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Rivaroxaban decided in Denmark, PI denied

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NO INFRINGEMENT OF RIVAROXABAN DOSAGE FREQUENCY PATENT – DANISH COURT REJECTS BAYER'S APPLICATION FOR PRELIMINARY IN-JUNCTION

1. Summary

On 9 October 2024, the Maritime and Commercial Court rendered its decision not to grant Bayer's applications for interim measures against four generics — Sandoz, Glenmark, and Stada — based on EP 1 845 961 ("EP 961").

Teva was originally the fourth defendant in the case but withdrew from the legal action at an early stage and undertook to respect the outcome of the court's decision.

The remaining three defendants argued that EP 961 was invalid and that, in any event, there could be no infringement of EP 961.

The court concluded that Bayer had not met the burden of proof to establish infringement of EP 961, and turned down Bayer's application, but took no position on the issue of inva-lidity.

2. Background and key themes of the case

The patent-in-suit, EP 961, protects the use of rivaroxaban for treating thromboembolic disorders, where the rivaroxaban is administered orally no more than once daily for at least five consecutive days, and where the compound has "a plasma concentration half-life of 10 hours or less" – with the latter feature (the "half-life feature") playing the central role in the recent legal actions across Europe as well as in Denmark.

The half-life feature had been dealt with by the Boards of Appeal of the European Patent Office ("TBA"), which upheld the patent noting that the half-life feature was "redundant".

In the Danish legal action, the parties, among other things, disagreed on

i) whether the half-life feature should be disregarded in the infringe-ment assessment, i.e., whether there could be infringement regard-less of whether the half-life was above or below 10 hours;

ii) whether the half-life should be understood as the "effective half-life" or the "terminal half-life";

iii) whether Bayer had demonstrated that the half-life in the relevant pa-tient population was 10 hours or less.

3. The Maritime and Commercial Court's decision

The Maritime and Commercial Court firstly noted that it would not assess the question of invalidity, as the Court had determined that there could be no patent infringement.

The Maritime and Commercial Court then held, in line with the defendants'—and particu-larly Sandoz's — submissions that

i) the TBA had only considered the half-life feature of "10 hours or less" to be "re-dundant" because the half-life of rivaroxaban was reported in the description as 4-6 hours. However, in the context of an infringement assessment, and given that the actual half-life of rivaroxaban was not 4-6 hours, the feature could not be disregarded and therefore must be met for there to be a finding of infringe-ment;

ii) the relevant half-life according to the skilled person on the priority date of EP 961 would be the terminal half-life based on the evidence in the case, including Bayer's own regulatory documents in which the terminal half-life specifically was referred to as the basis for testing a once-daily dosing regimen with riva-roxaban,

iii) infringement of EP 961 would require the terminal half-life to be 10 hours or less in the relevant patient population when measured on average (which Bayer had failed to establish).

Bayer's applications for interim measures were consequently turned down in full.

4. BUGGE VALENTIN's comments

The Maritime and Commercial Court's ruling reaffirms the self-evident principle that the legal effects of a decision by public authorities (such as the EPO) must be considered in the same context as the one that initially formed the administrative decision.

This means, in this specific case, that when the TBA relied on Bayer's description indicating that rivaroxaban had a half-life of 4-6 hours, and the half-life feature was deemed to be re-dundant on that basis, the same reasoning could not be directly applied in an infringement assessment in which the assumptions underlying the TBA's decision were no longer rele-vant. Otherwise, the patentee would have been allowed to unjustifiably extend the scope of patent's scope of protection.

The Court's ruling further suggests that the information provided by the patentee to the EPO, which forms the very basis of the decision to grant must necessarily set the general boundaries for subsequent patent construction in the context of enforcement proceedings.

The decision was rendered by one legal judge (the court's president) and two technical judges following extensive case preparation over six court days.

BUGGE VALENTIN represented Sandoz.

Reported by Patris Hajrizaj and Anders Valentin

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