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Are Method of Treatment Features To Be Considered for Patentability?

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Suppose you have an invention that resides in using a known substance in a known dosage for a known purpose, and your only distinguishing feature is that you apply a particular therapeutic measure after the administration of your substance. Can such a post-administration therapeutic measure, which is in essence a method of treatment, establish patentability of your invention?

It can. On February 25, 2014, the German Federal Court of Justice (FCJ) issued two decisions under the keywords „Kollagenase I“ (X ZB 5/13) and „Kollagenase II“ (X ZB 6/13). Both cases relate to collagenase as an active substance for the treatment of Dupuytren’s and Peyronie’s disease. Both of these are conditions that are caused by collagen deposits in the connective tissue. They cause painful plastic deformations in the palm or penis, respectively, and a known method to treat them has been to degrade those collagen deposits by a collagen-degrading enzyme, i.e. collagenase.

The main claims of the two patent applications at stake contained the following simplified claim wording:

Collagenase for use in the treatment of Dupuytren’s [or Peyronie’s] disease, wherein the collagenase is prepared for injection into a collagen strand [or plaque] in the palm [or the penis] (…), and for immobilizing the palm [or the penis] immediately after the injection for several hours.

The FCJ decided in 2006, (Carvedilol II, X ZR 236/01, Headnote 2) that if a dosage recommendation ineligible for patent protection is one of several features of a patent claim, the recommendation may not in any case be used when assessing novelty and inventive step. Applying this reasoning and arguing that the “immobilizing” feature is a mere instruction to the medical practitioner and hence a method of treatment which is per se ineligible for patent protection, the German Patent Office and the Federal Patent Court (FPC) rejected these claims. However, leave for appeal on a point of law was granted and the FCJ took the opportunity to clarify and extend its earlier case law.

The FCJ held that according to Sec. 3(4) PatG (German Patent Act) and Art. 54(5) EPC, purpose-related product protection may be available for a known substance for a new use in a method of treatment of the human or animal body by therapy or surgery (so-called second medical use). Such a new medical use may consist for example in the treatment of a disease but also in a specific dosage regimen (see decision G2/08 of the EPO’s Enlarged Board of Appeal, which the FCJ

explicitly endorsed).

In the Kollagenase decisions, the FCJ extended this “use” according to Sec. 3(4) PatG / Art. 54(5) EPC yet further. The court held that an “instruction feature” such as the immobilizing feature of the above claims must be taken into account for the assessment of patentability provided that the feature concerns a therapy-related instruction that objectively contributes to an improved effect of the substance. The FCJ found that this requirement was met in both cases, since the immobilization of the affected body part prevents diffusion of the injected collagenase into other parts of the body and thus enhances the therapeutic effect. Hence, the FCJ affirmed that, in principle, such a therapy-related instruction may confer novelty and inventive step to a purpose-related product claim, even if the instruction does not directly concern the application of the compound as such.

Both appeals on a point of law were therefore allowed and the cases remitted to the Federal Patent Court for further deliberation and decision, particularly on inventive step. The FCJ cautiously hinted that the immobilization of the affected body part may still be obvious and possibly belong to a medical practitioner’s standard repertoire, yet the court was not certain that this was conclusively established by the FPC and that the Appellant had a sufficient opportunity to comment on such a reasoning.

In summary, both Kollagenase decisions clarify that any use aspect of a “substance-for-use- claim” according to Sec. 3(4) PatG / Art. 54(5) EPC that objectively contributes to an improved effect of a drug, must be taken into consideration when examining novelty and inventive step. This may open new possibilities for creative claim drafting to applicants from pharmaceutical industry, provided of course that the method of (post-)treatment itself is novel and inventive.

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