

## EPO Enlarged Board of Appeal decides on treatments by surgery G 1/07, Treatment by surgery / MEDI-PHYSICS

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The present decision of the Enlarged Board of Appeal (EBoA) clarifies to a certain extent what has to be understood under a treatment by surgery that is excluded from patentability under Article 53(c) EPC.

In the application underlying the decision, claim 1 reads as follows:

1. A method for MRI imaging the pulmonary and/or cardiac vasculature using dissolved-phase polarized  $^{129}\text{Xe}$ , comprising the steps of;
  - (i) positioning a patient in an MRI apparatus...
  - (ii) **delivering polarized  $^{129}\text{Xe}$  gas to a predetermined region of the patient's body...**
  - (iii) exciting a predetermined region of the patient's body, having a portion of the dissolved phase polarized gas therein ... and
  - (iv) acquiring at least one MR image associated with the dissolved phase polarized gas after said exciting step.

The feature “**delivering polarized  $^{129}\text{Xe}$  gas to a predetermined region of the patient's body**” was described in the application to comprise inhalation and injection into the heart.

The Examining division refused the application on the grounds that the method was a diagnostic method practiced on the human or animal body and that it furthermore comprised a surgical step as far as it pertained to injection of  $^{129}\text{Xe}$ .

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

**Q1.** 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

practiced 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?

**Q2.** 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?

**Q3.** 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 EBoA decided as follows:**

**A1:** “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.”

Firstly, the EBoA did not adopt the position that the exclusion clause should be interpreted narrowly to exclude only “surgery for therapy” because it would then be redundant with the exclusion of methods by therapy. Rather, the purpose of the exclusion clause was held being decisive, this purpose being to protect the freedom of the medical practitioner. The three alternative exclusions in Article 53(c) (i.e. methods for treatment of the human or animal body by (i) surgery, (ii) therapy and (iii) diagnostic methods practised on the human or animal body), are thus cumulative.

The Board also ruled that for a multi-step method being inadmissible, it suffices that the method comprises one step that falls under the exemption of Article 53(c) EPC.

With respect to the scope of the term “surgery”, the Board adopted the view that not the purpose of the surgical treatment should be decisive, but instead the nature of the surgical treatment. The Board did not feel itself in the position for giving a definition of the term “surgery”, but it regarded “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” to fall under the definition of a treatment by surgery. The determination of whether a given treatment may be surgical must be decided on a case-by-case basis.

**A2a:** 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. The above also holds true, where the claim comprises a surgical step on a higher level of abstraction (“delivering”) without explicitly claiming the surgical step as such (“injection into the heart”).

**A2b:** “The exclusion from patentability under Article 53(c) EPC can be avoided by disclaiming the critical embodiment, it being understood that in order to be patentable the claim including the disclaimer must fulfill 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.”

The EBoA did not comment on potentially allowable disclaimers (e.g. “non-surgical”). The admissibility of a disclaimer was left to be decided on a case-by-case basis.

**A2c:** “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.”

The Board also confirmed the established case law 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 on the body is not excluded from patentability.

**A3:** The answer to Q3 is [no]: “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.”

**To summarize:** It suffices that one step of a method is interpreted as a surgical step for the method to be excluded from patentability; the meaning of the term “surgical” is not limited to therapeutic surgery but its precise meaning has to be evaluated on a case-by-case basis. The admissibility of disclaimers is to be ruled on a case-by-case basis.