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BGH restricts patentability of dosage regimens

In a recent decision (*Carvedilol II*; X ZR 236/01), the German Federal Supreme Court (BGH) has ruled on the validity of a second medical use claim comprising a dosage regimen for the beta-blocker carvedilol, the claim reading: “Use of carvedilol for the manufacture of a medicament ..., wherein the medicament is administered in an initial dose of 3.125 mg ... per day over a time period of 7 to 28 days, followed by dosage increases”

The BGH held that the prescription and dosing of a medicament is a distinctive part of the activity of a physician and therefore regarded the claim as a method of treatment that is excluded from patentability pursuant to § 2a(1) Number 2 German Patent Act.

Furthermore, the Court concluded that dosage instructions are not to be considered for assessing the novelty of the remaining part of the claim. However, the Court has left the question unanswered whether claims containing such dosage regimens are entirely invalid even though the remaining part may still be novel and inventive.

The opinion of the BGH is in marked contrast to the recent lenient policy of the European Patent Office (EPO) laid down in Technical Board of Appeal decision T 1020/03, where the Board acknowledged that any administration step (including dosage instructions) in a treatment regimen is in principle suitable for establishing novelty and inventive step of a second medical use claim.

In the carvedilol case an auxiliary request was filed with a claim in which the passage “wherein the medicament is administered” was replaced by “wherein the medicament is prepared for administration”. The Court acknowledged the latter wording to be admissible since the dosage regimen is here defined as a feature of the medicament as such and not as part of an administration scheme.

Interestingly, in *Actavis v Merck*, the Patents Court of England and Wales has taken a similar view.

The contradictory practices of the

EPO and the BGH regarding the patentability of dosage regimens pose the danger that second medical use claims granted by the EPO could be *a priori* invalid in Germany. Thus applicants would be well advised to pursue parallel claim versions reciting both of the above wordings in order to be sure of having directly enforceable claims in Germany.