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Strict interpretation of the patentability of dosage inventions under French law

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While the patentability of further medical use claim defined by a dosage regimen used to be ruled out, the EPO's Enlarged Board of Appeal has accepted them since decision G 2/08 in 2010. This patentability was also strongly debated before the French Courts, even after G 2/08, before being eventually recognized, although the interpretation of the patentability of this type of inventions remains strict, as recalled by a recent decision in the "rivaroxaban" case (Paris High Court, 28 March 2024).

In this case, Sandoz wanted to market in France a generic version of the drug Xarelto, which active ingredient is rivaroxaban, after the expiry of the European patent and then the SPC protecting the use of the said product for the treatment of thromboembolic diseases. However, Bayer, the holder of these two titles, also held another patent relating to the same treatment, but claiming a specific dosage. Sandoz therefore brought an action for nullity, considering that the sole purpose of this second patent was to delay the entry of generics onto the market.

The plaintiff claimed a lack of inventive step. The technical problem solved by the invention was that the medicine could be taken only once a day. Regarding the number of doses required for administration, the prior art documents demonstrated that a dosage of two doses per day was appropriate at the stage of a phase I study. However, certain documents strongly encouraged those skilled in the art to consider a dosage of a single dose per day, at least as a research alternative to the double dose mentioned in other documents. Finally, no technical difficulty was demonstrated in achieving the solution, since the demonstration of a difficulty did not concern the solution itself, but the phase II clinical trials, which could be envisaged by the person skilled in the art, with a view to confirming the hypothesis of a daily dose, and which should only be carried out with great caution. Moreover, if the tests were risky, the person skilled in the art would have been able to take the necessary safety measures. Thus, the claimed invention of a dosage consisting of once-daily administration of rivaroxaban by a rapid-release tablet was obvious to the person skilled in the art at the date of priority.

This new ruling is classic: the Judges focus solely on the condition of inventive step, as they would have done for any other invention in case of a revocation action. The fact remains, however, that the recognition of dosage inventions under French law stays particularly complex. The debate on this subject has been lively for about ten years. Although the Courts now recognize the patentability of dosage regimes, the assessment of their patentability is still very strict. For instance, in the famous "finasteride" case, the revocation of a finasteride dosage patent by the Paris

High Court ("Tribunal de Grande Instance") was upheld by the Paris Court of Appeal, which nonetheless stated that: "*while the patentability of a claim for a second therapeutic indication based solely on a dosage characteristic may be accepted even for a patent subject to the EPC 1973 interpreted in the light of the subsequent amendment to the Convention and the resulting case law, the claim must meet the requirement of the existence of a different technical teaching, and in order to do so must also take into account* […] *characteristics relating to dosage*." (*Paris Court of Appeal, 30 January 2015, n° 10/19659, confirmation of Paris High Court, 28 September 2010, Actavis Group et al. c. Merck Sharp & Dohme Corp., n° 07/16296, and confirmed by Cour de cassation, Commercial chamber, 6 December 2017, n° B 15-19.726*). This clarification by the Paris Court of Appeal followed a series of revocations by the French Courts. In 2014, the same Court had itself revoked certain claims relating to particular dosages for administering raloxifene, on the grounds that they were excluded from patentability (*Paris Court of Appeal, 12 March 2014, Eli Lilly and company et al. v. Teva Santé et al, No. 12/07203*), while a few months later the Paris High Court rejected patentability for successive daily dosage units for administering the active ingredient desogestrel, on the grounds that this was a therapeutic method excluded from patentability (*Paris High Court, 5 December 2014, Akzo Nobel NV et al. v. Teva Santé SAS et al., no. 12/13507*).

At the end of the day, while the "rivaroxaban" judgment does not add anything particularly new to this debate, it does serve as a reminder for those wishing to invoke patents relating to dosage regimes on French territory (as well as a reminder for those who do…).

This entry was posted on Monday, September 23rd, 2024 at 5:02 pm and is filed under France, Pharmaceutical patent
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