



JONES DAY
COMMENTARY

G1/07: EPO ENLARGED BOARD RULES ON METHODS OF SURGERY

One contrast between Europe and some other jurisdictions, notably the U.S., concerns the restrictive practice relating to patent claims for medical methods. According to Art. 53 (c) of the European Patent Convention, patents shall not be granted for methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body. The Enlarged Board of Appeal (“EBA”) has now provided some clarification on the first of these three exceptions, namely surgery.

TYPE OF METHOD ON WHICH THE BOARD RULED

The EBA’s ruling was in response to a referral from a Technical Board of Appeal on an appeal against a refusal of a patent application that included several independent claims to an MRI (magnetic resonance imaging) method involving a step of “administering” a certain imaging agent. One possible way of

administration disclosed in the application was by injection into the heart, but the independent claims were not limited to this alternative; inhalation by the patient was also mentioned as a possibility, depending on the part of the body to be imaged. The primary focus of the method was not to treat the patient but to obtain images. Nevertheless, the claimed method certainly was intended for use in providing images to a surgeon during an operation.

STRICT APPLICATION OF THE EXCLUSION OF MEDICAL METHODS REQUIRED

The EBA ruled that a claimed imaging method that comprises or encompasses an invasive step involving a substantial physical intervention on the body—one that requires professional medical expertise to be carried out and entails a substantial health risk even when carried out with the required professional care and expertise—is excluded from patentability as

a method of treatment by surgery. Thus, it does not matter that the step only encompasses but does not explicitly claim such a step. However, the EBA also ruled that, depending on the nature of the case, embodiments with a step of this kind can in principle be disclaimed, leaving only variants that do not include a “forbidden” step. What form of disclaimer would be allowable would depend on the exact circumstances of the case. In principle, one could use terms such as “pre-administered” to exclude the surgical administration step, or one could add to the claim a feature such as “with the exclusion of methods involving the surgical administration of”

In that case, the fact that the data obtained by means of the method immediately allows a surgeon to decide on the course of action to be taken during a surgical intervention does *not* make the method unpatentable.

With its decision, the EBA has overruled an earlier decision of a Technical Board of Appeal, in which it was decided that a method that involves a non-insignificant intentional physical intervention, but that is clearly not potentially suitable for maintaining or restoring the health, physical integrity, or physical well-being of a person, is not excluded from patentability. According to the EBA now, it is the nature, not the purpose, of a method that is to be assessed.

WHEN IS AN INTERVENTION SURGICAL?

Significantly, in the reasons for its decision, the EBA indicates that it considers earlier case law—according to which all non-insignificant interventions performed on the structure of an organism by noninvasive or invasive procedures are to be considered as surgical intervention—as too restrictive. There

is no new definition, but there are some pointers toward criteria for assessing whether an intervention is surgical in nature.

Basically, all kinds of method that represent the core of the medical profession’s activities—those that require medical skills and involve health risks even when performed with the required medical professional care and expertise—are to be considered surgical in nature and thus not patentable. The EBA does note that, in the case of the injection of a contrast agent or similar substance, the health risk would need to be associated with the mode of administration, not solely with the agent as such. Interestingly, the term “medical profession” is apparently to be construed broadly. The EBA states—referring to its own earlier ruling on diagnostic methods (G1/04)—that whether an intervention is to be considered surgical in nature does not depend on the active participation of a medical practitioner or on his bearing responsibility for the procedure, nor on the fact that the intervention could also be practiced by medical or nonmedical support staff, the patient, or an automated system.

Methods that do not affect the interests of public health or the protection of patients and do not affect medical professionals’ freedom to apply the treatment of their choice to their patients should be allowed. These are the kinds of safe and routine invasive techniques, at least when performed on uncritical parts of the body, that are commonly carried out in commercial settings such as cosmetic salons and beauty parlors.

Furthermore, the decision confirms that claims to methods that properly define the operation of a device, even if subsequent to a surgical procedure (e.g., methods defining the operation of a pacemaker) can be patentable, if novel and inventive.

A BALANCED OUTCOME FOR POTENTIAL PATENTEES

Overall, this decision limits the range of patentable subject matter, in that methods that are surgical by nature but not necessarily by purpose are not deemed eligible for patent protection. On the other hand, the EBA indicates that a method with surgical and nonsurgical variants can be patented by disclaiming the surgical variants. Moreover, because it indicates that whether or not a particular intervention on the human or animal body is surgical by nature must be assessed less strictly than set out in previous case law, this decision certainly should encourage the medical industry to patent its innovations in Europe. The lower instances will now have to develop workable criteria for determining when an invasive step constitutes a substantial physical intervention on the body that requires professional medical skills and involves a substantial health risk, even when carried out with the required care and expertise.

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