. At least equally, if not more important, is, besides the ordinary meaning to be given to the wording of the provision, that the provision is interpreted in such a manner that it takes its effect fully and achieves the purpose for which it was designed. As has been said before, this must apply to an exclusion clause in the same manner as to any other requirement for patentability.

