IS A DOSAGE REGIME PATENTABLE?

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In a decision of February 19, 2010, the Enlarged Board of Appeal interpreted the scope of Article 54(5) of the revised European Patent Convention (EPC), which entered into force on December 13, 2007. The board concluded that the article does not prevent patenting a medicine used for treating a condition as long as the treatment differs from the existing option by providing a new mode of administration, such as where a dosage regime is the only feature claimed that is not disclosed in the state of the art.

However, irrespective of this decision, the French Court of First Instance in Paris held on September 28, 2010 that a dosage regime is effectively a method of treatment and is, as such, excluded from patentability in view of Article 53 (c) of EPC 2000.

This particular case related to the French part of Merck & Co. Ltd's patent, filed in October 1994, which claimed "[t]he use of finasteride for the preparation of a medicament for oral administration for the treatment [of] androgenic alopecia in a person and wherein the dosage amount is about 0.05 to 1.0 mg".

The court held that both the active ingredient and its use for treating a specific illness (androgenic alopecia) were already known in the art, and that the claims were only new due to a specific dosage regime.

Androgenic alopecia is a phenomenon that involves a reduction in hair density or complete loss of hair, related to the excessive accumulation of androgen hormones (particularly, testosterone). In 1985, Merck filed a patent application disclosing the use of finasteride for treating hyperandrogenic conditions by oral or topical administration. In 1988, Merck filed another application disclosing the use of finasteride for treating androgenic alopecia (also a hyperandrogenic condition).

Consequently, the use of finasteride to treat androgenic alopecia, with various possible methods of administration (topical or systemic), was already known before the 1994 patent was filed. Accordingly, only the dosage regime for the active ingredient, finasteride, ranging from 0.05 to 1 mg, was new, since Merck's earlier applications disclosed specific dosages ranging from 5 to 2,000 mg.

However, the French court held that a specific dosage regime is not a medical use, but a therapeutic method excluded from patentability pursuant to Article 53(c) EPC 2000, and nullified the French part of Merck's European patent.

In this respect, the French court stated that it is possible to patent a medicine for the treatment of a first and then a second illness, but not a dosage adapted to the treatment of those illnesses, because by doing so, one attempts to patent a therapeutic method, which is excluded. The exclusion is justified because therapeutic methods belong to the field of care and depend on the freedom and responsibility of each doctor.

The French decision is also interesting because it clearly repudiates the interpretation of Article 54 (4) EPC 2000 adopted by the EPO Enlarged Board of Appeal in its decision G2/08 by stating: "Furthermore, Article 54(4) EPC, which allows a same medicine to be patented for a second therapeutic effect, is totally silent on the possibility of patenting a certain dosage so that the Enlarged Board of Appeal's answer according to which 'such patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art', cannot be inferred from the Convention but from an interpretation of what a dosage is, that is, a second therapeutic application, which plainly it is not."

The UK and Germany have also passed judgments on the same patent.

The UK High Court first revoked the Merck patent in 2008 for lack of novelty on the grounds that it was neither novel pursuant to Article 54 EPC nor patentable as a method of medical treatment. However, the UK Court of Appeal (Civil Division), decided in view of settled EPO case law (at the time) that a dosage regime was patentable and that, in this particular case, it was novel and non-obvious.

Similarly, in 2008, the German Federal Patent Court decided that a dosage regime was patentable; however, it also found that the dosage regime for this specific patent was lacking novelty.

The above decisions are clear examples that the same patent can be subject to different judgments in different EPC states and that a party wishing to enforce and/or revoke a EP patent may find themselves in the unsatisfactory position of having to initiate legal action in every single country of interest, leading to considerable legal uncertainty affecting both the parties concerned and the public.

Therefore, initiatives to provide a centralised European Patent Court in order to improve the framework for IPR protection are welcome. ■

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