GERMANY

Maiwald Patentanwalts GmbH
Munich

Martina Müller-Dyck.

New opportunities to obtain purpose-related patents

Where a substance or composition is already known in the art, it may still be patentable under Section 3(4) of the German Patent Law for a specific new and inventive use in a method for treatment of the human or animal body by surgery or therapy. It was also decided by the German Federal Supreme Court (BGH) that purpose-related product protection can be obtained for a use relating to a specific dosage instruction (BGH – Carvedilol II, BGH – Fettsäuren).

In two recent cases, also known as Kollagenase I and II, the BGH extended this patent practice to other instructions. The patent applications concerned collagenase claimed for use in the treatment of Dupuytren's disease (BGH X ZB 5/13) or Peyronie's disease (BGH X ZB 6/13). The use of collagenase for treating these conditions was known in the art, and in both cases the claimed use differed from the prior art in the instruction that the body parts affected should be immobilised for several hours immediately after the injection of collagenase.

Both patent applications were rejected by the Federal Patent Court (BPatG) on the ground that an instruction to immobilise a body part is not a feature relating to the preparation of a medicament for use in the treatment of a specific condition. Rather, it is merely an instruction to the medical practitioner, and thus, a method of treatment that is excluded from patentability.

Contrary to the BPatG, in both cases the BGH held that the instruction feature must be taken into account to assess patentability because it concerns a therapy-related instruction which enhances the therapeutic effect by preventing diffusion of the injected collagenase into other parts of the body, and remitted the cases to the BPatG in order to decide on novelty and inventive step. The BGH elaborated that also the route of administration (for example, orally, transdermally, or by injection), the nature of the substance (solid, liquid, or gaseous), the patient group or other parameters can be relevant with respect to the therapeutic effect of a substance.

In conclusion, purpose-related product protection may be obtained for any instruction or use aspect which objectively contributes to the improved effect of substance, provided it is novel and inventive.