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Barcelona Appeal Court reverses first instance judgment that had found apixaban patent to be invalid

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This morning, the Barcelona Appeal Court has announced a judgment of 18 July 2024, reversing the judgment of 15 January 2024 from Commercial Court number 4 of Barcelona, which had found patent EP 1,427,415 ("EP '415"), protecting apixaban, to be invalid. The main highlights of the decision may be summarized as follows:

The first interesting aspect is the finding in relation to the right to priority. As in other European countries, Teva had challenged BMS's right to priority on the grounds that the right to priority had not been correctly assigned from the BMS entity that filed the priority patent application, to the BMS entity that filed the application that resulted in the granting of EP '415. In short, the Court has denied Teva's locus standi to question the right to priority on this formalistic ground. In particular, it has found that it does not make sense for a third party to discuss the legal relationship between the first applicant and the second applicant when there is no conflict between them. So, without citing decisions G 1/22 and G 2/22, the Court has followed the same logic. The Court has added that, even if one were to accept a third party's locus standi in the circumstances described, the nullity attack should likewise be rejected, as it would be based on an extremely formal and, therefore, abusive, argument based on the different legal personality of the two companies of the same group. Finally, the Court has noted that BMS filed two legal opinions from two U.S. law experts which, at least, cast doubts on the strength of Teva's arguments on the merits (i.e. whether or not the assignment had taken place correctly under U.S. law). Taking into account that, according to Spanish procedural law, in case of doubt, the petition of the party having the burden of proof must be rejected, the Court concluded that Teva's lack of right to priority attack should have been dismissed in any event.

The second aspect addressed by the judgment is inventive step. As patent aficionados will no doubt be well aware, the main theme of Teva's inventive step attack around Europe has been that the patent application, as filed, did not make it plausible that apixaban had the alleged technical effect (factor Xa inhibition, etc.). In particular, in Spain, Teva based its inventive step attack on T 488/16 (Dasatinib) which, as is well known, was a classic example of the "ab initio plausibility" test. The Barcelona Appeal Court has first considered whether, in contrast to the European Patent Office ("EPO") Technical Boards of Appeal ("TBAs"), national courts must examine "plausibility" in the first place. In this regard, the Court has noted that, unlike the EPO's administrative organs, the function of national courts is to review whether a *granted* patent falls within any of the nullity grounds enshrined in article 138 of the European Patent Convention ("EPC"). In particular, the Court has noted that when, as in the case at hand, during prosecution the patent application was

limited to one compound only (i.e., apixaban), the only question to be answered is whether or not the claim as granted is affected by any of such nullity grounds. In this regard, the position followed by this judgment resembles the German position.

The Court has then moved to consider a second reason for rejecting Teva's inventive step attack. As mentioned earlier, in Spain, Teva mounted its lack of inventive step attack on T 488/16 (Dasatinib). After G 2/21 was published, Teva relied on par. 72 of G 2/21, where the Enlarged Board of Appeal tried to protect the EPO from the disarray brought by the three divergent lines of case law discussed in G 2/21 *("[…] the Enlarged Board is satisfied that the outcome in each particular case would not have been different from the actual finding of the respective board of appeal*"), to allege that the "ab initio plausibility" test applied in T 488/16 continued to be good law (i.e. nothing had changed). The Barcelona Appeal Court has noted that, contrary to Teva's position, one cannot extract from G 2/21 the teaching that "*everything has changed so that everything remains the same.*" The Court has added that, for this reason, it cannot embrace Teva's argument in the sense that G 2/21 has not left behind the "ab initio plausibility" test applied in T 488/16. This has been relevant for reversing the first instance decision which, after discussing G 2/21, ultimately upheld the inventive step attack applying Dasatinib (i.e., the "ab initio plausibility" test). In short, the Barcelona Appeal Court has considered that the Enlarged Board of Appeal, in G 2/21, introduced a more nuanced test. According to par. 5.24 of the judgment, the patent owner may rely on a technical effect if the person skilled in the art, departing from the application as filed and the common general knowledge, first, may conclude that such technical effect derives from the original technical teaching and, second, represents an embodiment of the same, meaning by technical teaching the invention claimed in the application. Against this background, the Court has noted that, once the patent has been granted, in the context of litigation before a national Court, the burden of proving that the conditions laid down by G2/21 are not fulfilled lies with the third party questioning the validity of the patent granted. Building from here, the Court has noted that Teva's case had been built on the premise that T 488/16 (Dasatinib) required the application as filed to include information that made the technical effect plausible. It has then added that the new test introduced by G 2/21 does not require this. To sum-up, the Court has concluded that the legal test on which Teva based its inventive step attack has been left behind by G 2/21.

Finally, following the order of Teva's complaint, the Court has dealt with sufficiency. In this context, it should be clarified that the arguments used by Teva to question sufficiency were exactly the same lack of "plausibility" arguments used to combat inventive step. Like in the case of inventive step, the Court started its analysis highlighting that, once the patent has been granted, a national Court must examine the sufficiency of the claim as granted. In particular, in par. 8.8 of the judgment, the Court has noted that, contrary to Teva's assertion, one does not have to look for a needle in a haystack because during prosecution, to overcome the examiner's objections, *"[…] the applicant simply cleaned-up the haystack and kept the needle*." Also, in par. 8.15-8.16 of the judgment, the Court has walked a very fine line in drawing a very important distinction between the reflections developed by the Enlarged Board of Appeal in par. 73-77 of G 2/21, meant to apply to second medical use claims, and the claims of the case at hand, which are not second medical use claims but medical use claims contained in the patent that disclosed apixaban for the first time. In par. 8.15, the Court has noted that since, in the case of second medical use claims, the patentability can only be justified by having invented a new medical use of a compound that was already known, the test must be stricter than in the latter case. The Court has added that, in any event, even if one were to apply to the medical use claims of EP '415, the test applied to second medical use claims, Teva had not established that the person skilled in the art would not have considered the technical effect of apixaban credible.

All in all, this important judgment has aligned Spanish case law on this lively area with the position on inventive step and sufficiency taken by all other Courts in Continental Europe in the same case.

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