Kluwer Patent Blog

Dutch District Court upholds BMS's apixaban patent

Eveline Lots (Brinkhof) · Tuesday, December 24th, 2024

On 30 October 2024, the District Court of the Hague handed down two merits decisions on the widely litigated apixaban patent of Bristol-Myers Squibb (see here and here – Dutch language versions). EP 1 427 415 B1 (EP 415), which lapsed in 2022, and the corresponding supplementary protection certificates (SPCs) have been subject to litigation throughout Europe (see e.g. the previous posts on the UK, France and Spain).

In 2023 the Dutch Court of Appeal already granted preliminary injunctions against Sandoz and Teva and Stada as it found that there was *not* a serious chance that the apixaban patent and SPC would be held invalid in merits proceedings. Both Sandoz and Teva appealed this decision to the Supreme Court.

In these merits proceedings Sandoz and Teva had filed invalidity claims to pave the way for generic apixaban in the Netherlands. The Dutch court found the patent and SPC (no 300500) to be valid and granted an injunction against Sandoz.

In its decisions the Dutch court addressed two pivotal aspects: (formal) priority of the patent in light of the G 1/22 and G 2/22 decisions of the Enlarged Board of Appeal (EBA); and inventive step in light of the EBA's G 2/21 decision to determine whether BMS could rely on the purported technical effect.

Priority

Teva had argued that BMS Company, applicant of the patent, was not entitled to the priority right when it filed the application. The inventors had initially transferred the priority document to BMS Pharma, but the subsequent PCT application, from which EP 415 stems, named BMS Company as applicant. Only after the application was filed, the priority document was transferred from BMS Pharma to BMS Company.

The court dismisses the argument. As was held by the EBA in G 1/22 and G 2/22 and now repeated by the court, there is a rebuttable presumption that the subsequent applicant is entitled to the priority right. The presumption can only be rebutted in exceptional cases. It is for the party challenging the entitlement to priority to prove that this entitlement is missing; merely raising speculative doubts is not sufficient.

BMS Company is therefore presumed to have been entitled to the priority right, which presumption was not rebutted by Teva. According to the court, there can be no doubt that the intention within

the BMS group was to file the application with a valid priority claim. Referencing the EBA in G 1/22, the court considers that the applicant should be protected from the situation like the one at hand, where their own intermediate prior art is published under the assumption of the applicant's entitlement to the priority right. The court further considers that the validity of the priority claim is confirmed by the *nunc pro tunc* transfer (i.e. a later, confirmatory transfer) of the priority document from BMS Pharma to BMS Company, which transfer is deemed effective as of the moment of the PCT application.

Inventive step and G2/21

To determine if the patent is inventive, the court applies the EPO's problem-solution approach. Parties agree that apixaban is a so-called selection invention in which case an inventive step may be accepted only if the selection is connected to a particular technical effect and if no hints existed which lead the skilled person to the selection. Thus, the selection of apixaban from the compounds disclosed in the closest prior art should be coupled to a particular (new or improved) technical effect. Parties assume that this effect (in any case) is that of Factor Xa inhibition. Since the same effect is attained by the compounds disclosed in the prior art, the effect must be present to an unexpected degree. Consequently, the question that lies before the court is whether BMS can rely on the purported technical effect of *improved* Factor Xa inhibition.

The court thereto recalls the standard set out by the EBA in G 2/21: the patentee may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention. If the G2/21 test is met, the patentee may still present evidence during the examination that the alleged technical effect actually occurs, i.e. post-filed evidence can be taken into account.

An assessment of the patent application and the common general knowledge leads the court to conclude that the technical effect on which BMS wishes to rely for inventive step, namely improved Factor Xa inhibition, will be considered by the skilled person as encompassed by the technical teaching. According to the court, the skilled person would derive from the application that it not only aims to provide *new* compounds as Factor Xa inhibitors, but also *improved* Factor Xa inhibitors over those in the prior art. The specific technical means that the application provides to solve this problem comprise at least the synthesized compounds disclosed in the examples of the application (among which apixaban). Moreover, the skilled person will assume that these compounds have been tested but they will also be able to synthesize the compounds themselves and easily test the compounds for their efficacy as Factor Xa inhibitors. It is then not required for the application to contain test results or other evidence, nor is it required that the application explicitly mentions the technical effect that is relied on. What is relevant is that the effect does not change the nature of the claimed invention.

According to the court, BMS's post-filed evidence demonstrates that apixaban is a better inhibitor of Factor Xa than the compounds disclosed in the prior art. The court concludes that apixaban would not be obvious to the skilled person.

Foreign rulings

The court notes that its assessment of the inventive step aligns with that of the French, Norwegian and Swedish courts. In contrast, the English High Court of Justice and Court of Appeal came to a

different finding, which the Dutch court says is the result of the application of the test formulated by the Supreme Court in Warner-Lambert v Generics [2018] UKSC 56. The Irish court applied a test similar to that of the English court, resulting in a different outcome there as well.

The District Court follows the reasoning of the Dutch Court of Appeal in 2023 (see this earlier post here). The Court of Appeal at the time considered the Warner-Lambert test, applied by the English courts, to be developed specifically for sufficiency of disclosure and not for assessing inventive step. The District Court – like the Court of Appeal – emphasizes that the G2/21 threshold for inventive step is distinct from and easier to meet than the standard for sufficiency. Accordingly, both the Court of Appeal and the District Court could justify the differing outcomes. A clear Dutch approach thus appears to be emerging.

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