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Spanish Supreme Court adopts the “plausibility” test introduced by G 0002/21

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As patent aficionados are well aware, after the European Patent Office (“EPO”) published Decision G 0002/21, there was widespread expectation across Europe regarding whether or not the few national courts that require some sort of “plausibility” as a precondition for inventive step and/or sufficiency, would adapt their case law to the test introduced by G 0002/21.

In a landmark recent judgment dated 24 April 2025, the Spanish Supreme Court has done so, becoming the first European Supreme Court to apply G 0002/21 in main proceedings. The Dutch Supreme Court had previously adopted a similar stance in preliminary injunction proceedings after an extremely detailed Opinion from Advocate General Van Peursem.

The background of the case may be summarized as follows:

In 2022, a leading manufacturer of generics filed a nullity action before the Courts of Barcelona against patent EP 1.427.415 (“EP ‘415”), which protects apixaban. In a nutshell, it alleged that all the claims lacked inventive step because, according to the complainant, the application as filed did not make it plausible that apixaban exhibited the advantages corroborated by the comparative tests filed during the prosecution of the application. Therefore, those advantages should not be taken into account to define the objective technical problem, which should therefore be defined as simply providing an “alternative” compound. It added that, in the absence of such unexpected advantages, apixaban was an arbitrary selection and, as such, non-inventive. The argument was mainly based on T 488/16 (dasatinib), a classic example of the “ab initio plausibility” doctrine. The complainant also questioned the sufficiency of the “use claims” (claims 5-29) deploying the same arguments. Finally, it also challenged the novelty of claims 1-6 on the grounds that the priority right had not been correctly transferred to the applicant.

Commercial Court number 4 of Barcelona, on 15 January 2024, handed down a judgment where it found: 1) claims 7-9 (which the Court understood to be second medical use claims) to be insufficient due to lack of plausibility; and 2) claims 1-6 to be non-inventive due to lack of plausibility. Having found all the claims to be invalid due to lack of sufficiency or inventive step, the Court considered that it was unnecessary to make a decision on novelty.

The patentee filed an appeal before the Barcelona Court of Appeal which, just 6 months later, on 18 July 2024 to be precise, handed down a judgment reversing the first instance decision. In particular, regarding novelty, the Court, among other arguments, found that the third party that had

filed the nullity action lacked locus standi to question whether the transfer of the priority right had been correctly made. It added that, in any event, the complainant had failed to discharge its burden of proof.

Moving on to inventive step, the Court dismissed the arguments developed in the complaint, using a two-tier line of argument: first, that Spanish case law does not require "plausibility" as a precondition for inventive step; and second, that in any event, after the publication of G 0002/21, the complainant did not adjust its inventive step attack to the new test introduced by the EBA (i.e., that the complainant continued to base its arguments on the "ab initio plausibility" doctrine), which the Court found to be the relevant test if any "plausibility" test needed to be applied.

Finally, in relation to sufficiency, the Court noted that, unlike in the typical cases dealing with the "plausibility" of second medical use patents, strictly speaking, claims 7-29 of EP '415 are not "second" medical use claims because apixaban was not known at the priority date. It added that, in any event, the information contained in the application as filed, together with the common general knowledge, made it plausible that apixaban would be suitable for the medical uses claimed.

As mentioned at the outset, on 24 April 2025, the Supreme Court dismissed the appeal in cassation filed by the complainant against this judgment. The decision has arrived just 9 months after the second instance decision, which is unprecedented in Spanish patent litigation (an appeal in cassation normally takes 3-5 years). Beginning with novelty, the Court has declared the ground for appeal inadmissible because the complainant had only challenged one of the three legal grounds used by the second instance decision to reject the novelty attack. Therefore, even if the ground for appeal were to be upheld, the conclusions rejecting the novelty attack would need to be confirmed in any event.

Moving on to inventive step, the Court has found that, although "plausibility" is not a ground for patentability, it is inherent to the analysis of inventive step that the technical effect sought derives from the technical teaching. In particular, the Court has decided to follow the test introduced by G 0002/21 noting that "although we are not bound by the Decisions of the EBA […] we follow its opinion in view of its authority in the field and the conviction of its reasoning." After analysing the two answers provided by G 0002/21, the Court has come to the conclusion that G 0002/21 is better aligned with the "ab initio implausibility" doctrine than with the "ab initio plausibility" doctrine. After making this general introduction, the Court has gone on to examine whether, on the specific facts of the case, the two conditions laid down in the operative part of G 0002/21 were fulfilled. Following a line of reasoning similar to the one followed by the Hague Court of Appeal in its Decision of 15 August 2023 (apixaban), the Court has come to the conclusion that the claims of EP '415 pass the test introduced by G 0002/21.

The Court has added that it has not taken into account the judgment of 4 May 2023 from the English Court of Appeal because it did not follow G 0002/21 but rather the sufficiency test introduced by the English Supreme Court for claims protecting second medical uses in the Warner Lambert judgment.

Finally, regarding sufficiency, the Court has noted that paragraph 77 of G 0002/21 in which, in an "obiter dicta", the EBA, under certain circumstances, appeared to demand a somewhat stricter test when examining sufficiency, applies to second medical use claims only. The Court noted that it was common ground that claims 5-29 were not second medical use claims. Building from here, the Court concluded that paragraph 77 of G 0002/21 was not applicable to the use claims of the patent

at hand. The Court added, out of caution, that in any event, at the priority date, it formed part of the common general knowledge that direct factor Xa inhibitors were useful to treat thromboembolic disorders, which would have contributed to the skilled person finding it credible that apixaban could be used to treat the disorders mentioned in those claims.

All in all, this judgment is of utmost importance because, beyond deciding the case at hand, it will enlighten lower-level courts when applying the new test introduced by G 0002/21 in the years to come.

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