Decision on treatment by surgery/Medi-Physics, G-1/7

(Enlarged Board of Appeal, European Patent Office, 15 February 2010)

Prepared by UNCTAD's Intellectual Property Unit

Summary

The Enlarged Board of Appeal (EBoA) decided that:

- The presence of one surgical step in a multi-step method is sufficient to exclude the method from patentability;
- The exclusion of methods of surgery is not limited to a therapeutic purpose. Medical skills and health risks are further criteria to determine a method as surgical;
- The possible use of a non-surgical method in a surgical method does not result in the non-surgical method being excluded from patentability.

Facts

Article 52(4) of the European Patent Convention (EPC, 1973) (after EPC revision now Article 53(c)) excludes from patentability methods for treatment by surgery or therapy and diagnostic methods practised on the human or animal body. Medi-Physics, Inc. applied for patents relating to magnetic resonance (MR) methods for imaging certain vasculature and evaluating blood flow using a dissolved agent. The MR imaging methods of the invention may precede surgery or a drug therapy for treating pulmonary or cardiac vasculature problems. In 2003, the Examining Division of the European Patent Office (EPO) decided that the claims constituted diagnostic methods practised on the human or animal body and also comprised the step of administering agent to a subject by injection involving a surgical step, and thus were excluded from patent protection. Medi-Physics, Inc appealed to the Technical Board of Appeal (TBA) against the decision of the Patent Office. In October 2006, the TBA decided to refer questions to the The Enlarged Board of Appeal (EBoA) for clarification. A number of other decisions of EBoA and the TBA addressed the definition and scope of exclusion of methods of treatment by surgery and therapy. While some of the earlier decisions favour the meaning of the term surgery in today's usage to include those not directed to restoring health, other decisions maintain that method of surgery that is not potentially suitable for maintaining or restoring health, does not fall within the exclusion from patent protection. The EBoA had clarified the exclusion of diagnostic methods in its Decision on Diagnostic methods (G-1/04) in 2005.[1]

Legal issues

The TBA referred three questions to EBoA. The summary below includes the decisions of the EBoA on the first and third questions that deal with the scope of exclusion. The second question concerned the possibility for a patent claim to be construed in a manner that avoids a subject matter excluded from patent protection. The EBoA confirmed its

[1] A summary of the G-1/04 decision is also provided in this database.

conclusion in its Decision on Diagnostic methods (G-1/04) that such is possible provided that the claims explicitly specify all of the essential features needed to define the invention.

Interpretation of an exclusion clause and the ratio legis of the exclusion provision:

EBoA rejected the argument that the Vienna Convention on the Law of Treaties provides for the principle of narrower interpretation of exclusion clauses. The rules of interpretation laid down in the Vienna Convention require looking at the ordinary meaning of terms of a provision and its object and purpose. The fact that a provision provides exclusion to the 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. Besides following the ordinary meaning of terms, provisions, including exclusions, should be interpreted in such a manner that the provision takes its effect fully and achieves the purpose for which it was designed.

In this relation, the EBoA also considered the objective behind the provision excluding methods of treatment. According to EBoA, the *ratio legis* is 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.

Question 1: Is a claimed imaging method for a diagnostic purpose, *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" if such step does not per se aim at maintaining life and health?*

In responding to this question, the EBoA examined a subset of issues that can help arrive at a decision on the scope of exclusion of treatment by surgery.

1. *Does the presence of one surgical step in a multi-step method exclude that method from patentability?* The EBoA first ruled that the only condition arising from Article 52(4) of 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. 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.
2. *Is the exclusion of treatments by surgery limited to surgery for a therapeutic purpose?* The EBoA stated that 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 therapeutic or curative surgery. Hence, the EBoA 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. *The scope of interventions being "treatment by surgery"*: The earlier decision of the EBoA (G 1/04) underscored that any physical intervention on the human or animal body is excluded. Under this case, however, the EBoA concluded that excluding from

patentability safe routine techniques, even when of invasive nature, appears to go beyond the purpose of the exclusion. It is in the area of physical interventions on the body, which require professional medical skills that the *ratio legis* of the provision comes into play, ruling out uncritical surgical methods involving only a minor intervention and no substantial health risks from exclusion. An invasive step, such as 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 is covered by the exclusion of treatment by surgery.

For these reasons, the EBoA concluded that: A claimed method (in this case 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.

Question 3. Is a claimed imaging method for a diagnostic purpose 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 considered this question as addressing a scenario where the patent application has been amended to avoid claims of methods of treatment, but its method claim can provide a complete teaching *per se* for surgeons. The EBoA ruled that the fact that the teaching of the claimed invention can be used in a potentially particularly advantageous way in the course of a surgical intervention does not preclude the method from being claimed *per se*. 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. For these reasons, the EBoA decided that: A claimed imaging method is not to be considered as being a "treatment of the human or animal body by surgery" 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.

Points of Significance

1. The EBoA acknowledges the conflicting jurisprudence on the interpretation of exclusion clauses. Interpretation of exclusion clauses is not limited to their design with a narrower application. As any other provision of an international treaty, interpretation of exclusion clauses should take into account the object and purpose, the ordinary meaning of terms used in the provision, and in a manner that give effect to all the terms of a treaty.
2. The EBoA decision will exclude the patenting of a multi-step method that comprises one step that is therapeutic, diagnostic or surgical. However, it leaves open for the possibility for patent applicants to present their claims in a way that

avoids the therapeutic, diagnostic or surgical step. The EBoA anticipates that the rules on disclosure of all essential features needed to define a claimed invention will prevent undue patent claims of methods that would otherwise be excluded as methods of is therapeutic, diagnostic or surgical.

Keywords: Vienna Convention, methods of treatment by surgery.

Available at:https://www.epo.org/law-practice/case-law-appeals/recent/g070001ex1.html