

## GERMANY



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## EPO Enlarged Board to consider dosage regimen claims

It is persistent European Patent Office (EPO) case law that, while therapeutic methods are excluded from patentability, not only a claim to a known substance for its first medical use, but also for its second medical use (that is, its use in the therapy of a different disease) is patentable (G 5/83). There is, however, a dispute over whether a mere change in dosage regimen configures a patentable second medical use even when the medicament and disease remain unchanged.

The revised EPC 2000 has not resolved this question. The admissibility of a dosage regimen claim now additionally depends on the interpretation of Article 54(5) EPC, which had no counterpart in the EPC 1973 and which stipulates that a substance for a specific use in a therapeutic method is patentable.

These uncertainties may be ended in the near future. In a recent decision (T 1319/04) the questions of (1) whether a known medicament for a known disease may be patented for a different mode of treatment of the same disease, and (2) whether that patenting were also possible if the only distinguishing feature of said treatment mode were a dosage regimen were referred to the Enlarged Board of Appeal of the EPO (Referral G 2/08).

T 1319/04 related to a patent application for a dosage regimen of nicotinic acid in the treatment of hyperlipidaemia. The contentious claim read on a medicament for use “by oral administration once per day prior to sleep ...”, and differed from the prior art merely in the frequency and time of administration.

In some aspects, the decision is a direct riposte to decision T 1020/03, where for the first time a medicament (IGF-I) characterized by a pure dosage regimen was recognized as being patentable.

For applicants, it must be kept in mind that even if the Enlarged Board of Appeal follows the approach of T 1020/03, some dosage regimen claims

will still run the risk of being invalidated or unenforceable after their grant by the EPO. In Germany (BGH-*Carvedilol II*, X ZR 236/01) and in the UK (*Actavis v Merck*) the exact wording of the claims may be decisive. A second medical use claim on a medicament “wherein the medicament is prepared for administration” was found to be admissible in both countries, contrary to a claim “wherein the medicament is administered”.

It therefore remains to be seen whether the outcome of G 2/08 will dispense at least with some of the side effects of dosage regimen claims in the future.