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DOSAGE REGIME NOW DECLARED PATENTABLE BY THE EPO

Finally putting an end to the question of patentability of dosage regimes (i.e. inventions where the active ingredient and the related therapeutic indications are known, and the point of novelty lies in the amount and/or frequency of administration), on February 19, 2010 the Enlarged Board of Appeal of the European Patent Office (EPO) rendered an important decision confirming the patentability of such dosage regimes. In particular, the Board has established that **a new medical use for which protection is sought may also consist in a new way of administering a known medicament, for instance through a new dosage regime**.

The subject matter of the decision leading to the referral of the question of dosage regime patentability to the Enlarged Board of Appeal was an application claiming the use of a compound for the manufacture of a medicament to be administered orally for the treatment of hyperlipidaemia, the novel feature of such use lying in the fact that the compound should be administered once per day prior to sleep.

The application was refused by the Examining Division of the EPO on the basis that the novel feature, i.e. the way of administering the compound, was to be regarded as a medical activity, as such excluded from patentability by the European Patent Convention (EPC).

An appeal was filed against the refusal decision; during the appeal phase, the case was then referred to the Enlarged Board of Appeal with the following questions:

- *"Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented […] for use in a different, new and inventive treatment by therapy of the same illness?"*
- *In the affirmative, "is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?"*

As regards the first question, the Enlarged Board noted that while the new EPC provisions, which entered into force in December 2007, allow the further protection of a known medicament provided its new therapeutic use is specific, they do not determine what features the new use should have to be specific. However, on the basis of general law principles and the intention of the legislator the Enlarged Board reached the conclusion that the new use need not be the treatment of another disease for it to be regarded as specific and thus patentable. In other words, **the patentable new use of a known medicament is not necessarily confined to an entirely new indication**.

The Enlarged Board then replied affirmatively also to the second question, maintaining that there does not appear to be any reason why a new dosage regime should be treated differently from any other specific use recognized by the case law, such as that relating to a new group of patients or to a novel mode of administration.

The Enlarged Board acknowledged that its interpretation could possibly lead to an unfair extension of the patent protection as a consequence of claims allegedly deriving their novelty and non-obviousness requirements from a newly defined dosage regime. In order to overcome this risk, the Enlarged Board specified that the claimed dosage regime must *"not only be verbally different from what was described in the state of the art but also reflect a different technical teaching"*.

Finally, the Enlarged Board stated that in the light of its decision the so-called Swiss-type claims will no longer be allowed (in other words, **only the new product-for-use claim format will be allowed for new medical uses**). This last provision will have no retroactive effect and will enter into force three months after the publication of this decision in the Official Journal of the EPO. At the moment of the drafting of this article, such publication had not yet occurred.

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