

Medical Technology: EPO Enlarged Board of Appeal Decision G1/07

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If you are looking to patent medical technology in Europe, this decision will be of interest to you. In this decision the Enlarged Board of Appeal of the European Patent Office considers surgical treatments and sets out a new approach to determining the allowability of patent applications directed to methods of surgery including physical interventions on the body.

Under European law, methods for the treatment of the human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body, are excluded from patentability.

The Enlarged Board of Appeal was asked in this case to consider whether the inclusion of any physical intervention in a claimed method led to that method being excluded from patentability, regardless of whether the step was not per se aimed at maintaining life and health.

The Board said that methods for treatment by surgery should be defined by their nature (surgical or non-surgical) rather than their purpose (therapeutic or non-therapeutic). The Board went on to state that "treatment by surgery is not to be interpreted as being confined to surgical methods pursuing a therapeutic purpose". Accordingly, the exclusion from patentability is not limited to surgical methods having a therapeutic purpose or effect and non-therapeutic surgical methods, such as cosmetic surgery and organ donation, may also be excluded from patentability.

The Board defined "treatment by surgery" as "physical interventions on the body which require professional medical skills to be carried out and which involve health risks even when carried out with the required medical professional care and expertise".

A method will therefore 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. It appears that minor procedures, not involving substantial health risks, fall outside the exclusion. The Enlarged Board mentioned in particular techniques such as tattooing,

piercing, hair removal by optical radiation and micro-abrasion in this regard. It is likely that minor procedures such as injections through the skin will not be excluded from patentability, but the Enlarged Board considered that injection directly into the heart was an example of a potentially risky surgical intervention that would fall within the exclusion.

Further, the Board confirmed that any method claim embracing a single unallowable surgical step of this nature defines an invention excluded from patentability before the European Patent Office.

Finally, any 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.

It was stressed by the Board that the conclusions reached were limited to the facts of the particular case. However, the decision strongly suggests that any surgical method will be excluded from patentability, regardless of whether it is aimed at maintaining life and health.