

GERMANY



**Maiwald Patentanwalts
GmbH
Munich**

Dirk Bühler



*and
Holger Glas*

Utility models for new medical indications

Under German law an invention may be protected simultaneously by a granted patent and a registered utility model.

Unlike patents, German utility models are examined for formal requirements only and are usually registered about two to three months from the filing date. After registration, a utility model confers the same legal effects as a patent albeit only for 10 years. The validity of a utility model may be attacked in an infringement suit or in separate nullity proceedings. It is important to note that a utility model can also be derived from any pending patent application having effect in Germany (including European patent applications). This opens the possibility for tailoring an enforceable protective right covering specific products offered or marketed by a competitor when the corresponding patent application is still under examination.

It is to be noted that German utility models – contrary to patents – do not allow for the protection of methods and processes. The prevailing opinion of literature therefore assumes that use claims are also excluded from utility model protection, since use claims are commonly assigned to the claim category of process claims. This, however, would bar inventions relating to a second medical use, that is a novel therapeutic use of a known drug, from utility model protection.

In a recent decision (X ZB 7/03), the German Supreme Court stated that a claim referring to the use of an active agent in a medicament for treating a specific condition is an allowable claim format for a utility model. In the grounds for the decision, the Supreme Court considered the exclusion of process claims according to the German Utility Model Law to relate to manufacturing methods or actual processing methods. However, in the Supreme

Court's opinion, a claim referring to the use of a known drug for a new medicinal indication has more elements of a product claim than of a process claim.

As a consequence, applicants who want to promptly obtain an enforceable protective right in Germany covering a new medical use of a known drug should, in future cases, put filing utility models on their agenda. A registered German utility model which is derived from (for example) a European patent application and protecting a second medical indication can be a suitable tool to prevent competitors from entering the market in Germany.