



The Exclusion from Patentability of Surgical Methods at the European Patent Office

Article 53(c) EPC specifies a number of exceptions to patentability in the field of medicine, including “*methods for the treatment of the human or animal body by surgery*”. These exceptions to patentability were included in the EPC on socio-ethical and public health grounds to ensure that medical and veterinary practitioners remain free to take any action necessary to treat or diagnose illnesses.

The exclusion for surgical methods was considered in 2010 in opinion G 1/07 of the Enlarged Board of Appeal. The Enlarged Board’s main conclusion was that a method will be excluded from patentability as a surgical method if it comprises or encompasses an invasive step representing a substantial physical intervention on the human or animal 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.

This decision provided the basic framework for assessing whether a claimed invention is an unallowable method of treatment by surgery. Several decisions since then have further developed the reasoning of G 1/07.

Purpose and Nature of a Surgical Step

The Enlarged Board dismissed the interpretation of Article 53(c) EPC in which only those surgical methods that have a curative purpose are excluded from patentability.

In doing that, the Enlarged Board noted that under today’s usage, the term “*surgery*” also encompasses various non-curative treatments such as cosmetic treatments.

The Enlarged Board also acknowledged that the interpretation excluding methods involving any direct physical intervention on the body is too broad, because it serves to exclude methods involving safe routine techniques that are not considered surgical in today’s technical reality.

A new understanding of the scope of the exclusion was suggested, in which the EPO should not consider whether the surgical procedure is curative or non-curative, but should instead have regard solely to the nature of the step and whether that step involves a substantial physical intervention on the body in which maintaining the life and health of the subject is of paramount importance.

Destructive methods, such as those in which experimental animals are to be sacrificed, are not covered by the exclusion. The exclusion does, however, potentially include many non-therapeutic methods, such as cosmetic surgery and organ donation, since it will be of importance in many of those methods

to maintain the health of the subject.

The Enlarged Board identified several factors that are indications that a claimed method is a treatment by surgery. However, no one factor is decisive and ultimately a judgement must be made based on all of the factors. The factors are considered below.

Medical Skill and Expertise

The Enlarged Board ruled that a “*treatment by surgery*” should encompass only those physical interventions that are substantial enough to require professional medical skills to be carried out.

Subsequent decisions by Technical Boards of Appeal have provided further guidance regarding what sort of medical skills are relevant and may indicate that an intervention should be excluded. In particular, in T 1695/07 it was ruled that the term “*medical profession*” is not restricted to physicians and covers all health care workers. Accordingly, inserting and monitoring dialysis needles was considered substantial enough to qualify as a surgical method, even though it is often delegated to paramedical personnel.

Furthermore, in T 2699/17 the skill required for performing the claimed actions was considered, rather than the qualifications of the individual that normally performs the relevant process. The claimed method related to one step in the preparation of dental crowns, and the Technical Board concluded that “*the specific training necessary for performing the method is minimal, as is the medical expertise required from the person applying the method*”. Furthermore, the Technical Board commented that the claimed step was “*not at the core of the dental practitioner’s freedom to choose the best treatment for the patient*”, which instead related to other decisions and steps. Therefore, there was no need to exclude the claimed method to ensure dental practitioners are free to apply the treatment of choice.

These decisions demonstrate that nature of the claimed steps is to be considered, and the identity of the professional performing them is of less relevance.

Health risks

The Enlarged Board ruled that a “*treatment by surgery*” should encompass only those physical interventions which involve health risks even when carried out with the required medical expertise.

This rules out from the exclusion methods involving only a minor intervention where there are no substantial health risks to the subject. The Enlarged Board mentioned in particular techniques such as tattooing, piercing, hair removal by optical radiation and micro-abrasion. Although it is likely that minor procedures such as simple injections through the skin will not be excluded from

patentability, it seems that any procedures involving health risks exceeding those of common cosmetic methods (piercing, tattooing etc) will not be looked on favourably. Thus, any potentially risky surgical interventions are likely to be excluded from patentability and the Enlarged Board specifically mentioned that injection directly into the heart was an example of a potentially risky surgical intervention.

The Enlarged Board however noted that the relevant health risk should be one resulting from the surgical intervention itself and not resulting solely from, for example, the nature of the agent being administered. For example, administration of a potentially dangerous agent by injection through the skin would likely not be excluded from patentability as a surgical method, because the health risk would derive from the agent rather than the surgical intervention required to administer it. Furthermore, subsequent decisions by Technical Boards of Appeal including T 2699/17 have clarified that the relevant health risk is that applicable to an appropriate patient, not a higher risk that the same intervention may present to a contraindicated patient.

Operation of a Device

An invention purely concerning a method for operating a medical device should not be excluded as a surgical method, insofar as the method only concerns the operation of the device, without any functional link to the effects produced by the device on the body. This follows the older case law exemplified by T 245/87.

This applies even if the device is used in a therapeutic treatment and even if the device requires a surgical step, such as implantation, before the device can be operated according to the claimed method. For example, claims directed to a technical method for improving the performance of a pacemaker should be allowable, even though the pacemaker must be implanted in a body to function.

Claim Category

Only method claims are vulnerable to this exclusion. Apparatus claims cannot be rejected under Article 53(c) EPC, even though apparatus claims cover all uses of the claimed apparatus and even if the apparatus claims define the apparatus functionally (T 1695/07, T 1798/08).

Implicit Step

Even if a claim omits to mention any surgical step, it may still be rejected under Article 53(c) EPC if such a surgical step is nevertheless implicit. Usually, the description is used to determine what, if any, implicit steps fall within the claim (T 1005/98, T 1102/02, T 1376/06).

Nevertheless, T 992/03, on which the original referral to the Enlarged Board of Appeal was based, ruled that an amendment to omit the initial step of providing the xenon gas (considered to include a surgical administration of injection into the heart) rendered the claim allowable, as the administration step was no longer “encompassed” by the claim. It seems that this board took an interpretation of “encompassing” as meaning the claimed steps did not include a time period where the alleged surgical step took place - “temporal encompassing”.

A similar approach was taken more recently in T 1631/17, but with the opposite conclusion. An unclaimed surgical step was considered implicit to the claimed method, because it fell “*in time and space*” between an earlier (also unclaimed) preparatory step that represented the contribution of the invention, and the

explicitly claimed steps.

Methods involving measurement of devices in the human body are often considered to be excluded from patentability, even if no surgical steps are claimed. For example, in T 923/08 it was held that fixing the measuring device to the body was indispensable for performance of the method and so was implicitly claimed and could not be disclaimed. Similarly, in T 318/21 a method of determining the position of an endoscope was rejected under Article 53(c) EPC because it involved movement of the endoscope, which inevitably takes place in the body. The board dismissed an earlier approach taken in T 836/08 that was more generous to the patentee.

Definition of Surgery - Conclusion

There is no precise definition of which surgical methods are to be excluded from patentability under Article 53(c) EPC. Instead, an assessment is to be made on a case-by-case basis using the criteria discussed above. In general, a method involving 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 using such expertise, will be excluded from patentability under Article 53(c) EPC.

The Enlarged Board also noted that a method claim will fall under the exclusion of Article 53(c) EPC if it comprises or embraces at least one surgical step as defined above. Thus, claims written broadly, without explicitly mentioning any surgical step may nonetheless define excluded matter if it is apparent from the description that a claimed step can involve a substantial surgical intervention.

Purpose limited product claims

In some cases, it may be possible to obtain protection for excluded surgical methods by drafting claims in the form “*substance or composition X for use in [specific surgical method]*”. The scope of such a claim is limited by the specified surgical use under Article 54(5) EPC. Importantly, the EPO is likely to allow such claims only where a suitable substance or composition (such as a chemical compound) can be defined. Such claims are unlikely to be allowable where the invention resides in the use of a device or apparatus, because the EPO has traditionally interpreted “substance or composition” as substances or compositions that are consumed in use (T 227/91, T 1172/03, T 1314/05).

Recommendations

The time to consider these issues is when drafting patent applications. An appropriately drafted application can maximise the chance of avoiding the surgical method exclusion of Article 53(c) EPC. For example, applicants should where possible avoid explicitly claiming any method steps that may be considered surgical in nature. Where possible, claims should be drafted to specify that the necessary surgical steps take place separately from the claimed method by using language such as “*pre-implanted*” or “*pre-delivered*”.

It would also be advantageous to draft the patent application such that the claimed method is both temporally and spatially distinct from any surgical steps, perhaps by defining strict start and end points for the claimed method.

Regard should also be had to the examples and embodiments that are used to exemplify the claims. The examples and embodiments

should preferably not demonstrate that the claimed subject matter involves both of a substantial physical intervention on the body and a substantial health risk to the subject.

For cases already on file, it may be possible to amend the pending claims to avoid the exclusion. The exact form of the amendment will be case-specific but, in general, surgical steps may be omitted from a claim only where there is basis in the application as filed for their removal.

If a claim is amended to exclude a surgical step, the claim must still comply with the other requirements of the EPC, notably clarity and sufficiency of disclosure. A claim must include all features essential to the definition of the invention. When assessing this, regard is had to the problem solved and the solution disclosed in the application. Thus, if a surgical step is inherent or essential to an invention, it will lead to the method being excluded from patentability, even if that surgical step is not explicitly stated in the claim. This is why care should be taken when drafting the application to ensure that the “invention” defined in the application does not involve a surgical step as defined by the Enlarged Board.

Unallowable surgical methods may also be excluded from the scope of a claim by use of a disclaimer. Such a disclaimer can be

introduced even if it does not find basis in the application as filed, but only if (a) it excludes solely the unallowable subject matter, and (b) there is at least one non-surgical embodiment left after the disclaimer. Thus, if only surgical embodiments are disclosed, they cannot be disclaimed. The allowability of such disclaimers has been confirmed by the Enlarged Board in G1/16. For more information on the allowability of disclaimers, please see our separate briefing paper on that topic.

It is advantageous to consider these issues when drafting the initial application. For cases taking the PCT route, this means when drafting the PCT application. We would be happy to review any applications before a PCT application is filed, and to provide advice on presenting the invention in the best way to avoid exclusion under Article 53(c) EPC.

It is also to be noted that some aspects of US drafting practice, for example the best-mode requirement and the allowability of surgical method claims, may be at odds with some of the recommendations outlined above for avoiding the exclusion to surgical methods in the EPC. In some important cases, it may therefore be worthwhile filing separate specifications for the USA and the EPO, rather than relying on a single PCT application to cover both jurisdictions.

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