

GERMANY



**Maiwald Patentanwalts
GmbH
Munich**

Luder Behrens

Impact of G2/08 on claims relating to dosage regimens

In a recent decision (G2/08) published on February 19 2010 the Enlarged Board of Appeal (EBA) of the European Patent Office (EPO) ruled, *inter alia*, on the patentability of claims relating to the use of a known active ingredient in the preparation of a medicament for the treatment of a known medical indication where the treatment differs merely with respect to the administration regimen (generally referred to as dosage regimen).

The EBA decided that claims comprising dosage instructions are in principle patentable, provided the specific dosage regimen fulfills also the patentability requirements of novelty (Article 54 EPC) and inventive step (Article 56). In this respect, the EBA referred to the jurisprudence on selection inventions developed by the boards of appeal. Furthermore, the EBA emphasized that the specific dosage regimen must be associated with a technical effect different from what was known in the state of the art.

In an additional aspect of G2/08, the EBA ruled that Swiss-type claims are no longer admissible for applications filed three months after publication of the decision. Consequently, as of May 19 2010, applicants must use the claim format provided for in Article 54(5) EPC, permitting purpose-related product protection for any specific use of a known medicament in a method of therapy.

However, claims written in the format prescribed by Article 54(5) EPC will not automatically overcome obstacles established by the jurisprudence of the German Federal Supreme Court (BGH). In the decision *Carvedilol II* (X ZR 236/01), the BGH ruled that claims comprising expressions such as “wherein the medicament *is administered* according to dosage regimen XY” are excluded from patentability pursuant to § 2a(1) Number 2 German Patent Act. On the other hand, claims comprising the expression “wherein the medicament *is prepared for* administration according to dosage regimen XY” were held to be admissible. The court

acknowledged that the latter wording is acceptable for the reason that the dosage regimen is defined as a feature of the medicament and not as part of an administration scheme.

For European patent applications comprising claims pursuant to Article 54(5) EPC that are validated in Germany, it still appears to be preferable to use claim language accepted by the BGH.