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EPO Enlarged Board of Appeal Rules on Interpretation of Surgical Methods Exclusion

The Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) has issued their decision (G1/07) on when a surgical method is to be excluded from patentability.

In several decisions, the Technical Boards of Appeal of the EPO have attempted to define the limits of the exclusion of surgical methods from patentability. However, the results of these decisions are divergent. Some case law suggests that it is the purpose of the claimed method which is decisive, such that only those surgical methods aimed at restoring or maintaining life or health would be excluded. Other case law dictates that it is the nature of the method which is relevant, regardless of whether there is any therapeutic purpose.

In view of this conflict, the EBA were asked several questions relating to the definition of surgical methods and the limits of the exclusion.

Whilst pointing out that their decision is specific to the case in point, the EBA ruled that a surgical method does not have to have a therapeutic purpose to be excluded from patentability. Thus, it is the nature of the method, rather than its purpose, which is decisive in determining whether the exclusion applies. Clearly, broadening the scope of the exclusion to surgical methods which are not therapeutic will not be welcomed by many applicants in this field.

The case in issue claimed a method for MRI imaging of the pulmonary and/or cardiac vasculature of a patient, for diagnostic purposes. The method included a step of delivering a contrast agent into a pre-determined region of the patient's body. The description of the application mentioned that delivery could be via injection into the heart. As this injection step was clearly not aimed at maintaining life or health of a patient, the EBA were asked whether it was to be regarded as a method of surgery.

In addition to their conclusion that "treatment by surgery is not to be interpreted as being confined to surgical methods pursuing a therapeutic purpose", the EBA also ruled that a method will also be excluded from patentability if it encompasses, without specifically defining, a step comprising a method of "treatment of the human or animal body by surgery". For example, in the referred application, the claimed method encompassed a method of injecting the contrast agent into the heart, even though this was not explicitly defined.

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Despite seemingly broadening the scope of excluded subject matter, the EBA have confirmed that it is allowable to avoid refusal under Article 53(c) EPC by disclaiming the excluded subject matter, provided that the disclaimer meets with the requirements of the EPC and existing case law. Under current European practice, a disclaimer can be introduced regardless of whether basis exists in the application as originally filed.

Several other points of law were clarified in the decision. The EBA also confirmed the previous position that a claimed method is excluded if it comprises a single step which defines a method of medical treatment by surgery or therapy, or a method of diagnosis, within a multi-step process. In addition, they held that an imaging method is not to be considered as being a surgical method merely because the data obtained by the use of the method immediately allows a surgeon to decide on the course of action to be taken during a surgical intervention.

Whilst at first the decision may be discouraging to applicants in the field of medical methods, the EBA have suggested that in view of today's 'technical reality' surgical methods carried out in non-medical commercial environments, such as laser hair removal, should not be excluded. This suggestion that routine and safe surgical methods may be patentable, offers at least some comfort to applicants.

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