

G 1/07 AND THE EXCLUSION FROM PATENTABILITY OF SURGICAL METHODS AT THE EUROPEAN PATENT OFFICE

Summary

The exclusion under Article 53(c) EPC of methods for treatment of the human or animal body by surgery was considered in opinion G 1/07 of the Enlarged Board of Appeal. The Enlarged Board's conclusions may be summarised as follows:

- 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.
- The exclusion from patentability is not limited to surgical methods having a therapeutic purpose or effect. Non-therapeutic surgical methods, such as cosmetic surgery and organ donation, may also be excluded from patentability.
- Any method claim embracing a single unallowable surgical step of this nature defines an invention excluded from patentability before the EPO.
- Methods concerning only the operation of a device, without any functional link to the effects produced by the device on the body, are not excluded.

Introduction

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 exclusions 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.

Some decisions of the EPO's Technical Boards of Appeal had suggested that only surgical steps with a curative purpose should be excluded from patentability. For example, methods of purely cosmetic surgery would not be excluded from patentability under this approach. Other decisions had suggested that any methods involving a direct physical intervention on the body should be excluded from patentability, irrespective of the purpose of the method.

As a result of this conflict in the case law, the Enlarged Board of Appeal was asked to clarify the breadth of the exclusion relating to methods for the treatment of the human or animal body by surgery. The questions put to the Enlarged Board and the Enlarged Board's answers to those questions are set out in the Annex to this circular.

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. 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.

Medical skill and expertise

The Enlarged Board also 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 and 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. It is also likely that minor procedures such as injections through the skin will not be excluded from patentability. However, any potentially risky surgical interventions are likely to be excluded from patentability based on this analysis. The Enlarged Board considered that injection directly into the heart was an example of such a potentially risky surgical intervention.

The Enlarged Board also 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.

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 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.

Definition of surgery - conclusion

The Enlarged Board of Appeal does not give a precise definition of which surgical methods should be excluded from patentability under Article 53(c) EPC. They instead indicate that this will need to be assessed on a case-by-case basis based on the criteria discussed above. However, the Enlarged Board did conclude that 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.

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*”.

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 it excludes solely the unallowable subject matter. The Enlarged Board declined to comment in G1/07 on whether a general statement such as “*non-surgical*” could validly be introduced into a claim in order to exclude non-patentable surgical methods.

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. However, the EPO is only likely to allow such claims where a suitable substance or composition 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.

As discussed above, 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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February 2010

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ANNEX

Article 53 EPC: Exceptions to patentability

European patents shall not be granted in respect of:

...

(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

Questions referred to the Enlarged Board

1. 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 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*" pursuant to Article 52(4) EPC if such step does not per se aim at maintaining life and health?

2. 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?

3. 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 Enlarged Board's answers to the referred questions

1. 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.

2a. 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.

2b. The exclusion from patentability under Article 53(c) EPC can be avoided by disclaiming the embodiment, it being understood that in order to be patentable the claim including the disclaimer must fulfil 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.

2c. 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.

3. 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.