Recent EPO case law confirms relaxation of exclusion of surgical methods

Article 53(c) EPC excludes methods for the treatment of the human or animal body by therapy or surgery from patentability at the EPO. The most significant discussion on the meaning of "treatment by surgery" is in the Enlarged Board of Appeal case, G1/07. The Enlarged Board of Appeal at the EPO decide on matters where the case law of the EPO Boards of Appeal diverges. A recent decision from the Board of Appeal, T 663/02, applies the new approach set out in G1/07 and provides an example of a patentable method that may previously have been excluded.

As explained in more detail in the note entitled "Patentability of Surgical Methods at the EPO", prior to G1/07 some EPO decisions had taken the stance that any physical intervention on the body (for example, any step that pierces the skin) should lead to a method being considered as surgical and hence excluded from patent protection under the EPC. In G1/07 the Enlarged Board of Appeal suggested that this approach was not correct and should be reconsidered. They also disagreed with a comment in a previous Enlarged Board of Appeal Decision (G1/04) that "any physical intervention" is an excluded method of surgery, and suggested that this definition of the exclusion was overly broad.

G1/07 stated that the purpose of a physical intervention on the body does not affect whether or not a method is excluded from patentability. Instead, the nature of the physical intervention on the body is of paramount importance. For a step involving administering a substance to the body by a physical intervention, this requires the mode of administration to be assessed, with the health risk from the substance being ignored. The Enlarged Board indicated that an excluded method of treatment by surgery is one including a step that is a substantial physical intervention on the body, that requires professional medical expertise, and that entails a health risk even when carried out with the required professional medical expertise. However, the Enlarged Board did not define a test for a substantial physical intervention or define the nature of the health risk. Hence, G1/07 did not set out exact boundaries of what should be meant by the proposed narrower definition of "treatment by surgery", but left this open for Examiners and the Boards of Appeal to determine on a case by case basis, based on the technical facts of each case.

In T 663/02 the Board of Appeal considered a method of magnetic resonance imaging that included a step of injection of a contrast media into a vein. Under the prior regime at the EPO this method may have been considered as an excluded method due to the physical intervention on the body occurring during insertion of catheter for injection and during injection of the contrast media.

The Board determined that placement of intravenous catheters is a very common invasive procedure and does not require the involvement of a fully qualified doctor. The fact that this procedure is often delegated to less qualified personnel was considered to imply a low level of risk to the patient's health. The Board also noted that G1/07 required the assessment of the health risk to be carried out without reference to the injected substance. Hence, possible complications arising from the injected substance were not to be taken account of when considering the risks.

In addition to determining the health risk for an intravenous injection as being an implicit low health risk due to the usual practice of delegation to less qualified personnel, the Board also propose a more structured test for a health risk based on the use of a risk matrix.
The proposed matrix is constructed with the probability of a complication along one axis, and the seriousness of the impact to the patient's health along another axis. Procedures with a high likelihood of a complication and/or a risk of a potentially very serious complication would be considered to give risk to a significant health risk. Conversely, procedures with a low likelihood of a complication and only the possibility of a negligible and/or easily reversible impact on the patient's health might be seen as having an insignificant health risk, resulting in a potentially non-excluded surgical step.

Overall, for the facts of this particular case, the Board of Appeal concluded that whilst the method included a physical intervention on the body this was a minor and routine intervention involving no substantial health risk. Hence, the step of intravenous injection of a substance was not excluded from patentability and the method as a whole was therefore found to be not excluded from patentability at the EPO.

T663/20 hence confirms that the G1/07 decision can result in patentability for methods that may previously have been considered to be excluded. Clearly, this would include methods that require a step of intravenous injection as the only physical intervention on the body. In addition it can be expected that other similar interventions may no longer give rise to a method claim being excluded from patent protection. For example, method steps where exclusion as a surgical step should be reconsidered would include injection of a substance into body tissue via a conventional syringe, commonplace techniques of palpation and manipulation of the body, methods involving the use of existing bodily orifices for accessing the body without creating a substantial health risk, and other procedures that might typically be delegated by a fully qualified doctor to less qualified personnel.

By way of contrast, Board of Appeal decision T1075/06, which was also issued taking account of G1/07, provides an example of a physical intervention that was considered to be a substantial intervention and to give rise to a substantial health risk. In this case the physical intervention was venipuncture used to remove a relatively large volume of blood from the patient. The Board found that this procedure was an excluded method of surgery in view of the high level of medical expertise required, the possibility of severe and irreversible damage to the patient's health and the large diameter of the needle used in the vein.

Applicants with pending and prospective EPO patent applications including methods requiring a physical intervention on the body should consider the possibility of including a method claim or reintroducing previously deleted method claims. This applies if the physical intervention could be argued to present a low risk to the patient's health and to be a minor or routine intervention. If the usual practice in the field of the invention is for a fully qualified doctor supervising the procedure to delegate the method step to less qualified personnel then this is an indicator of a low health risk. Application of the risk matrix proposed in T 663/02 could be used both to assess the potential allowability of medical methods and also to support arguments submitted to the EPO. The same approach may also be followed by the national patent offices and courts in EPC member states.

For Opponents using the EPO Opposition procedure to challenge the validity of a patent relating to methods of surgery the reverse applies. The strength of an attack on a European patent using an argument that a method is excluded due to being a method of treatment by surgery will need to be reconsidered.

Dehns can review a patent portfolio and advise on action that should be taken to improve pending claims or to adjust an attack on the validity of claims of third party patent applications.

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