

The Federal Supreme Court in Germany does not follow the case law of the EPO regarding second medical use claims

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In its decision Carvedilol II the Federal Supreme Court does not follow the liberal practice of the EPO regarding allowability of second medical use claims. In its decision Carvedilol II (X ZR 236/01) the Supreme Court is of the opinion that treatment steps, like the administration of a medicament in a certain dosage, cannot be used for delimiting a second medical use claim over the prior art.

This decision is based on the following claim:

*Use of carvedilol for the preparation of a medicament for reducing mortality ... wherein the medicament **is administered** in an initial dosage of ... followed by an increase of dosage ...*

The Supreme Court was of the opinion that the administration of a medicament for the treatment of a certain disease as such is a therapeutic treatment of the human body and not part of the preparation of a medicament to be used for the treatment of a certain disease.

The Supreme Court further stated that the subject of the examination of patentability can only be those features not related to the dosage regimen. The Supreme Court further questions whether additional goals of the therapy, like the reduction of mortality, would be suitable for demonstrating patentability of the claim.

Both opinions of the Supreme Court are in marked contrast to the practice of the EPO Appeal Boards as, e.g., given in **T 1020/03**, where the Board acknowledged that any measure in the course of a treatment regimen in principle is suitable for establishing novelty and inventive step of a second medical use claim.

In the decision Carvedilol II the Supreme Court, however, acknowledged that a dosage regimen could be used as a

distinguishing feature over the prior art if the dosage regimen is part of the preparation of the medicament. Accordingly, a claim according to the second auxiliary request as filed with the Court with the following wording was found to be admissible:

*Use of carvedilol for the preparation of a medicament for reducing mortality ... wherein the medicament **is prepared for the administration** in an initial dosage ...*

This means in practice that the claims of a European patent application directed to a second medical indication should contain, at least as an alternative claim wording, a wording which is allowed by the Federal Supreme Court.