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PHARMACEUTICALS AND DOSAGE REGIMEN CLAIMS AT THE EUROPEAN PATENT OFFICE

In the field of pharmaceuticals, it often happens that once an active ingredient is discovered and a first suitable formulation is devised, later investigations lead to the development of further dosage regimens for that active ingredient, for the same therapeutic indications as those associated with the first formulation or for different ones.

Dosage regimens are, as such, patentable at the European Patent Office (EPO).

However, also because of the economic interests involved, dosage regimen patents are frequently challenged at the EPO, e.g. based on the argument that the new dosage regimen would have been obvious to try. This argument is especially common when, before the priority date of the European patent, phase 2 clinical trials with the particular dosage regimen claimed had already been published.

A recent decision of the EPO Boards of Appeal ruled on a case where, owing to particular circumstances, the Board held that the claimed dosage regimen was not obvious to try.

The case relates to the treatment of multiple sclerosis (MS), a disease characterized by unusual variability in the occurrence of symptoms, with frequent episodes of relapse and remission being common, which leads to particular difficulties in recognizing the clinical benefit of therapies. In that case, the Board considered that *"presumably due to the high intra-patient and inter-patient variability of disease symptoms in the case of MS … it actually turned out to be exceptionally difficult in this case to provide the required proof of efficacy"*. Nevertheless, the Board carefully assessed the statistical technique that the patentee had developed in order to determine whether the MS treatment with the claimed dosage regimen was effective. The Board found that only by developing, post hoc, that new and non-obvious statistical technique was the patentee able to prove that the novel dosage regimen had efficacy. The Board thus concluded that the claimed dosage regimen was not obvious to try, as the skilled person would not have had an expectation of success in connection with that dosage regimen due to the difficulty in assessing the dosage regimen's efficacy via standard statistical models.

In this case, the opponents also argued that the dosage regimen claims lacked sufficiency of disclosure (i.e. they were not enabled), because the patent itself acknowledged that only about one-third of patients ("responders") responded to treatment with the claimed active ingredient, while the remainder ("non-responders") did not. Contrary to this argument, the Board found that "[t]*he existence of a substantial proportion of patients who are non-responders is a common phenomenon observed with drugs in many treatment areas, such as diabetes, migraine or cancer. It is common practice to treat patients with a drug and change their medication should it turn out that they do not respond to the treatment.*" Thus, the Board concluded that if it could be shown that a relevant proportion of patients is able to benefit from a treatment, and that the safety of such treatment is acceptable, the criterion of sufficiency of disclosure would be met irrespective of the presence of non-responders. This is because, in the Board's view, the person skilled in the art would have the necessary technical information to perform the treatment.

This is certainly an interesting decision for all those operating in the field of pharmaceuticals, and its findings could also set a precedent in other cases where the efficacy of a claimed invention may be difficult to determine via standard models.

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