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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
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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.

In its opinion G 1/04, OJ EPO 2006, 334, point 6 of the Reasons, the Enlarged Board stated - thereby referring to decisions of the boards of appeal having acknowledged the existence of such an *a priori* principle - that the "frequently cited principle", according to which exclusion clauses from patentability laid down in the EPC are to be construed in a restrictive manner, does not apply without exception. Interestingly, in that opinion concerning the definition of the term diagnostic methods practised on the human or animal body, the Enlarged Board came to its conclusion that the said exclusion was indeed to be interpreted narrowly only after a thorough investigation of the wording and the purpose of the exclusion clause concerned.

The same approach is also transparent from the Enlarged Board's more recent decision G 2/06, OJ EPO 2009, 306. In that decision the Enlarged Board was concerned with the interpretation of the exclusion from patentability of biotechnological inventions relating to uses of human embryos for industrial or commercial purposes under Rule 28(c) EPC (and the corresponding Article 6(2) of the EC Directive on the legal protection of biotechnological inventions). In that decision the Enlarged Board does not mention the existence of a principle of narrow construction of exceptions from patentability at all. Instead, as method for interpreting the extent of the prohibition the Enlarged Board goes directly to the rules of interpretation laid down in the Vienna Convention, i.e. it looks at the terms of the provision and its object and purpose (point 16 of the Reasons). No mention is ever made in the further course of the reasons of that decision of any narrow or restrictive view which would have to be taken because the said prohibition was an exception to patentability and in the present case the Enlarged Board will proceed in the same way.

3.2 Does the presence of one surgical step in a multi-step method exclude that method from patentability?

It is clear from question 1 and the claims underlying the referral that the step potentially to be considered as a surgical step is only one step in a multi-step method and the claimed imaging method is not directed to surgery as such. Hence, if the answer to the above question was no, then referred question 1 would also have to be answered in the negative.

In one alternative question 1 is directed to the situation that the claimed method comprises a surgical step. The Enlarged Board notes that in the case underlying the referral there is at present no claim on file in which the potentially surgical step, i.e. the injection into the heart is claimed as such as one of the method steps but the feature referring to the delivery of the imaging agent to the subject (the patient) in independent claims 1, 11 and 17 encompasses the embodiment that said delivery is performed via injection (and the like) into the heart.

However, since in the case underlying the referral the appellant could still draw up a claim comprising the step that the imaging agent is delivered to the patient by an injection into the heart (by limitation or in a dependent claim), should the Enlarged Board not consider that as being excluded under Article 53(c) EPC, the Enlarged Board holds it appropriate to include this aspect of the question in its answer. This is all the more so, since the considerations which determine the answer to be given apply to both alternatives in the same manner and no distinction is made in this respect in the jurisprudence.

3.2.1 Opinion G 1/04

In its opinion G 1/04, loc cit, point 6.2.1 of the Reasons, the Enlarged Board stated:

"According to the established jurisprudence of the boards of appeal, a method claim falls under the prohibition of Article 52(4) EPC 1973 if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy. ... It follows that the surgical or therapeutic nature of a method claim can perfectly be established by a single method step without contravening Article 84 EPC."

3.2.2 The counterposition

This approach has been criticised by the appellant and by the *amici curiae*. They argue that such a broad view of the exclusion is not necessary to give effect to the stated underlying policy of a medical practitioner's, specifically, in the present context, a surgeon's freedom to practise. If a surgeon carries out only one surgical step of a multi-step method he or she will not be practising the claim as a whole, so there is no need for any protective exclusion. If, on the other hand, 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. Furthermore, the statement in opinion G 1/04 and its reference to "established jurisprudence" was essentially *obiter* and was based on decision T 182/90 (which fell into error on this point) and the later decisions following that decision. There was, however, no earlier case law on the matter.

3.2.3 Merits of the counterposition

3.2.3.1 The principle that the presence in a multi-step method of one step excluded from patentability by Article 52(4) EPC 1973 makes the claim unpatentable has been derived in the jurisprudence of the boards of appeal as an *argumentum e contrario* from Article 52(3) EPC 1973 providing for the inventions enumerated in Article 52(2) EPC 1973 that they are excluded from patentability to the extent to which a European patent application or European patent relates to such subject-matter or activities as such. No such *provisio* limiting the exclusion from patentability existing in Article 52(4) EPC 1973, the boards held that methods excluded from patentability under Article 52(4) EPC 1973 cannot be the subject-matter or part of the subject-matter covered by the claim. The said principle has been uniformly applied to the exclusion of therapeutic methods from patentability as well as to surgical methods (see e.g. T 820/92, OJ EPO 1995, 113, point 5.4 and 5.5 of the Reasons, in which several previous decisions concerning methods for therapy are referred to but T 182/90 is also cited).

In the above cited passage of its opinion G 1/04 the Enlarged Board clearly and explicitly approved that jurisprudence, as regards method steps for treatment by surgery or therapy. Whether an *obiter dictum* or not, the cited passage is drafted in such clear terms as to leave no doubt that the Enlarged Board thereby endorsed the principle developed in the jurisprudence of the boards of appeal that a method claim falls under the prohibition of Article 52(4) EPC 1973 if it includes at least one feature defining a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy. The said principle having by then been established in the jurisprudence long since, it is irrelevant whether it was first acknowledged in decision T 182/90. Furthermore, no mention at all is made in opinion G 1/04 of decision T 182/90. Hence, the appellant's contention that the

cited statement in opinion G 1/04 was based on decision T 182/90 is not corroborated by any fact.

3.2.3.2 Even though it may not be entirely unreasonable to assume that a practitioner, practising a single therapeutic or surgical step of a multi-step method would not normally thereby infringe a patent claim directed to that multi-step method, any issues of infringement ultimately depend on the construction of the applicable national laws. It is also common ground that the socio-ethical consideration underlying the exclusion of therapeutic, surgical and diagnostic methods from patentability to free the medical profession from possible constraints imposed on them by patents is of relevance for the interpretation of Article 53(c) EPC. There is, however, no term in Article 53(c) EPC which would allow concluding that hampering of the practitioner's freedom is a prerequisite for the exclusion to apply in the individual case considered. The only condition defined in Article 53(c) EPC for a claim to be excluded from patentability is that it contains subject-matter being a method for treatment of the human or animal body by surgery or therapy or a diagnostic method. If so, it is excluded from patentability and it is then irrelevant whether in the individual situation under consideration a medical practitioner would or could infringe the claim. That this approach is right becomes clear when considering the appellant's argument (some *amici curiae* also argued in this way) submitted in favour of a narrow construction of the exclusion clause that product protection is available for medically-related products although these may also hamper the medical practitioner's freedom to operate. Whether correct or not, and particularly if correct, this argument shows that the conditions of patentability on the one hand but also those for an exclusion to apply are dependent on the general decision made by the legislator by the terms incorporated in the corresponding provisions on how to draw the line between patentable and unpatentable subject-matter.

Even if it was true that national legislations like the US law allowing patenting but providing that no sanctions may be issued with respect to a medical practitioner's performance of a medical activity that "constitutes an infringement" provide better solutions, the European legislator did not adopt it. On the contrary, in the EPC revision the European legislator deliberately maintained the exclusions under Article 52(4) EPC 1973 in the now Article 53(c) EPC. Thereby the principle has been confirmed that medical and veterinary practitioners' freedom to use the best available treatments to the benefit of their patients uninhibited by any worry that some treatment might be covered by a patent is protected by excluding these activities from patentability. Excluding from patentability also multi-step methods which comprise or encompass a therapeutic or a surgical step serves to give full effect to that legislative purpose. Therefore, the principle developed in the jurisprudence that the presence of one therapeutic or surgical step in a multi-step method excludes that method from patentability is not only formally justified by the fact that the exclusion under Article 53(c) EPC does not contain any limitation as to the defined methods being excluded only when claimed as such. More importantly, it is also justified as to substance, i.e. it serves to enable achieving the legislative purpose served by the exclusion.

3.2.4 Relevance of a further statement in opinion G 1/04 referred to by the appellant

As support for its further position that the problem of how to protect the physician, if any, be better solved by national (infringement) law than by an exclusion from patentability the appellant further relied on a statement in opinion G 1/04, loc.cit., point 6.1 of the Reasons, where the Enlarged Board said in

connection with its narrow definition of the term "diagnostic methods practiced on the human or animal body":

"Since a comprehensive protection of medical and veterinary practitioners may be achieved by other means if deemed necessary, in particular by enacting legal provisions on the national level of the Contracting States of the EPC, introducing a right to use the methods in question, a narrow interpretation of the scope of the exclusion from patentability referred to above is therefore equitable".

This passage is correctly interpreted when read in its context and not taken in isolation. Its context is first, that in that very same opinion the Enlarged Board has explicitly endorsed the view that a method claim falls under the prohibition of Article 52(4) EPC 1973 if it includes at least one feature defining a physical activity or action that constitutes a method for treatment of a human or animal body by surgery or therapy. Second, as derives from the sentences preceding and following the above quoted statement in point 6.1 of the Reasons, as well as from point 6.3 of the Reasons, these considerations relate to the difficulty, if not impossibility, perceived by the Enlarged Board of defining the persons that were considered to be such practitioners, on a European level within the framework of the EPC. It is then said that for reasons of legal certainty, the European patent grant procedure may not be rendered dependent on the involvement of such practitioners. This is more broadly set out in point 6.3 of the Reasons, where the importance of legal certainty is stressed again and several reasons are given why, whether a method is a (here: diagnostic) method within the meaning of Article 52(4) EPC 1973 "should neither depend on the participation of a medical or veterinary practitioner ..., nor on the fact that all method steps can also, or only, be practised by medicinal or non-medicinal support staff ...". Hence, in this context the argument that the protection of practitioners can be

achieved by other means if deemed necessary only served to explain that the restrictive view the Enlarged Board found necessary to adopt in the interest of legal certainty when interpreting the exclusion of diagnostic methods under Article 52(4) EPC 1973 as only meaning such methods that also comprise the diagnostic step *strictu sensu*, would not lead to totally unjustified results since there was the possibility for the national legislator to protect medical and veterinary practitioners more comprehensively if deemed necessary.

Hence, that passage rather confirms that the interpretation of the exclusions from patentability in Article 53(c) EPC is not to be made dependent on whether or not there would be infringement.

3.2.5 Conclusion

Concluding from the above, the Enlarged Board sees no good reason not to uphold the principle confirmed in opinion G 1/04, point 6.2.1 of the Reasons, and underlying the whole body of hitherto practice and jurisprudence that a method claim falls under the prohibition of patenting methods for treatment by therapy or surgery now under Article 53(c) EPC if it comprises or encompasses at least one feature defining a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy.

3.3 *Is the exclusion of treatments by surgery limited to surgery for a therapeutic purpose?*

The appellant has argued that that is not the question to be answered in the present context since the referred question is concerned with a method for a diagnostic purpose only. Even if the meaning of the term surgery was not limited to surgery for a therapeutic purpose the exclusion would still not apply to methods

for a diagnostic purpose even when these methods comprise or encompass a surgical step. When applying methods for a diagnostic purpose it was often necessary to make use of a potentially surgical step, e.g. for administering a contrast agent, in order to achieve diagnostically useful results. Regarding such methods as being excluded from patentability would undermine the narrow construction of the exclusion of diagnostic methods from patentability adopted in opinion G 1/04 having expressly allowed the patenting of methods which without being diagnostic methods *strictu sensu* are directed to yield diagnostically useful results.

In order to be patentable a claimed invention must fulfil all requirements for patentability and must not be excluded from patentability by any of the exclusions foreseen in the EPC. The three alternative exclusions in Article 53(c) EPC are thus cumulative requirements. In order to be patentable a claimed method must neither be a therapeutic nor a surgical nor a diagnostic one. Hence, the invention underlying the referral even though not being excluded from patentability as a diagnostic method within the meaning of Article 53(c) EPC could nevertheless still be excluded from patentability as a method for treatment by surgery within the meaning of Article 53(c) EPC if decision T 383/03 limiting the exclusion to treatments for a therapeutic purpose was not to be followed.

3.3.1 *The meaning of the wording of the provision*

In decision T 182/90, OJ EPO 1994, 641, the Board explored the meaning of the term "surgery" in general and found that in today's medical and legal linguistic usage, non-curative treatments are, if carried out by surgery, regarded as surgical treatments (points 2.2 to 2.4 of the Reasons). This statement has not been put into question as such in the later decisions. What is contested is that

Article 52(4) EPC 1973 intended to exclude these treatments from patentability.

The fact that the exclusion of methods of treatment by surgery from patentability is one of three alternative exclusion conditions *prima facie* indicates that the situations covered by each of the alternatives were not meant to be identical since the inclusion of the term "by surgery" in Article 53(c) EPC would be pointless if the meaning of that alternative was already entirely contained in the exclusion from patentability of the other alternative, i.e. the "treatments by therapy". In this context it is noteworthy that the exclusion condition referring to "surgery" was not initially contained in the draft EPC but was introduced later than the exclusions relating to therapeutic and diagnostic methods. Hence, it is useful to investigate the legislative history and the purpose of the insertion of the term "surgery" before a definition of the scope of that term is undertaken.

3.3.2 Assistance derivable from legal history

3.3.2.1 The EPC 2000

In the EPC revision the text of then Article 52(4) EPC 1973 was transferred to Article 53(c) EPC. The fiction contained in Article 52(4) EPC 1973 that methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body "shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1" was deleted for the reason that it was undesirable to uphold this fiction since methods of treatment and diagnostic methods are excluded from patentability in the interest of public health. It was considered preferable to include these inventions in the exceptions to patentability and to group these together in Article 53 EPC. The remaining text of former Article 52(4) EPC 1973

remained unchanged and it was understood that shifting Article 52(4) EPC 1973 to Article 53(c) EPC 2000 entailed no change to the EPO practice (see Revision of the European Patent Convention (EPC 2000), Synoptic presentation EPC 1973/2000 - Part I: The Articles, OJ EPO 2007, special edition 4, 50).

In its opinion G 1/04, *loc.cit.*, points 10 and 11 of the Reasons, the Enlarged Board has endorsed this view by taking the position that its interpretation of the scope of exclusion from patentability under existing Article 52(4) EPC 1973 in respect of diagnostic methods practised on the human or animal body would remain valid when EPC 2000 comes into force.

Hence, it is the preparatory work to the EPC 1973 which is to be considered when looking for the right meaning to be given to the term "treatment by surgery".

3.3.2.2 The EPC 1973, the *Travaux Préparatoires*

a) In decision T 383/03, OJ EPO 2005, 159, Technical Board of Appeal 3.2.02 based its conclusion that the intention of the legislator was only to exclude from patentability those treatments by surgery which concern curative activities, i.e. which are suitable for maintaining or restoring the health, the physical integrity, and the physical well-being of a human being or an animal and to prevent diseases (point 3.2b) at the end and 3.2c) of the Reasons), on two documents from the *Travaux Préparatoires*. The first document is the Proceedings (at that time only drawn up in German and French) of the 15th meeting of the working group "Patents" held in Brussels from 19 to 29 October 1964, 11821/IV/64-D, page 4. The statement referred to is that "Heilmethoden der Human- und Veterinärmedizin einschließlich diagnostischer Verfahren vom Begriff der Erfindung ausgenommen sind". In its French version 11821/IV/64-F the document reads that the aim of the provision is

to "indiquer l'exception des méthodes curatives du corps humain ou des animaux y compris les méthodes de diagnostic". The second document relied on is the Minutes of the 6th meeting of the Inter-Governmental Conference for the setting up of a European System for the Grant of Patents (Luxembourg, 19 to 30 June 1972), BR/219 e/72, where it is stated in point 27 in connection with a discussion on the treatment of animals that "the intention behind this text was merely to exclude from patentability all therapeutic treatments practised on animals, falling within the meaning of treatment intended to cure or alleviate the suffering of animals".

b) As regards the first document relied on by Board 3.2.02, it must be noted that at the point in time when document 11821/IV/64 was drawn up, an exclusion of surgical methods from patentability had not been considered as yet and the statement in the said document concerned the suggested incorporation in the then Article 9 of an exclusion from patentability of therapeutic and diagnostic methods only. It is in this context that the statement therein that "Heilmethoden der Human- und Veterinärmedizin einschließlich diagnostischer Verfahren vom Begriff der Erfindung ausgenommen sind" "indiquer l'exception des méthodes curatives du corps humain ou des animaux y compris les méthodes de diagnostic" is to be placed and no conclusion as regards any meaning the legislator wanted to give to the later incorporated term "treatment by surgery" can be derived from these remarks.

c) The exclusion from patentability of treatments by surgery was - only - incorporated into draft Article 9(2) during the meeting of Working Party I (Luxembourg, 8 - 11 July 1969, see the minutes of the meeting, BR/7e/69, point 22), in order to bring it into conformity with the corresponding draft Rule 39.1 PCT but no further information as to how the European drafters understood the term "treatment by surgery" so incorporated into the draft EPC is apparent from this document.

As regards Rule 39.1 PCT, the Records of the Washington Diplomatic Conference on the PCT, 1970 (Rule 39, points 1174 et seq.) show that the reason for introducing such a rule was the fear that International Searching Authorities would have difficulties in searching prior art for subject-matter that was unpatentable under national law. The Records report in this context a remark from the Japanese delegate that methods of treatment of the human body by surgery or therapy are not patentable under the patent law of Japan. However, no particular information on the reason for including surgical methods as a separate alternative in Rule 39.1 draft PCT appears therein.

d) In the following deliberations on the draft EPC a long discussion developed around the reference of the exclusion to "animals" (not hitherto in the draft EPC texts). It was suggested from various sides that that reference be deleted on the grounds

(i) that it would be difficult to distinguish between methods of breeding in animals and methods protecting animals from disease (Minutes of the 9th meeting of Working Party I held from 12 to 22 October 1971 in Luxembourg, BR/135 e/71, point 94),

(ii) in view of the difficulty of distinguishing between strictly veterinary methods of treatment and other methods, concerning stock-raising or sterilisation of certain species of insects, for example, which would be clearly of a more industrial nature (Minutes of the 5th Meeting of the Inter-Governmental conference for the setting up of a European System for the Grant of Patents, Part II, Hearing of the non-governmental international organisations ..., Luxembourg, 26 January to 1 February 1972, BR/169 e/72, point 17),

(iii) to enable jurisprudence to make a distinction between veterinary treatment and cases which were more typically industrial (i.e. the above mentioned examples), Minutes of the 5th Meeting of the Inter-Governmental conference ..., parts 1 and 3, Luxembourg, 24-25 January and 2-4 February 1972, BR/168e/72).

e) The only document explicitly addressing the issue as to whether surgical treatment of animals not intended for therapeutic purposes, but on the contrary for destructive purposes (e.g. the sterilisation of insects) was included in the provision, is the document cited by the appellant, i.e. the Report on the 11th meeting of Working Party I held in Luxembourg from 28 February to 3 March 1972, BR/177 e/72. It is noted therein in point 9(d): "The Working Party was of the opinion that treatment of this kind was not in fact intended to be included in this provision, but did not consider it necessary to draft a text stating this explicitly".

3.3.2.3 Conclusions from the Travaux Préparatoires

Hence, it appears that the question of the patentability of certain kinds of treatments of animals was perceived as being more generally concerned with finding an appropriate distinction between methods for the industrial exploitation of animals which should be patentable and methods for the therapeutic treatment of animals which were to be excluded from patentability on humanitarian grounds and in the interest of public health (BR/168 e/72, point 32). However, neither document BR/177/ e/72 nor any other document from the *Travaux Préparatoires* including the document cited by Board 3.2.02 reflect the general view that only such surgical methods as are of a therapeutic nature were intended by the legislator to be excluded from patentability by the wording chosen in Article 52(4) EPC 1973.

3.3.2.4 Later legislative work done

The same still transpires from the wording which was eventually adopted for Directive 98/44/EC of the European Parliament and the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ EPO 1999, 101). The President reports (see Facts and Submissions, VIII, 6, above) that the first draft of the EC Directive of 1988 contained an "interpretation rule" 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, based on the consideration that the legislator had insufficiently foreseen the development of surgical methods that were not therapeutic in nature, but industrial. However, besides that it only concerned animals, the said rule was contained neither in the second draft of the Directive nor in the adopted version. Recital 35 of the Directive only states that the Directive is without prejudice to the provisions of national patent law whereby processes for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are excluded from patentability. Furthermore, the EPC legislators also 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.

3.3.2.5 Conclusion on point 3.3.2

Hence, what would be the normal reading of the wording of Article 53(c) EPC as a provision containing three alternatives, i.e. that these alternatives are different in scope, and that, as a consequence, the exclusion of "treatments by surgery" cannot be seen as limited to surgery which is performed for a therapeutic

purpose, since it would then already be entirely covered by the exclusion of therapeutic methods from patentability, appears not to be in conflict with but rather to be supported by the course of the preparatory work for the EPC 1973 and by the outcome of later legislative initiatives.

3.3.3 The jurisprudence of Board 3.2.02 referred to by the referring Board

In decision T 182/90, OJ EPO 1994, 641, the Board of Appeal acknowledged by referring to the Guidelines for Examination that even though this may not be true in all cases, the term "surgery" in principle defines the nature of the treatment rather than its purpose.

In today's medical and legal linguistic usage the term "treatment" is not restricted to a treatment serving a curative purpose but may also include treatments for other, non-curative purposes such as cosmetic treatment, the termination of pregnancy, castration, sterilisation, artificial insemination, embryo transplants, treatments for experimental and research purposes and the removal of organs, skin or bone marrow from a living donor. When carried out by surgery, these treatments are regarded as surgical treatments. (Points 2.2, 2.4 and 2.5.2 of the Reasons).

This view was still confirmed in decision T 35/99, OJ EPO 2000, 447, where it was held (see the Headnote) that those physical interventions on the human or animal body which, whatever their specific purpose, give priority to maintaining the life or health of the body on which they are performed, are "in their nature" methods for treatment by surgery within the meaning of Article 52(4) EPC 1973. Therefore cosmetic surgery, and generally all physical interventions aimed at altering functions of the living body (e.g. castration to bring about changes in body functions linked to sex),

as well as the removal of body parts (e.g. for transplantation) are also covered by the exclusion (point 4.1 of the Reasons). Only such procedures whose end result is the death of the living being "under treatment", either deliberately or incidentally, i.e. "destructive treatments" are not covered by the exclusion since with the exclusion the legislator has laid down a separate framework for the medical sphere (point 4 seq. of the Reasons). Hence, a method comprising the steps of inserting a catheter into the heart was regarded as being excluded from patentability.

However, in decision T 383/03, OJ EPO 2005, 159, the Board then decided that where a method, although involving a non-insignificant intentional physical intervention which is to be regarded as a surgical operation, is clearly not potentially suitable for maintaining or restoring the health, physical integrity, or physical well-being of a person or animal, but merely results in an aesthetic improvement of the appearance of the person the claims are directed to a "cosmetic method" which is not to be considered as falling under the exclusion of protection foreseen in Article 52(4) EPC 1973 (point 3.4 et seq. of the Reasons). As a consequence, the claimed method for hair removal using optical radiation was considered patentable.

Although the later decisions T 1102/02 of 13 July 2006 and T 9/04 of 8 September 2006 cited by the referring Board appear to have been primarily based on the ground that the claimed inventions were regarded as purely technical methods only directed to the operating of the devices used and not concerned at all with a method for treatment of the human or animal body within the meaning of Article 52(4) EPC 1973 (see below under 4.3.2), both decisions furthermore formally confirmed the view taken in decision T 383/03, by referring to it and by stating that the methods in suit were "not a method suitable or potentially suitable for maintaining or restoring the health, the physical integrity, and the physical

well-being of a human being or animal and to prevent diseases (see T 383/03, OJ EPO 2005, 159, points 3.2 to 3.4)" (T 1102/02, point 3 of the Reasons, T 9/04, point 6 of the Reasons).

3.3.4 Guidelines for Search/Examination

The Guidelines for Examination in the European Patent Office in their April 2009 version continue to apply the approach that surgery defines the nature of the treatment rather than its purpose. They further state that thus, for example, a method of treatment by surgery for cosmetic purposes or for embryo transfer is excluded from patentability (C-IV, 4.8.1).

The PCT International Search and Preliminary Examination Guidelines specifically state in Part III, Chapter 9, point 9.10: "surgery is not limited to healing treatment, being more indicative of the nature of the treatment; methods of cosmetic surgery may thus be excluded from search or preliminary examination". Earlier on under point 9.09 it is said that "a search or preliminary examination on a cosmetic treatment involving surgery need not, however, be carried out (see the last sentence of paragraph 9.10)".

3.3.5 Opinion G 1/04

In its opinion G 1/04, loc. cit, the Enlarged Board stated in point 6.2.1 of the Reasons that "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".

In that opinion the Enlarged Board was primarily concerned with defining the meaning of the exclusion from patentability of diagnostic methods under Article 52(4) EPC 1973 and not with giving a definition of the term "treatment by surgery". In this context,

the Enlarged Board's considerations on methods of surgery or therapy only serve the purpose of delimiting the diagnostic methods therefrom by qualifying the latter as being per definition multi-step methods. Furthermore, the use of the word "including" in the cited sentence already indicates that the Enlarged Board did not intend thereby to give an exhaustive definition of the term "methods of treatment by surgery".

Saying that treatments by surgery include any physical interventions on the human or animal body "in which maintaining the life and health of the subject is of paramount importance" is not equivalent to saying that the term "treatment by surgery" is limited to therapeutic methods. It is evident that in all but destructive surgical methods, e.g. in the already mentioned cosmetic surgery, organ removal, embryo transfer etc., but also in the imaging methods claimed in the application underlying the referral, in particular when involving potentially risky interventions like an injection into the heart, maintaining the life and health of the subject is of paramount importance. Hence, the definition given by the Enlarged Board in its opinion G 1/04 cannot be understood in the sense that the Enlarged Board thereby endorsed the view that the term "treatment by surgery" is limited to therapeutic surgery. On the contrary, the definition fits in very well with the previously established jurisprudence, decisions T 182/90 and 35/99, having held that the term surgical treatment embraces those interventions which, whatever their specific purpose, give priority to maintaining life and health of the human or animal body on which they are performed (T 35/99, loc.cit., point 4.1 of the Reasons), but that in view of the purpose of the exclusion to lay down a separate framework for the medical sphere, it cannot be so broadly construed as to include destructive treatments, i.e. such procedures whose conscious (deliberate or incidental) end result is the death of the living being "under treatment" (T 182/90, loc.cit., point 2.5.2 of the Reasons, T 35/99, loc.cit., points 3

et seq. of the Reasons). Such procedures do not qualify as methods in which maintaining the life and health of the subject is of paramount importance". Hence, the definition given by the Enlarged Board in its opinion G 1/04 can, as such, not be interpreted as going beyond the approach adopted in decisions T 182/90 and T 35/99.

Similarly, the example of the lumbar puncture given in that context cannot be interpreted as expressing the Enlarged Board's position that "treatments by surgery" are only those methods pursuing a therapeutic purpose. The fact that therapeutic surgery is considered excluded from patentability tells nothing about what would be the Enlarged Board's position with respect to non-therapeutic surgery.

3.3.6 *The ratio legis of Article 53(c) EPC*

As has been set out above the *Travaux Préparatoires* do not reveal a specific legal purpose for the introduction of the exclusion of surgical treatments in the EPC. By contrast, as regards the general purpose of the exclusion of therapeutic, diagnostic and surgical methods from patentability, already under the EPC 1973 it was commonly accepted that the real reason for excluding the defined methods from patentability were socio-ethical considerations and considerations of public health. Excluding methods for treatment of the human or animal body by surgery or therapy and diagnostic methods from patentability by way of the legal fiction that they were not to be regarded as inventions susceptible of industrial application was only the legislative mechanism by which this was achieved. Medical and veterinary practitioners should be free to use their skills and knowledge of the best available treatments to achieve the utmost benefit for their patients uninhibited by any worry that some treatment might be covered by a patent. By incorporating Article 52(4) EPC 1973 into Article 53(c) EPC the

legislator of the EPC 2000 has brought out this idea much more clearly.

3.3.7 Impact of the ratio legis on the interpretation of "treatment by surgery"

At least with respect to humans a limitation of the exclusion to such surgical methods which serve a therapeutic purpose does not take full account of and does not give full effect to the purpose of the exclusion. In particular as regards serious and risky surgical interventions, e.g. in cosmetic surgery, organ transplantation, embryo transfer, sex change operations, sterilisation and castration, i.e. surgical methods which require considerable professional medical expertise to be carried out and involve serious health risks even when carried out with the required professional care and expertise, the ratio legis of the exclusion, i.e. to free practitioners from being potentially hampered by patents in the application of the best possible treatment on their patients, does apply, is important and calls for their exclusion from patentability.

While with respect to animals it could be an *a priori* defensible concept to regard surgical methods like organ transplantation, embryo transfer, sterilisation and castration as methods of industrial exploitation which might be patentable, the situation under the EPC remains nevertheless that the legislator has decided otherwise: After long discussions the legislator has decided for reasons of public health to extend the exclusion from patentability to animals based on the same criteria as are applied to humans and more recent discussions on that subject in the context of drafting the EC Biotech Directive have still led to the same result (see point 3.3.2.4 above). Hence, no distinction can be made between humans and animals when the scope of the exclusion is interpreted.

3.3.8 Impact of decision T 383/03's approach

As has been set out in detail by the President in point 13 et seq. of her comments, the approach as actually adopted in decision T 383/03 creates discrepancies between the definition of what is to be understood as therapeutic in the context of a "treatment by therapy" and in the context of a "treatment by surgery".

3.3.8.1 First, while for "treatment by therapy" it is recognised that symptomatic therapy which cures a symptom but not the underlying disease falls under the exclusion that does not appear to be recognised, at least not to the same extent, with respect to a potentially surgical method. In decision T 383/03 the Board indicated in an *obiter dictum* that both a method of breast enlargement by surgery and a correction of the shape of the nose would fall within the scope of Article 52(4) EPC 1973 because they could also be used to restore the physical integrity of the body (following a cancer operation or after a car accident). By contrast, a method of hair removal by optical radiation was not considered as being excluded from patentability although the board acknowledged that excess (as unwanted) hair can be caused by a variety of underlying pathologies and can thus be a symptom of a disease. Nevertheless the method was regarded patentable since excess hair itself was not harmful and its removal neither cured the underlying cause nor was relevant to the physical health of the person treated (points 4.1 and 4.2 of the Reasons).

3.3.8.2 Second, it appears from this definition that according to the Board in T 383/03 in the said purpose/related construction only aspects relating to physical health should be taken into consideration but the term "treatment by therapy" also includes treatments aimed at maintaining or restoring the mental health of the subject. The President has cited as an example that in the case of children, the cost of otoplastic surgery to set sticking-out

ears closer to the head is, under certain conditions, covered by German health insurance policies.

3.3.8.3 Third, as regards methods which are commonly considered as surgical treatments, which may be carried out for therapeutic purposes or for non-therapeutic ones, e.g. for aesthetical or other personal reasons, it would have to be established in each case whether or not the non-therapeutic effect is distinguishable from the therapeutic effect. If that is not the case then the claimed method is excluded from patentability (see the decisions cited in T 1172/03 of Board 2.2.05, point 2.2 of the Reasons).

3.3.8.4 By contrast to decision T 383/03 in which the therapeutic and thereby the surgical character of curing a symptom (excess hair) was denied although it was acknowledged that excess hair may be a symptom of a disease, in decision T 1172/03 the therapeutic and thereby surgical character of the method claimed as a cosmetic method for tightening the skin's surface by delivery of electromagnetic energy through the skin surface and the epidermis to a deeper collagen containing tissue site was acknowledged, the reason being that the claimed method could be used for several therapeutic purposes including the application on the face or neck for reconstructive purposes.

3.3.8.5 Comparing the cases underlying decisions T 1172/03 and T 383/03 it appears at least not *prima facie* evident why removing excess hair would not be a therapeutic treatment even if the cause for the excess hair is a disease and it would then be the symptom of a disease which is cured and why on the other hand "altering the consistency and geometry of soft tissue" is excluded from patentability - even if limited to cosmetic methods - for the sole reason that it can be used for reconstructive (i.e. therapeutic) purposes (T 1172/03, point 2.3 of the Reasons).

3.3.8.6 The foregoing considerations, in particular also the comparison between the cases as decided in T 1172/03 on the one hand and T 383/03 on the other hand, show how inconsistent the decisions to be made may become, if the term "treatment by surgery" is seen as limited to therapeutic surgery only. Admittedly, it is often also difficult to precisely delimit excluded therapeutic from patentable cosmetic treatments. However, in this context the problem cannot be avoided, since it is the express wording of Article 53(c) EPC that only therapeutic methods are excluded from patentability (and thus cosmetic methods are not) and the exclusion cannot be extended to treatments which are not therapeutic in character (T 1172/03, point 2.2 of the Reasons, making reference to T 144/83, OJ EPO 1986, 301).

3.3.9 Comparative considerations

In points 54 to 58 of her comments the President has described the situation under the PCT and in Swiss, German and UK law (see Facts and Submissions, VIII, 4, above) and set out that in these laws and practices the nature of the treatment is regarded as the relevant aspect and the exclusion is not considered limited to therapeutic surgery, see e.g. the reference in Footnote 68 of the President's comments to the decision of the German Federal Patent Court concerning a hair implanting method which was regarded unpatentable, since it was a surgical method ("Glatzenoperation"). This is in direct contrast to decision T 383/03, except that that decision did not concern the implantation but the removal of hair. As reported by the President, in the UK the Examination Guidelines expressly state that the approach taken by decision T 383/03 is not being followed. Interestingly, the only comparative example cited by the appellant concerns the US law which is an entirely different construction.

3.3.10 Conclusion

Summarising the above, neither the legal history nor the object and purpose ("*ratio legis*") of the exclusions from patentability in Article 53(c) EPC justify a limitation of the term "treatment by surgery" to curative surgery, contrary to what the ordinary meaning of the word "surgery" implies and contrary to the fact that Article 53(c) EPC defines three separate alternative exclusions thereby suggesting that these are not merely identical in scope.

Hence, the Enlarged Board concludes that the meaning of the term "treatment by surgery" is not to be interpreted as being confined to surgical methods pursuing a therapeutic purpose.

3.4 The scope of interventions being "treatment by surgery"

3.4.1 Necessary involvement of a practitioner?

This question has been comprehensively dealt with and answered by the Enlarged Board in opinion G 1/04, point 6.3 of the reasons, and the Enlarged Board will not go into detail again in the present context. Whether or not a method is excluded from patentability under Article 53(c) EPC cannot depend on the person carrying it out. The findings of the Enlarged Board in point 6.3 of the Reasons relate to diagnostic methods, but they quite generally deal with the exclusion from patentability under Article 52(4) EPC 1973 and are thus equally valid with respect to the other exclusion conditions contained in today's Article 53(c) EPC. That the drafters of the EPC, historically, have discussed the problem they perceived in relation to the medical and veterinary practitioners cannot be a reason for not adapting the application of the exclusion to the changing reality in the field of the medical and veterinary profession caused by the technological advances altering

how and by whom health care is administered, as the Enlarged Board has explained in its opinion G 1/04 in point 6.3 of the Reasons.

3.4.2 Interventions being "treatment by surgery" by their nature

3.4.2.1 The broad construction

The broad construction of the kind of interventions being of a surgical nature developed in decision T 182/90, points 2.2 and 2.3 of the Reasons, that it covers any non-insignificant intervention performed on the structure of an organism by conservative ("closed, non-invasive") procedures such as repositioning or by operative (invasive) procedures using instruments including endoscopy, puncture, injection, excision, opening of the bodily cavities and catheterisation, has not as such been challenged by decision T 383/03 and the later decisions following it having additionally required a therapeutic purpose in order for the exclusion to apply.

The current practice of the EPO and the position advocated by the President in this respect have been set out in points 64 to 72, more particularly in points 68 to 70 of her comments. Based on decisions T 182/90 and T 35/99 methods involving irreversible damage to or destruction of living cells or tissues of the living body are regarded as non-insignificant interventions and thus as surgical treatments, irrespective of the underlying mechanism of the intervention (e.g. mechanical, electrical, thermal, chemical).

3.4.2.2 Is such broad construction still justified?

This broad view of what should be regarded as surgical activities excluded from patentability has in the Enlarged Board's view rightly been criticised by the appellant as being or having become overly broad when considering today's technical reality.

The advances in safety and the now routine character of certain, albeit invasive techniques, at least when performed on uncritical parts of the body, have entailed that many such techniques are nowadays generally carried out in a non-medical, commercial environment like in cosmetic salons and in beauty parlours and it appears, hence, hardly still justified to exclude such methods from patentability. This applies as a rule to treatments such as tattooing, piercing, hair removal by optical radiation, micro abrasion of the skin.

If so, that can also not be ignored when it comes to the application of routine interventions in the medical field.

Today, numerous and advanced technologies do exist in the medical field concerning the use of devices which in order to operate must in some way be connected to the patient. Methods for retrieving patient data useful for diagnosis may require administering an agent to the patient, potentially by an invasive step like by injection, in order to yield results or at least they yield better results when using such a step.

Considering this technical reality, excluding from patentability also such methods as make use of in principle safe routine techniques, even when of invasive nature, appears to go beyond the purpose of the exclusion of treatments by surgery from patentability in the interest of public health.

Insofar the definition given in opinion G 1/04 that "'any physical intervention" on the human or animal body ..." is a method of surgery within the meaning of Article 52(4) EPC 1973 (point 6.2.1 of the Reasons) appears too broad.

3.4.2.3 Elements of a narrower understanding

Hence, a narrower understanding of what constitutes by its nature a "treatment by surgery" within the meaning of Article 53(c) EPC is required. It must allow the purpose of the exclusion to be effective but it must also not go beyond it. The exclusion serves the purpose of, in the interests of public health and of patients, specifically freeing the medical profession from constraints which would be imposed on them by patents granted on methods for surgical or therapeutic treatment, thus any definition of the term "treatment by surgery" must cover the kind of interventions which represent the core of the medical profession's activities, i.e. the kind of interventions for which their members are specifically trained and for which they assume a particular responsibility.

These are the physical interventions on the body which require professional medical skills to be carried out and which involve health risks even when carried out with the required medical professional care and expertise. It is in this area that the *ratio legis* of the provision to free the medical profession from constraints by patents comes into play. Such a narrower understanding rules out from the scope of the application of the exclusion clause uncritical methods involving only a minor intervention and no substantial health risks, when carried out with the required care and skill, while still adequately protecting the medical profession.

One *amicus curiae* observed that the administration of diagnostic agents often causes negative side effects. It is therefore convenient to clarify 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.

It was also remarked that it would be absurd if administering a diagnostic agent by an injection was excluded from patentability but administering by inhalation was not. It is not for the Enlarged Board to decide whether a method involving the injection of a contrast agent is in fact excluded from patentability under the definition of "treatment by surgery" given here. As a matter of patent law, however, this argument does not hold good, since, by contrast to one early draft version of Article 52(4) EPC 1973, neither its final version nor Article 53(c) EPC stipulate an overall exclusion of medical methods from patentability. Both provisions only exclude the therapeutic, diagnostic and surgical methods listed in the Articles. Hence, where a step is neither a therapeutic nor a diagnostic nor a surgical method the legal situation was and is that it is not excluded from patentability.

3.4.2.4 Scope of definition given in this decision

Clearly, it is not possible for the Enlarged Board in the context of the present referral when trying to redefine the meaning of the term "treatment by surgery" to give a definition which would, once and for all, also delimit the exact boundaries of such a new concept with respect to the whole comprehensive body of technical situations which might be concerned by it.

Assuming such a task would go far beyond the scope of present referred question 1. The set of circumstances underlying the referral has been determined in the referring decision as encompassing an invasive step representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a health risk. Hence, what the Enlarged Board must do in answering question 1, is to define the scope of the term "treatment by surgery" to an extent which allows the referring Board to decide whether or not the step claimed in the application-in-suit falls under that definition.

This will also indicate the direction in which further practice and jurisprudence should develop. The required new direction is that the exclusion from patentability should not be applied to methods in respect of which the interests of public health, of protection of patients and as a counterpart to that of the freedom of the medical profession to apply the treatment of choice to their patients does not call for their exclusion from patentability.

The first instance bodies and the boards of appeal are much better suited to define the boundaries of a more narrowly construed concept of "treatment by surgery" in situations other than the one underlying the present referral, based on the technical reality of the individual cases under consideration.

This includes that the required medical expertise and the health risk involved may not be the only criteria which may be used to determine that a claimed method actually is a "treatment by surgery" within the meaning of Article 53(c) EPC. The referring decision and the President have mentioned the degree of invasiveness or the complexity of the operation performed but these do not appear to be issues in the case underlying the referring decision. At least, the referring decision contains no statement of fact establishing the presence of such circumstances which the Enlarged Board would have to consider when determining the scope of its answer given. Although it appears likely that interventions involving a high degree of complexity and/or a high degree of invasiveness would normally also be such as to require professional medical expertise and entail health risks even when carried out with the required care and expertise, the Enlarged Board does not wish to rule out from the outset that, depending on the circumstances of the individual case under consideration, other criteria could not also determine that a physical intervention on

the human or animal body is a "treatment by surgery" within the meaning of Article 53(c) EPC.

3.4.2.5 Variability of concept of "surgery" in the medical sense

Another reason why the Enlarged Board cannot, in the context of the present referral, give an authoritative once and for all definition of what the term "treatment by surgery" may comprise is that in the ever changing technical and medical reality the term "surgery" itself does not appear to have a once and for all fixed meaning, either. There appears to be no general common concept for the acts which are commonly regarded as surgical in the medical sense. Rather, it appears that what is to be understood by "surgery" in the medical sense is to a large extent a matter of convention. Thus, in order to be surgical, it is not necessary that the intervention be invasive or that tissues be penetrated (T 5/04 of 17 January 2006, point 2 of the Reasons). Repositioning body limbs or manipulating a body part is traditionally considered surgical. The mere catheterisation or the insertion of components of a device into the body is already regarded as prohibited as being a surgical step even if it does not require the penetration of tissues (T 5/04, loc.cit.). All this implies that the scope of what is surgery may change with time and with new technical developments emerging, as was already acknowledged in decision T 182/90, loc.cit., point 2.4 of the Reasons.

3.4.2.6 Developing a new concept

Admittedly, in many situations it will not be an easy task to determine whether or not an invasive step constituting a substantial physical intervention on the body comprised or encompassed by a claim requires professional medical skills to be carried out and involves a substantial health risk even when carried out with the required care and expertise. However, even the

President, speaking for the first instance, has acknowledged with respect to a criterion which would require a certain degree of invasiveness that although a clear line could not be easily drawn, such a criterion could be expected to be handled on a case-by-case basis with quite reasonable, acceptable results, as this was already presently the case with respect to the definition of what constitutes a "non-insignificant" intervention qualifying as "treatment".

Some of the *amici curiae* involved in developing technologies in the medical field which may be concerned by the exclusion of surgical methods from patentability emphasised the importance of legal certainty as regards being able to assess in advance what could be patented and what was excluded. However, in the view of the Enlarged Board it is equally important to give these inventions the protection they deserve and to come to a balanced system of exclusion on one hand and patentability on the other hand. Where a new direction is taken in interpreting a requirement for patentability, be it in the form of an exclusion or in the form of a positive requirement, it is normal and unavoidable that practice and jurisprudence need time and the handling of a number of cases in order to develop a line which then creates a new uniform system of applying a new concept. The present referral possibly leaves open, and must do so, considerations which may be necessary to decide certain kinds of further cases. However, in view of the fact that the field of methods which potentially involve surgical steps is vast, each category of cases will have to be assessed on its own merits. In the view of the Enlarged Board this can, however, not be a reason for not opting for new solutions, as the hitherto approach is considered unsatisfactory.

3.4.2.7 Conclusions

For the foregoing reasons, when dealing with this issue in the present decision, the Enlarged Board holds it appropriate to confine its answer to defining the term "method for treatment by surgery" within the meaning of Article 53(c) EPC to the extent as is necessary for the referring Board to decide whether the steps encompassed by the claimed invention fall within the meaning of that term. The referring Board has made it clear that the case underlying referred question 1 concerns an invasive step (i.e. an injection into the heart) representing a substantial physical intervention on the body which requires professional medical expertise to be carried out and which entails a health risk even when carried out with the required professional care and expertise. Hence, the Enlarged Board's answer to question 1 is directed to that issue.

4. Question 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?

4.1 Claim left to encompass a surgical step

It is established in the jurisprudence of the boards of appeal that a claim encompassing an embodiment which is excluded from patentability under now Article 53(c) EPC, then Article 52(4) EPC 1973, cannot be left unamended.

Against this, the appellant refers to the Enlarged Board of Appeal's decision G 1/98, OJ EPO 2000, 111, as lending support for the conclusion that a claim of a higher level of abstraction

embracing ("encompassing" in the terminology of the present decision) subject-matter excluded from patent protection without explicitly claiming it should be allowed. In decision G 1/98 the Enlarged Board held that a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC 1973 even though it may embrace plant varieties (Headnote I).

In point 3.3.3 of the Reasons for that decision the Enlarged Board said that the rule assumed by the then referring Board that an invention is not patentable because it covers an embodiment which does not fulfil the requirements for patentability is not without exception. That such a general rule existed had been based by the referring board *inter alia* on the jurisprudence of the boards of appeal in cases relating to Article 52(4) EPC 1973 (point 63 of the Reasons of the referring decision T 1054/96, OJ EPO 1998, 511).

The examples given by the Enlarged Board to show that the rule assumed by the referring board is not without exception do however not address Article 52(4) EPC 1973 but concern Article 53(a) EPC and Article 83 EPC 1973. Hence, the findings of the referring Board with respect to Article 52(4) EPC 1973 were not put into question by the Enlarged Board.

According to the Enlarged Board the answer to the question "which interpretation is the correct one?" has to be given in the light of the context as well as the object and purpose of the provision.

As regards Article 53(b) EPC 1973 the idea underlying the provision was not that there should be no patent protection for plant varieties (see points 3.4 at the end and 3.6 of the Reasons) but the exclusion in the EPC should correspond to the availability of protection in UPOV so that the two forms of protection would constitute a single comprehensive system of industrial property

protection for plant innovations permitting neither overlapping nor gaps in the protection of eligible subject-matter. In this respect, the Enlarged Board says, the purpose of Article 53(b) EPC 1973 is quite different from the purpose of Article 52(4) EPC 1973. "In the latter provision, gaps in the protection of eligible subject-matter are deliberately accepted in order to free from restraint non-commercial and non-industrial medical and veterinary activities (G 5/83, OJ EPO 1985, 64, point 22 of the Reasons)" (G 1/98, point 3.7, last para. of the Reasons).

Hence, as regards the exclusion in Article 53(c) EPC (52(4) EPC 1973), the findings of the Enlarged Board in decision G 1/98 do not put into doubt but on the contrary confirm the principle that a claim which encompasses an embodiment which is excluded from patentability under Article 53(c) EPC cannot be left to encompass that embodiment.

4.2 Disclaimer

4.2.1 In accordance with decisions G 1/03 and G 2/03 (OJ EPO 2004, 413, point 2 of the Reasons), the term "disclaimer" means an amendment to a claim resulting in the incorporation therein of a "negative" technical feature, typically excluding from a general feature specific embodiments or areas. Hence, the use of terms like "pre-delivered", "pre-implanted" is not a disclaimer within the meaning of decisions G 1/03 and G 2/03 but is a form of omitting the step from the claim by making it clear that the step does not form part of the claimed method. Therefore, whether and, if so, under which circumstances such drafting is allowable will be dealt with in the following section relating to the question whether such a step can be omitted from the claim.

4.2.2 In its question 2 the referring Board has asked whether the exclusion from patent protection under then Article 52(4) EPC 1973, now Article 53(c) EPC, can be avoided by amending the wording of the claim so as to disclaim the step (i.e. the embodiment, see 4.2.1 above) at issue. Taking this part of the question as it stands, it appears difficult to imagine how there could still be a problem under Article 53(c) EPC if the claimed invention no longer contains any subject-matter excluded from patentability under that article as a result of the surgical subject-matter having been disclaimed.

Rather, it appears that any problems arising from such disclaimers would relate to the conditions for them to be compatible with the remaining requirements of the EPC, in particular with Article 84 EPC. Articles 56 and 83 EPC may, however, also be concerned, e.g. in a case in which the only example for carrying out the method would be the disclaimed surgical one.

Hence, the answer to be given to this aspect of question 2 is that the exclusion from patentability under Article 53(c) EPC can be avoided by disclaiming an embodiment or embodiments which are methods of treatment by surgery within the meaning of Article 53(c) EPC, but the overall patentability of any such claim depends on the remaining requirements of the EPC, and, where applicable, the conditions as defined in decisions G 1/03 and 2/03 also being fulfilled.

Whether or not this is the case, is to be decided in each case, individually. This applies also to the question of which form the disclaimer can or must take, i.e. whether - only - a particular embodiment can or must be disclaimed or whether a disclaimer can and/or must take a more general form, as e.g. by use of the word "non-surgical".

4.2.3 The Enlarged Board is aware that subsequent to the Enlarged Board's decisions G 1 and G 2/03 different opinions have been expressed in the jurisprudence of the boards of appeal on whether decisions G 1 and 2/03 relate to the disclaiming of embodiments which - as in the application underlying the present referral - are disclosed in the application as filed or whether in that situation it is the hitherto jurisprudence, following decision T 4/80, OJ EPO 1982, 149, which applies (see the comprehensive discussion of the issue in decision T 1107/06 of 3 December 2008, points 31 et seq. and the many further decisions cited therein).

However, in view of the fact that the referring Board has only asked whether the exclusion from patentability under Article 53(c) EPC can be avoided by disclaiming the surgical embodiment, the Enlarged Board would find it inappropriate to express itself on that question in the context of the present referral. The present referral is, as a whole, directed to an entirely different and unrelated issue, in which referred question 2 only aims at more generally asking the Enlarged Board for solutions available as a matter of principle in terms of possible claim amendments if the Enlarged Board comes to an answer to question 1 which would negatively affect the patentability of the current version of the claims on file under Article 53(c) EPC. Hence, like any other further issue potentially determining the allowability of a disclaimer in the case underlying the referral should the appellant decide to draw up such a claim, the aforementioned question is not something to be decided by the Enlarged Board in the context of the present referral. It would be for the referring Board to determine the criteria to be applied to a disclaimer excluding an embodiment characterised as surgical within the meaning of Article 53(c) EPC should the appellant decide to draw up such a claim.

4.3 Omission of the step

4.3.1 General remarks

Article 84 EPC in conjunction with Rule 43 EPC requires that the claims shall define the matter for which protection is sought. Hence, the claim should explicitly specify all of the essential features needed to define the invention. Furthermore, the claim must be clear (G 1/04, *supra*, point 6.2 of the Reasons). Under Article 84 EPC, whether or not a step being or encompassing a surgical step excluded from patentability can be omitted either by using positive wording for such omission like "pre-delivered" or by simply leaving it out from the claim depends on whether the claimed invention is fully and completely defined by the features of the claim without that step. That requires an assessment of the individual case under consideration.

4.3.2 Methods only concerning the operation of a device

However, a typical class of cases in which the invention would be fully defined without requiring the presence of the potentially surgical step as a positive feature of the claim would be cases in which the invention only concerns the operating of a device. With respect to such inventions the boards of appeal have constantly held that a method which is only concerned with the operating of a device without any functional link between the claimed method and the effects produced by the device on the body does not qualify at all as a method for treatment within the meaning of Article 52(4) EPC 1973 (T 245/87, OJ EPO 1989, 171, point 3.2.3 of the Reasons, T 789/96, OJ EPO 2002, 364, points 2.2.2.1 et seq. of the Reasons). If, on the contrary, there is such a functional link the method is excluded from patentability (T 82/93, OJ EPO 1996, 274, point 1.5 of the Reasons).

These principles have been acknowledged in cases in which the device was for use in a therapeutic treatment (T 245/87, T 82/93 and T 789/96) but also to the extent that the application of the device as such needed a surgical step to be practised on the body (T 329/94, OJ EPO 1998, 241 points 4 et seq. of the Reasons and the decisions cited below) and, where the operating of the device as such comprised making use of a surgical step, expressions like "predelivered" or "preimplanted" have been allowed to make clear that the feature pertaining to that step was not part of the claimed invention.

While formally supporting the position adopted in decision T 383/03 as regards the limitation of the exclusion to surgical methods for a therapeutic purpose, the decisions T 1102/02 and T 9/04 cited by the referring Board also fall in the category of inventions having been considered as purely technical methods. The same principle was relied on by Technical Board 3.2.02 in its decisions T 542/06 of 10 September 2007 and T 810/06 of 9 October 2007 cited by the appellant in its letter dated 20 October 2009. It is also acknowledged by practice (see the Guidelines for Examination, C-IV, 12).

The approach adopted in that jurisprudence has not been put into question in these proceedings and the Enlarged Board also sees no reasons for doing so. Methods which are merely directed to the operating of a device without themselves providing any functional interaction with the effects produced by the device on the body are teachings in which the performance of a physical activity or action that constitutes a method step for treatment of a human or animal body by surgery or therapy is not required in order for the teaching of the claimed invention to be complete. Hence, even if in such a case the use of the device itself requires the application of a surgical step to the body or is for therapeutic treatment the same does not apply to the claimed method for operating the device.

It appears therefore to be correct to say that such inventions are not methods for treatment of the human or animal body within the meaning of Article 53(c) EPC and that the distinction made in the jurisprudence of the technical boards properly delimits patentable methods of a merely technical nature from such inventions as fall within the exclusion under Article 53(c) EPC. Whether or not a claimed invention only concerns the operation of a device without any functional link to the effects of the device on the body, is not an issue of law but requires an evaluation of the overall technical circumstances of the case and is therefore a matter to be determined by the first instance and the technical boards of appeal in the individual cases under consideration.

4.3.3 Further requirements for the omission to be allowable

When omission of a step from a claim is being considered the remaining requirements of the EPC for the allowability of such omission and the patentability of a claim not containing the omitted feature must furthermore also be fulfilled. These are in particular Article 123(2) EPC and, in opposition proceedings, Article 123(3) EPC, but Articles 83 or 56 EPC may also come into play, e.g. if, as a result of the omission the claimed invention can no longer be carried out over the whole breadth of the claim or the problem is not so solved.

5. Question 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?

The referring Board has not explained which particular legal problem they intend to address with this question. The question can apparently only become relevant to the extent that when applying the foregoing considerations the claimed imaging method is not *per se* excluded from patentability under Article 53(c) EPC or if the claims would have been amended so as to comply with Article 53(c) EPC.

Since in that case the imaging method is a complete teaching *per se* the fact that it can be used in a potentially particularly advantageous way in the course of a surgical intervention does not preclude the imaging method from being claimed *per se*. Furthermore, even if used in the course of a surgical intervention that does not alter the character of the imaging method of not being a surgical step in itself.

Article 53(c) EPC prohibits the patenting of surgical methods and not the patenting of any methods which can be used in the context of carrying out a surgical method. Otherwise, many methods which are used during surgical interventions even if not requiring themselves a surgical step to be carried out on the body, e.g. all methods for operating devices used in context with surgical activities would be unpatentable.

In its opinion G 1/04, *supra*, point 6.2.4 of the Reasons, the Enlarged Board discussed which features have to be included in a claim relating to a diagnostic method under Article 84 EPC. The answer given by the Enlarged Board was that Article 84 requires that an - independent - claim must recite all the essential features which are necessary for clearly and completely defining the invention. If it is unambiguously inferable from the application that the diagnosis is to be regarded as "constitutive" for defining the invention, it must likewise be included as an essential feature in the claim.

This situation is not comparable to the situation addressed in question 3 of the referring decision, since in the latter situation the imaging method is a complete teaching per se. Hence, the fact that one of the possible and described uses of the imaging method is the use by a surgeon during a surgical intervention allowing the surgeon to decide on the course of action to be taken in the intervention by taking note of the immediately produced image data, does not render that imaging method excluded from patentability.

Order

For these reasons it is decided that:

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.

The Registrar:

The Chairman:

W. Roepstorff

P. Messerli



**Europäisches
Patentamt**

Große
Beschwerdekammer

**European
Patent Office**

Enlarged
Board of Appeal

**Office européen
des brevets**

Grande
Chambre de recours

Case Number: G 0001/07

D E C I S I O N
of the Enlarged Board of Appeal of 22 February 2010
correcting an error in the decision of the Enlarged Board of Appeal
of 15 February 2010

Appellant: Medi-Physics, Inc. 100 Abbott Park Road
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Referring Decision: 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

Pursuant to Rule 140 EPC, the Decision G 1/07 of the Enlarged Board of Appeal given on 15 February 2010 is hereby corrected on the front page as follows:

Replace "Decision under appeal:" by "Referring Decision:".

The Registrar:

The Chairman:

W. Roepstorff

P. Messerli