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## CLIENT ALERT

### *EPO Issues Decisions On Methods Of Treatment By Surgery And Dosage Regimens*

Two recent decisions from the EPO Enlarged Board of Appeal have resolved several issues related to the patentability of claims that relate to methods of treatment.

#### **G1/07**

A number of questions had been referred to the Enlarged Board of Appeal concerning an imaging method and whether a claim step that encompassed injection of a contrast agent into the heart foreclosed patentability. The Enlarged Board of Appeal decided that:

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 of 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.
2. 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. The exclusion from patentability under Article 53(c) EPC can be avoided, however, by disclaiming the embodiment. 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.

While the Decision is fairly lengthy, the general position taken by the Enlarged Board can be seen from the following excerpts from the Decision:

“The advances in safety and the now routine character of certain, albeit invasive techniques, at least when performed on uncritical parts of the body, have entailed that many such techniques are nowadays generally carried out in a non-medical, commercial environment like in cosmetic salons and in beauty parlours and it appears, hence, hardly still justified to exclude such methods from patentability. This applies as a rule to treatments such as tattooing, piercing, hair removal by optical radiation, micro abrasion of the skin.”

“Considering this technical reality, excluding from patentability also such methods as make use of in principle safe routine techniques, even when of invasive nature, appears to go beyond the purpose of the exclusion of treatments by surgery from patentability in the interest of public health.”



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From a practical point of view, and in view of part 2 above, we continue to recommend inclusion of language such as “previously obtained”, “previously injected”, “pre-delivered contrast agent”, etc. in the specification to provide basis for claim language which does not include a step of alleged surgical intervention.

## **G2/08**

Decision G2/08 resolves several issues relating to medical uses of known compounds. Perhaps most importantly, the Enlarged Board of Appeal decided that “where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83.” Instead, such claims MUST now be presented in the “product for use” format now allowed under EPC 2000: *i.e.*, such claims must now use the format of “[known substance or composition] for use in [new therapeutic use].” This restriction on claim format will NOT be applied retrospectively, however.

The Decision also addressed the issue of whether Article 54(5) EPC excludes patentability where both the medicament and its use in treating an illness is already known, with the only distinction over the prior art being related to novel and inventive aspects of the treatment regimen. In this regard, the Board held:

1. Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness.
2. Such patenting is also not excluded where a dosage regime is the only feature claimed which is not composed in the state of the art.

Thus, Decision G2/08 explicitly permits the patenting of inventions directed to new dosage regimens, such as those based on route, rate, or frequency of administration. Although this Decision did not address the issue directly, it seems likely that this would permit patentability of dosage regimes based on achieving specific pharmacokinetic parameters in a patient, such as  $T_{max}$ ,  $C_{max}$  and AUC.

For further information and advice, please feel free to contact S. Maurice Valla at (215) 568-3100.

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