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Ponente: IGNACIO SANCHO GARGALLO
Tipo de Resolución: Judgment

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STS 1714/2025

T R I B U N A L S U P P R E M 0

Civil Division

Judgment No. 625/2025

Date of judgment: 24/04/2025

Type of proceeding: APPEAL IN CASE Number

of the proceeding: 7920/2024

Judgment/Agreement:

Date of hearing: 20/02/2025

Speaker' His Excellency Mr. Ignacio Sancho Gargallo

Court of Appeals: Audiencia Provincial de Barcelona, Section 1S.°.

Counsel for the Administration of Justice: Ilmo. Mr. Fernando Javier Navalón Romero

Transcribed by: RSJ

Note:

APPEAL IN CASE No.: 7920/2024

Speaker: Mr. D. Ignacio Sancho Gargallo

Counsel for the Administration of Justice: Ilmo. Mr. D. Fernando Javier Navalón Romero

SUPREME COURT

Civil Chamber

Ruling No. 625/2025

Honorable Messrs.

D. Ignacio Sancho Gargallo, President

D. Rafael Sarazá Jimena

D. Pedro José Vela Torres

In Madrid, on April 24, 2025.

This Chamber has heard the appeal filed against the judgment handed down on appeal by Section 15 of the Provincial Court of Barcelona, as a result of an ordinary lawsuit filed before Commercial Court No. 4 of Barcelona. The appellant is Teva Pharma S.L.U., represented by attorney Ignacio López Chocarro and under the legal direction of Oriol Ramón Sauri, who appeared on the day of the hearing. Bristrol Myers Squibb Holdings Ireland Unlimited Company, represented by attorney Ángel Quemada Cuatrecasas and assisted by attorney Eduardo Castillo San Martí and Miguel Montaña Mora, who appeared on the day of the hearing.

Mr. Ignacio Sancho Gargallo has been the rapporteur.

FACTUAL BACKGROUND

FIRST. *First instance proceedings*

1. The attorney Ignacio López Chocarro, in the name and on behalf of Teva Pharma S.L.U., filed an ordinary lawsuit before the Commercial Court No. 4 of Barcelona, against Bristol-Myers Squibb Ho|dings Iceland Unlimited Company, in order to obtain a judgment by which:

"fully upholding the present claim and, consequently, declaring the nullity of the Spanish part of the European patent EP 1 427 415 ES 2 329 881 and of the Supplementary Protection Certificate C201100043, ordering its cancellation at the Spanish Patent and Trademark Office, and all of the above with the defendant being ordered to pay the costs".

2. The attorney Ángel Cluemada Cuatrecasas, representing Bristol-Myers Squibb Holdings Ireland Unlimited Company, answered the claim and requested the Court to issue a judgment:

"whereby, fully absolving my client of the claims formulated on the contrary, the claim be dismissed in its entirety and the validity of patent EP 1427415 - ES 2329881 and the supplementary protection certificate C201100043 be declared valid".

3. The Commercial Court No. 4 of Barcelona issued a judgment on January 15, 2024, the operative part of which is as follows:

"Judgment: We fully uphold the claim filed by the procedural representation of Teva Pharma, S.L.U., Therefore, we declare the nullity of claims 1 to 6 of patent ES 2,329,881 for lack of inventive step and of claims 7 to 29 of said patent for descriptive insufficiency, owned by Bristol-Myers Squibb Holding Iceland Unlimited Company, and, consequently, we order the cancellation of said claims in the Spanish Patent and Trademark Office. We also declare the nullity of the supplementary protection certificate C201100043. Likewise, the costs of the lawsuit are imposed on the defendant Bristol-Myers Squibb Holding Ireland Unlimited Company".

SECOND. Proceedings *at second instance*

J.The first *instance* judgment was appealed by the representation of Bristrol-Myers Squibb Holdings Iceland Unlimited Company. The procedural representation of Teva Pharma S.L.U. filed an appeal.
S.L.U. filed a written appeal.

The resolution of this appeal corresponded to Section 15 á of the Provincial Court of Barcelona by judgment of July 18, 2024, the operative part of which is as follows:

"We rule: We dismiss the challenge filed by Teva Pharma S.L.U and uphold the appeal filed by Bristol-Myers Squibb Holdings Ireland Unlimited Company against the decision of Commercial Court no. 4 of Barcelona dated January 15, 2024, issued in the proceedings from which this appeal arises, which is revoked in its entirety, and consequently, the claim is dismissed and Bristol Myers Squibb Holdings Iceland Unlimited Company is acquitted of its claims, with no special imposition of the costs of either the first instance or the second instance (appeal and challenge), with return of the deposit".

THIRD: *Filing and* processing of *the appeal in cassation*.

1. The attorney Ignacio López Chocarro, representing Teva Pharma S.L.U., filed an appeal in cassation before the 15th Section of the Provincial Court of Barcelona.

The grounds of the appeal were;

"1) It is alleged the infringement of arts. 54.1 and 89 CPE, in relation to arts. 87.1, b) CPE, 4.

"2°) Infringement of arts. 56, 83 EPC in relation to arts. 54.1, 63.1 and 123.2 EPC is alleged with respect to the plausibility of the claimed technical effect in accordance with the technical teaching of the patent application WO'652.

"(3°) Infringement of art. 56 EPC is alleged in relation to the verification of the technical effect of the claimed invention.

"(4°) Infringement of art. 83 EPC is alleged in relation to the non-application of a plausibility criterion.".

2. By order of 27 September 2024, the Provincial Court of Barcelona (Section 15.") considered the aforementioned cassation appeal as filed, and agreed to send the proceedings to the First Chamber of the Supreme Court with summons of the parties to appear for a term of thirty days.

3. Once the proceedings were received in this Court, Teva Pharma S.L.U., represented by attorney Ignacio López Chocarro, appeared as appellant; and Bristol-Myers Squibb Holdings Ireland Unlimited Company, represented by attorney Angel Quemada Cuatrecasas, appeared as respondent.

4. This court issued an order dated November 27, 2024, the operative part of which is as follows:

"Admit the cassation appeal filed by the legal representation of Teva Pharma S.L.U. against the sentence issued on July 18, 2024 by the Provincial Court of Barcelona, Section 15, in appeal no. 240/2024, arising from the ordinary trial no. 573/2022 of the Commercial Court no. 4 of Barcelona".

S.Having been served, the procedural representation of the entity Bristol-Myers Squibb Holdings *!reland* Unlimited Company filed a writ of opposition to the appeal formulated on the contrary.

6.For the resolution of the present appeal, a public hearing was scheduled for February 20, 2025, which took place.

LEGAL GROUNDS

FIRST. *Summary of the background*

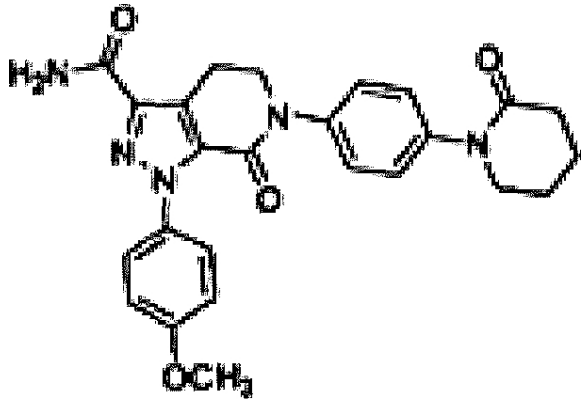
1. For the resolution of the present appeal, we must start from the list of relevant facts accredited in the instance, as stated in the appealed judgment.

1.1. Bristol-Myers Squibb Holdings Iceland Unlimited Company (BSM holding) is the current holder of patent ES 2,329,881 (ES'881), translation of European patent EP 1 .427,415 (hereinafter EP'415), entitled: *"Lactam-containing compounds and derivatives* thereof *as inhibitors of* factor Xa",as well as of the Supplementary Protection Certificate C201100043. The priority date of the patent is September 21, 2001, the filing date of patent US 324165 P (US'165).

On September 17, 2002, BSM Company had filed international patent application W0'652.

1.2. The content of the claims of EP'4J 5, as granted, is as follows:

"1. A compound, which is represented by the formula (1): or a pharmaceutically acceptable salt thereof. thereof.



"2. A compound according to claim 1, which is represented by formula (1).

"3. A pharmaceutical composition, comprising: a pharmaceutically acceptable vehicle and a therapeutically effective amount of the compound of formula (1) of claim 1 or a pharmaceutically acceptable salt thereof.

"4. A pharmaceutical composition, comprising: the pharmaceutically acceptable vehicle and a therapeutically effective amount of the compound of claim 2.

"5. A compound of claim 1 or 2 for use in therapy.

"6. A pharmaceutical composition of claim 3 or 4 for use in therapy.

"7. A compound of claim 1 or 2 for use in the treatment of a thromboembolic disorder.

"8. A pharmaceutical composition of claim 3 or 4 for use in the treatment of a thromboembolic disorder.

"9. Use of a compound of claim 1 or 2 in the preparation of a medicament for use in the treatment of a thromboembolic disorder.

"10. Use of a pharmaceutical composition of claim 3 or 4 in the preparation of a medicament for use in the treatment of a thromboembolic disorder.

"11. A compound for use in the treatment of a thromboembolic disorder according to claim 7 or use of a compound according to claim 9, wherein the thromboembolic disorder is selected from the group consisting of arterial cardiovascular thromboembolic disorders, venous cardiovascular thromboembolic disorders and thromboembolic disorders in the heart chambers.

"12. A compound for use in the treatment of a thromboembolic disorder according to claim 7 or use of a compound according to claim 9, wherein the thromboembolic disorder is selected from unstable angina, an acute coronary syndrome, first myocardial infarction, recurrent myocardial infarction, sudden ischemic death, transient ischemic attack, stroke, atherosclerosis, occlusive peripheral arterial disease, venous thrombosis, deep vein thrombosis, thrombophlebitis, arterial embolism, coronary artery thrombosis, cerebral arterial thrombosis, cerebral embolism, renal embolism, pulmonary embolism and thrombosis resulting from (a) prosthetic valves or other implants, (b) indwelling catheters, (c) stents, (d) cardiopulmonary bypass, (e) hemodialysis, or (f) other procedures in which the blood is exposed to an artificial surface that stimulates thrombosis.

"13. A compound for use in the treatment of a thromboembolic disorder according to claim 12 or use of a compound according to claim 12, wherein the thromboembolic disorder is an acute coronary syndrome.

"14. A compound for use in the treatment of a thromboembolic disorder according to claim 12 or use of a compound according to claim 12, wherein the thromboembolic disorder is sudden ischemic death, transient ischemic attack or stroke.

"15. A compound *for use in* the treatment of *a* 1thromboembolic *disorder* according to claim 12 or use of a compound according to claim 12, wherein the thromboembolic disorder is deep vein thrombosis.

"16. A compound for use in the treatment of a thromboembolic disorder according to claim 12 or use of a compound according to claim 12, wherein the thromboembolic disorder is pulmonary embolism.

"17. A pharmaceutical composition for use in the treatment of a thromboembolic disorder according to claim 8 or use of a pharmaceutical composition according to claim J0, wherein the thromboembolic disorder is selected from the group consisting of arterial cardiovascular thromboembolic disorders, venous cardiovascular thromboembolic disorders and thromboembolic disorders in the heart chambers.

"18. A pharmaceutical composition for use in the treatment of a thromboembolic disorder according to claim 8 or use of a pharmaceutical composition according to claim 10, wherein the thromboembolic disorder is selected from unstable angina, an acute corollary syndrome, first myocardial infarction, recurrent myocardial infarction, sudden ischemic death, transient ischemic attack, stroke, atherosclerosis, occlusive peripheral arterial disease, venous thrombosis, deep vein thrombosis, thromboph!ebitis, arterial embolism, coronary artery thrombosis, arterial thrombosis

cerebral embolism, cerebral embolism, renal embolism, pulmonary embolism, and thrombosis produced as a result of (a) prosthetic valves or other implants, (b) indwelling catheters, (c) stents, (d) cardiopulmonary bypass, (e) hemodialysis, or (f) other procedures in which blood is exposed to an artificial surface that stimulates thrombosis.

"19. A pharmaceutical composition for use in the treatment of a thromboembolic disorder according to claim 18 or use of a pharmaceutical composition according to claim 18, wherein the thromboembolic disorder is an acute coronary syndrome.

"20. A pharmaceutical composition for use in the treatment of a thromboembolic disorder according to claim 18 or use of a pharmaceutical composition according to claim 18, wherein the thromboembolic *disorder is* sudden ischemic *death*, transient ischemic *attack* or stroke.

"21. A pharmaceutical composition for use in the treatment of a thromboembolic disorder according to claim 18 or use of a pharmaceutical composition according to claim 18, wherein the thromboembolic disorder is deep vein thrombosis.

"22. A pharmaceutical composition *for* use in the treatment of a thromboembolic *disorder* according to claim 18 or use of a pharmaceutical composition according to claim 18, wherein the thromboembolic disorder is pulmonary embolism.

"23. A compound and a second therapeutic agent, for use in thetreatment of a thrombolytic disorder, *wherein* the compound is a compound of claim 2 and the second therapeutic agent is at least one agent selected from a second factor Xa inhibitor, an anticoagulant agent, an antiplatelet agent, a thrombin inhibitor agent, a thrombolytic agent, and a fibrinolytic agent.

"24. Use of a compound and a second therapeutic agent in the preparation of a medicament for use in the treatment of a thrombolytic disorder, wherein the compound is a compound of claim 2 and the second therapeutic agent is at least one agent selected from a second factor Xa inhibitor, an anticoagulant agent, an antiplatelet agent, a thrombin inhibitor agent, a thrombolytic agent, and a fibrinolytic agent.

"25. A compound and a second therapeutic agent, for use in the treatment of a thrombolytic disorder according to claim 23 or use of a compound and a second therapeutic agent according to claim 24, wherein the second therapeutic agent is at least one agent selected from warfarin, unfractionated heparin, low molecular weight heparin, synthetic pentasaccharide, hirudin, argatroban, aspirin, ibuprofen, naproxen, sulindac, indomethacin, mefenamate, droxicam, diclofenac, sulfinpyrazone, piroxicam, ticlopidine, clopidogrel, tirofban, eptifibatide, abciximab, melagatran, disulfatohirudin, activated plasminogen activators, modified tissue plasminogen activator, anistreplase, urokinase and streptokinase,

"26. A compound and a second therapeutic agent, for use in the treatment of a thrombolytic disorder according to claim 23 or use of a compound and a second therapeutic agent according to claim 24, wherein the second therapeutic agent is at least one antiplatelet agent.

"27. A compound and a second therapeutic agent, for use in the treatment of a thrombolytic disorder, according to claim 26 or use of a compound and a second therapeutic agent according to claim 26, wherein the second therapeutic agent is at least one of aspirin and clopidogrel.

"28. A compound and a second therapeutic agent, for use in the treatment of a lrombolytic disorder according to claim 27 or use of a compound and a second therapeutic agent according to claim 27, wherein the antiplatelet agent is clopidogrel.

"29. A compound and a second therapeutic agent, for use in the treatment of a thrombolytic disorder, according to claim 27 or use of a compound and a second therapeutic agent according to claim 27, wherein the antiplatelet agent is aspirin."

Claim No. 1 relates to a compound represented by a chemical formula identifying the active principle **apixaban** or a pharmaceutically acceptable salt.

Claims Nos. 2 to 4 are dependent upon and provide generic information about the compound apixaban, pharmaceutical compositions and their use in therapy.

Claims Nos. 5 to 22 relate to the use of apixaban or pharmaceutical compositions comprising an effective amount of **apixaban;** as a therapeutic agent (claims 5 and 6); as a product in the treatment of thromboembolic disorders (claims 7 to 10); and as a product in the treatment of specific thromboembolic disorders (claims 11 to 22).

The following claims Nos. 23 to 29 relate to the use of apixaban or a pharmaceutical composition comprising a therapeutically effective amount of apixaban in the treatment of thromboembolic disorders in combination with another compound to be chosen from among different possibilities.

1.3. During the patent granting procedure, in the face of the objections raised, the patent applicant limited the claims to the compound apixaban and excluded the rest of the compounds that appeared in the patent application.

1.4. BSM Holding acquired Patent EP' 415 (ES' 881) from the original owner, Bristol-Myers Squibb Company (BMS Company), which is the company listed in the European and Spanish patent prospectus.

The international application PCT/US02/29491, from which Patent EP'415 is derived, was filed by BMS Company on September 17, 2002 claiming priority to US Patent US'165, filed on September 21, 2001 with the United States Patent and Trademark Office by its inventors Torcuato and Carmen , at that time employees of DuPont Pharmaceuticals Company.

On October 1, 2001, DuPont Pharmaceuticals was acquired by BMS Company, of which it became a wholly owned subsidiary and changed its name to BMS Pharma.

On November 3, 2001, the inventors of US'165, Torcuato and Carmen, signed an agreement to assign all rights to the US'165 patent to BMS Pharma, including the right to claim priority.

Defendant BMS Holding acknowledges that there was no express written assignment of patent rights (including the right of priority) between BMS Pharma and BMS Company during the priority year.

Claims 1 to 6 of EP'415 are anticipated by the patent application, international application W0 03/049681 A2, filed on December 3, 2002, therefore, between the priority date and the application date.

2. The lawsuit that initiated this proceeding, filed by Teva Pharma, S.L.U. (TEVA) against BMS Holding, seeks the nullity of patent ES'881, translation of European patent EP'415, and of Supplementary Protection Certificate C201100043, for the following reasons:

i} Claims 1 to 6 (4) l a c k novelty, since they cannot benefit from t h e claimed priority date. It understands that patent EP'415, filed on September 17, 2002, cannot assert the priority it invokes from United States patent application 60/324165 (US 324165 P, US'165), filed on September 21, 2001. Therefore, the relevant date for assessing novelty and inventive step is the filing date of the application, w h i c h renders the novelty of claims 1 to 6 prejudiced by international application WO 03/049681 A2, filed on December 3, 2002 claiming the priority of December 10, 2001.

ii) Invalidity of all claims for lack of inventive step, since it is not plausible that the compounds of the patent application, and not even apixaban, were compounds suitable for the treatment of thromboembolic diseases and even less that they represent an improvement over the state of the art.

TEVA considers that the holder of EP'415 (BMS), cannot defend inventive step on the basis of the technical effect pursued by the compounds disclosed in patent application WO'652, including apixaban. The technical effect is to inhibit factor Xa in a sufficiently effective and specific manner for its therapeutic purpose. And according to TEVA that application did not provide the skilled person with sufficient information to make such technical effect or, in this case, therapeutic effect, plausible.

And iii) the invalidity of claims 5 to 29 of the patent due to insufficiency of the description, since the claimed therapeutic uses were not plausible. It understands that art. 83 EPC was not complied with, since it was not plausible that apixaban was an inhibitor of factor Xa. There is no evidence in the patent application of its therapeutic activity. He argues that "it is settled case law of the Boards of Appeal that for a medical use claim to meet the requirements of Art. 83 EPC, unless it is already known to the skilled person on the priority date, that the patent must disclose the suitability of the product to be manufactured for the claimed therapeutic application. A claimed therapeutic application may be proved by any type of test as long as it reflects the therapeutic effect on which the therapeutic application is based (see T 814/12)."

3. The first instance judgment upheld the claim and declared all the claims of the patent invalid on two grounds; claims 1 to 6 for lack of inventive step and claims 7 to 29 for lack of descriptive sufficiency.

3.1. Regarding the insufficiency of the description of claims 5 to 29, the court understands that plausibility, although not a requirement of pateritability itself, in relation to second medical use patents, constitutes an element of proof of their descriptive sufficiency.

The court clarifies that claims 7 to 29 are proper second medical use claims. Claims 5 and 6 are first medical use claims and are unrelated to the claimed inadequacy of the description. Thus, the issue focuses on the affected claims (7 to 29).

The court explains what the test of sufficiency of description consists of:

"(.") the sufficiency of description test consists of determining whether a person reasonably skilled in the art can perform or use the invention from the information contained in the patent together with information known in the prior art without undue experimentation. In the case of a patent for a new product or process, this test works when the person skilled in the art can duplicate the product or process in accordance with the claim. However, this is not the case when we are dealing with a second medical use patent, since the invention is not the compound or the process for its manufacture. The skilled person already knows how to manufacture the product from the prior art described in the original patent. The invention consists in the new purpose for which the product is to be manufactured. The invention lies only in the identification of the utility of the product. Hence, the patent application must disclose the suitability of the product to be manufactured for the claimed therapeutic application. This implies that the sufficiency of description test in a second medical use patent requires an assessment of *whether* the patent application discloses the potential suitability of the substance, as defined in the claim, to exert the claimed therapeutic effect."

It also analyzes the doctrine contained in Decision G 2/21 of the Ata Chamber of Appeal of the EPO, in relation to the plausibility of the technical effect pursued with the invention. This decision prescribes the following:

"to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, proof of] claimed therapeutic effect must be provided in the application as filed, particularly if, in the absence of experimental data in the application as filed, it would not be credible to the person skilled in the art that the therapeutic effect has been achieved. A deficiency in this respect cannot be cured by post-publication evidence" (77).

The court considers that in the patent in question "the proof of the technical effect (treatment of a thromboembolic disorder) was not provided in the patent application, as it was filed, since it lacked experimental data proving the efficacy for the mentioned treatment. In this sense, BMS's own expert, Mr. Pio, acknowledged that there is no therapeutic efficacy data in the patent application as filed. The aforementioned data were provided in a later publication (documents 31, 35 and 36 of the complaint, called DIRECCIONOOO , DIRECCION001 and DIRECCION002). And this later publication cannot make up for the lack of the aforementioned proof, as required by decision G 2/21. This implies that the alleged claims would be invalid due to descriptive insufficiency (...)".

3.2. Regarding the lack of inventive step, the court understands that "plausibility is an issue to be taken into account in relation to the inventive step of the invention *(exarts.* 56 of the EPC and 8 of the SPA), since the lack of such plausibility would result in the said invention not complying with the need for inventive step". And to this effect, it analyzes "whether the applicant or patent holder may rely on post-publication evidence (specifically, evidence subsequent to the filing of the patent application) to demonstrate or support the technical effect expressed in such application". For this purpose, it refers to the aforementioned Decision G 2y'21, according to which "the essential question lies in what is understood by the person skilled in the art, with the common general knowledge in mind, at the filing date of the application, as originally filed, as the technical teaching of the claimed invention". And "whether or not the technical effect claimed by the applicant or patentee was or was not derivable, to the person skilled in the art, from the technical teaching included in the application".

After reproducing paragraphs 91 to 95 of G 2/21, the court concludes:

"In the light of what is stated by decision G 2/21, we can understand that the main question to be analyzed by a judicial body when judging the inventive step of an invention is whether the technical effect claimed by the applicant or patentee is deducible by the person skilled in the art from the patent application, as filed, and read with the common general knowledge".

Then, under these premises, which start from the consideration that "according to decision G 2/21, these questions of technical effect in the analysis of inventive step must be evaluated by reference to the application, as filed, and not to the granted patent", it understands that:

"This leads us to the conclusion that the determination of the technical effect resulting from the difference between the closest prior art (W0 131) and the ES 881 patent must be analyzed in light of the teachings of the G 2/21 decision. Therefore, we have to ask ourselves whether the person skilled in the art (bearing in mind the common general knowledge and based on the application as originally filed) would consider that the technical effect claimed by BMS to consider apixaban as a new factor Xa inhibitor with improved pharmacological properties] is comprised in the technical teaching and embodied by the invention itself, as originally disclosed. As the aforementioned decision G 2/21 indicates, the aforementioned technical effect invoked by BMS in the later phase through the *post-published* evidence [documents 31, 35 and 36 of the complaint (called DIRECCIONOOO , DIRECCION001 and DIRECCI0N002)] must be comprised in that technical teaching and embody the same invention, because such effect does not change the nature of the claimed invention".

In relation to the technical problem that the invention is intended to solve, the court determines who would be the person skilled in the art and the teachings of application WO'652, to then address what it considers to be the disputed issues: the experimental evidence, the consideration of apixaban as a preferred compound and selectivity. On apixaban as a preferred compound, after a detailed examination of the patent application, he concludes that "the team of experts reading application WO 652 could not understand that apixaban is the preferred compound in said application". And as a conclusion on the formulation of the objective technical problem, it states the following:

"5.92 The analysis carried out leads us to be able to answer the question on the determination of the technical effect resulting from the difference between the closest prior art (WO 131) and patent ES 881, in the light of the teachings of decision G 2/21. Therefore, we can conclude that the person skilled in the art (bearing in mind the common general knowledge and based on the application as originally filed) does not consider that the alleged technical effect claimed by BMS [to consider apixaban as a new factor Xa inhibitor with improved pharmacological properties] is comprised in the technical teaching and embodied by the same ¡nvention, as originally disclosed. The aforesaid technical effect invoked by BMS in the later stage through the *post-publjshed* evIdence [documents 31, 35 and 36 of the complaint (called DIRECTIONOOO , DIRECTION001 and DIRECTION002)] is not comprised in said technical teaching and embodied in the referred invention.

"5.93 Therefore, we can conclude that the objective technical problem sought to be *solved* is how to obtain an alternative compound."

Finally, the court makes the obviousness judgment and reaches the following result:

"5.101 By virtue of the foregoing, if we start from the closest prior art document WO 131 which discloses the same references on factor Xa inhibition, on e] Ki value and which covers apixaban as an alternative, although it does not disclose it, R1 is obvious (which implies that the IR has no inventive step) because there is no invention in simply choosing a compound different from those cited in WO 131 without the need for it to be better.

"5.102 In relation to the dependent claims, claims 2, 3 and 4 have not been alleged to have patentable content independent of the IP and *this* is not evident to us either, since such claims merely specify various design options, since they refer to a therapeutically effective amount of the compound listed in the dependent claims, including salts or other pharmaceutically acceptable vehicles, which is already described in the closest prior art document.

"5.103 As for the dependent claims 5 and 6, they do not contribute any invention since the therapeutic uses were already disclosed and known, as stated in the prior art document and in the CGKUK, among others, Leadley.

"5.104 On the rest of the claims it is not necessary to rule as they have already been declared invalid in the previous legal basis.

"5.105 Consequently, claims 1, 2, 3, 4, 5 and 6 are invalid for lack of inventive step".

4. The first instance judgment was appealed by the defendant, BMS. And the plaintiff, TEVA, not only opposed the appeal, but also challenged the judgment for having omitted pronouncements.

The Court upheld BSM's appeal and dismissed TEVA's challenge.

4.1. The Court reanalyzes the alleged lack of novelty of claims 1 to 4, for not being able to benefit from the claimed priority date, and dismisses it.

TEVA argues that, with respect to the ownership of the EP'4J 5 patent, BMS Company does not bring cause from BMS Pharma, a company that, during the priority year, acquired the rights of the inventors who applied for the US'165 patent. Therefore, it denies that BMS Company, owner of EP'415, can claim the priority of the US'165 patent application owned by BMS Pharma.

The Court of Appeals r e j e c t s this claim, f i r s t l y, because it considers that TEVA lacks standing to do so:

"2.11. E| art. 103.1 Law 24/2015, of July 24, 2015, on Patents LP establishes that *"the* action *to challenge the validity* of the patent *shall be public*'but excepts the nullity action provided for in art. 102.1.e LP, *"when the patentee is not entitled to obtain it in accordance with* the *provisions of article* 70".Art. 10.1 establishes that *"the right to the* patent *belongs to the inventor or his successors in title and is transferable by all the means that* the *law* recognizes". Therefore, the action for nullity of a patent because the registered owner is not the person entitled to obtain the patent or his successor in title, can only be brought by "the *person entitled to obtain the patent"* (*art.* 103.1 PL).

"2.12. By analogy, following the same reasoning, the standing to bring a nullity action, when it is based on the challenge of the right of priority invoked because the defendant is not the owner of the first deposit, must also be limited to the person who could have made use of said right of priority. Something different would happen if another of the requirements were disputed, such as, for example, that it is *the same* invention, but it makes no sense to discuss the legal relationship between the owner of the first and the second deposit, when there is no conflict between them".

And, even if TEVA was recognized as having standing to challenge on this ground the right of priority invoked in EP'415, the Court considers that "in this case it would also be an extremely formal and, therefore, abusive exercise of the different personalities of the two companies. The plaintiff, more than twenty-four years later, claims that BMS Company, which was the parent company of BMS Pharma, cannot invoke a right of priority of its subsidiary, when that company was the one entrusted with the management of the industrial property of the group and, moreover, it is not disputed that years later they were formally assigned".

4.2. The Court also analyzed the objections raised on the plausibility of the technical effect pursued with the patent, and its incidence in judging the inventive step and the sufficiency of the description.

He first summarizes those objections raised by TEVA: (i) the technical effect sought by the compounds disclosed in patent application WO'652 is to inhibit factor Xa in a manner sufficiently effective and specific for its therapeutic purpose; (ii) at the date of priority, such effect was not plausible to a person skilled in the art reading the WO'652 application on the basis of common general knowledge;
iii) for that reason, the applicant could not rely on that technical effect, i.e., inhibiting factor Xa in a sufficiently effective and specific manner for its therapeutic purpose; iv) therefore, all the claims of ES'415, the granted patent, would be invalid for lack of inventive step, since apixaban would be an arbitrary selection based on prior art compounds;
v) likewise, since such technical effect is not plausible, claims 5 to 29, which protect the therapeutic uses of apixaban, would be invalid due to insufficiency of the description; vi) consequently, the patent should not have been granted by the EPO Examination Division.

The Court understands that what TEVA argues is that the patent holder cannot rely on the technical effect attributed to the invention to demonstrate its inventive step, if such effect is not plausible for a person skilled in the art based on the information provided by the patent application and the common general knowledge. And, therefore, it goes on to warn that "if, contrary to what TEVA maintains, the patent holder could rely on that technical effect, the patent would be inventive".

The Court clarifies that "the question that arises is whether it is sufficient for the applicant to assert that the invention produces certain technical effects or whether it is also necessary that such technical effects are plausible (credible, plausible) for a person skilled in the art, in view of the information contained in the patent and the common general knowledge and whether or not evidence published after the date of the application can be admitted".

And then he makes an exposition of the doctrine of the EPO Courts of Appeal (T 939/92, Agrevo, September 12, 1995 and T 1329/04, June 28, 2005, John Hopkins), which came to demand this requirement in order to prevent the granting of merely speculative patents, which do not represent a real contribution to the state of the art. And also from decision G 2/21 of 23 March 2023 of the Enlarged Board *of Appeal of* the EPO, which, in response to a preliminary question raised by one of the technical chambers of appeal, addressed the issue of plausibility, in particular in relation to

The purpose is to unify the different interpretative lines of the Chambers of Appeals, and to decide whether or not the evidence published after the date of the application is admissible.

The High Chamber, after analyzing the decisions of the different lines, states that the essential question underlying all of them "lies in what the person skilled in the art understands, with the common general knowledge in mind, at the date of filing of the application as originally filed, as the technical teaching of the claimed invention" (71). And it complements that comment, saying that "(72) applying this interpretation to the above-mentioned decisions (...) the Board is convinced that the result in each specific case would not have been different from the conclusion actually reached by the corresponding Board of Appeal".

This decision G 2/21, after clarifying that the term plausibility is neither a requirement of patentability (art. 56 EPC) nor of descriptive sufficiency (art. 83 EPC), since it does not obey a univocal legal concept, explains which is the relevant criterion for the applicant to rely on the technical effect of the invention to assess the inventive step:

"93. The relevant criterion for relying on an alleged technical effect in assessing whether or not the claimed subject matter involves inventive step relates to the question of what a skilled person, having regard to the common general knowledge, would understand at the filing date of the application as originally filed as the technical teaching of the claimed invention. The technical effect claimed, even on a later *basis*, must fall *within that* technical *teaching* and embody the same invention, because such effect does not change the nature of the claimed invention.

"94. Therefore, an applicant or patentee may rely on a technical effect for inventive step if the skilled person, having in mind the common general knowledge, and based on the application as originally filed, would consider that such effect is comprised in the technical teaching and embodied by the same invention originally disclosed."

And finally concludes in the second paragraph that:

"2. An applicant or patentee may rely on a technical effect for inventive step if the skilled person, having in mind the common general knowledge, and relying on the application as originally filed, would derive such effect as comprised by the technical teaching and embodied by the invention itself as originally disclosed."

For the Court "the High Court holds that in order for the owner to be able to rely on the claimed technical effect when assessing the inventive step, it is necessary that an expert, based on the information contained in the application and the common general knowledge, concludes, first, that said technical effect derives from the original technical teaching and, second, that it effectively implies a realization of the latter. Original technical education being understood as the invention claimed in the application".

4.3. He then states the first reason why the claim for invalidity of claims 1 to 6 for lack of inventive step should be rejected 1 to 6 for lack of inventive step.

To this end, the appellate ruling goes on to analyze whether national courts should apply this test. It first clarifies that in our case "it is not disputed that apixaban is indeed a superb factor Xa inhibitor with enhanced pharmacological properties. What is at issue in demanding the plausibility requirement is whether the applicant was required to provide the person skilled in the art with sufficient information in the application, as originally filed, to make it plausible or credible that apixaban exhibited such technical effects. The question is whether, in order to avoid merely speculative patents, national courts have to depart from the standard grounds for invalidity (art. 138.1 EPC) and apply the EPO test".

In relation to this particular case, the Court notes that during the prosecution of the patent grant, "the examiner pointed out to the applicant that "it is not credible that all the compounds of claim 1 possess some degree of factor Xa inhibitory activity", which is why the applicant first limited the application to apixaban and then submitted eXperimental evidence of such effects, which convinced the Examination Division to grant the EP'415 patent. Therefore, the administrative bodies of the EPO did their job to avoid granting a speculative patent, decisions that no interested party challenged before the Opposition Division and which forced the applicant to limit its application". Having said that, the Court asks "whether it is reasonable for the Spanish Courts, now, twenty-three years later, to declare the nullity of the patent granted on a successful product, because the application, as it was originally filed, in addition to apixaban, included millions of compounds for which the claimed technical effects were not plausible for an expert and whose protection was waived by the applicant during the prosecution".

The Hearing reflects on the role of the Courts of Appeal and the National Courts, and understands it to be somewhat different:

"6.16. In short, the function of the Chambers of Appeal, as a judicial body, is to review the decision of the administrative bodies of the EPO, both the decisions that grant patents and those that refuse them, so they must review the material assessed by those bodies, starting from]the patent application.

"6.17. The National Courts are only responsible for the review of the last decision, the one in which the patent is granted, on the grounds provided for in art. 138.1 EPC. It is not up to us to eXamine the granting process, that examination, as we have said, corresponds in the case of the European patent to the Courts of Appeal. In short, we do not have to decide whether the examiner correctly assessed the technical effects claimed in the patent application. We are faced with a granted patent, which, at the very least, enjoys a presumption of validity and which provides the patentee with a monopoly over the patented product or process".

The Court reasoned that insofar as "the applicant amended the application to limit its claims to a single compound, apixaban, and its therapeutic uses, and did so at the request of the examiner", the inventive step must be analyzed according to how it was amended and finally granted. Otherwise, articles 123 and 138.1.a) EPC would be infringed. And conclude:

"6.28. Therefore, once the patent has been granted, the national courts must determine its scope of protection in accordance with its claims, interpreted according to the description and drawings. In our opinion, the Convention does not protect us from not recognizing the inventive step of a granted claim to a single product, because the original application sought, together with the protection of that product, the protection of other products or compounds that might not have the desired technical effect, when in fact these other products have not been the object of protection".

"6.29. As we have said, TEVA argues that the applicant could not rely on the technical effect, pursued by the compounds disclosed in patent application WO'652, i.e., inhibit factor Xa in a sufficiently efficacious and specińc manner for its therapeutic purpose, since, in its opinion, at the priority date, such effect was not plausible to a person skilled in the art, reading the WO'652 application on the basis of common general knowledge,

"6.30. If we re¢ect that criterion to be applied for the aforementioned reasons, even with the new interpretation made by the High Court in G2/21, we must reject the claim of nullity for lack of inventive step of the 29 claims, as articulated by TEVA".

4.4. It then sets out the second ground for dismissing the invalidity claim for lack of inventive step. The Court, in order to exhaust the reasoning, accepts as a hypothesis that the national courts must apply the criterion of plausibility to assess inventive step, in the terms in which it has been reinterpreted by the High Court of Appeal in G 2/21. Based on this premise, it arrives at the same dismissal decision. From its reasoning we highlight the following:

"7.18. In short, we believe that the requirement of plausibility is not required as it has been argued by the plaintiff throughout these two instances. TEVA has relied on the decisions of the Courts of Appeal and, in particular, in T 488/13 (Dasatinib). In its appeal it argues that G 2/21 has not entailed a modification of that criterion, a statement that we do not share as we have eXplained, therefore when applying the new test it insists that, when checking the second presupposition (that of the technical effect being embodied or encompassed *(embodiedJen* the original invention), it understands that it is necessary that the application had made it plausible that said technical effect was the embodiment of the original invention. In other words, in the application of this new criterion, it continues to hold that the technical effect must be plausible for the skilled person.

"7.19. Decision G 2/21 does not say that, on the contrary, when the referring Court of Appeal applied the answers it had given to its preliminary ruling (T 116/18), it stated that "11.11 As regards the second requirement (ii) set out in Ord. 2, namely that the effect must be capable of deriving from the same invention as the one originally disclosed, in the opinion of the Board, the following question must be asked: would the skilled person, having regard to the common general knowledge at the filing date, and on the basis of the application as filed, have legitimate reasons to doubt that the technical teaching in question, i.e. the claimed technical effect, together with the claimed subject matter, is a realization of the originally disclosed invention, i.e. the broader technical teaching of the application as filed?".

"7.20. What we would need, under the interpretation of G 2/21, are reasons to believe that the intended effect of the claimed subject matter, i.e. of apixaban and its ability to inhibit factor Xa, are not

a concrete realization of the original invention. That has not been the approach of TEVA, which has continued to insist that the technical effect must be plausible, an approach that we believe has been abandoned by the Courts of Appeal in G 2/21.

"7.21. Therefore, we must reject TEVA's argument and consider that BMS can be based on the technical effect of apixaban as a "new factor Xa inhibitor with improved pharmacological properties", so that claims 1 to 29 are inventive. All this leads us once again to dismiss the invalidity action for lack of inventive step (...)".

4.5. Finally, the Court analyzes the alleged invalidity of claims 5 to 29 for insufficiency of the description. For this purpose, it starts from the regulation, specifically from arts. 83 and 138.1 EPC!

"Article 83 EPC establishes that "the invention must be described in the European patent application in a sufficiently clear and complete manner for a person skilled in the art to be able to apply it". For its part, art. 138.1 EPC, establishes that "the European patent may only be declared null and void, with effects for a Contracting State, in the following cases:" b) when the European patent does not describe the invention in a sufficiently clear and complete manner for a person skilled in the art to be able to apply it"".

It then clarifies that "the first of the precepts refers to the patent application, while the second refers to the granted patent. It is true that the invention must be fully disclosed at the date of priority, at which time it must meet the three requirements of patentability, but the Convention is very clear in stating that descriptive sufficiency refers to the granted patent. If the patent contained information that was not contained in the application, there could be a cause of nullity for addition of mater la, but this is not a cause of nullity alleged in this trial". And it highlights that the lawsuit "when analyzing the plausibility of the therapeutic effects of apixaban refers to the original patent application and not to the patent granted after its amendment, as it had been analyzed by TEVA to deny the inventive step". And it returns to the idea that "it is not up to us (the *national courts)* to review the actions of the Office when granting the patent. Specifically, (...} whether or not the Examination Division correctly applied Art. 83 EPC. That is, whether, as applied for, the therapeutic use of apixaban was plausible. What we must examine is whether or not the granted patent complies with the requirement of descriptive sufficiency as provided for in the aforementioned art. 138.1.c) EPC".

And, then, it reasons why, in any case, this nullity claim should be dismissed:

"8.19. (...) since claims 5 to 29 are not properly claims to second or further therapeutic uses of known products, which is the type of claims referred to in G 2/21, the claim for invalidity should be dismissed.

"8.20. In any case, even if we were to consider applicable to all therapeutic use claims, including claims 5 to 29 of EP'415, according to G 2/21, for the requirement of descriptive sufficiency to be met, it is not necessary to provide experimental data with the application, unless the expert did not consider the therapeutic effect to be plausible.

"8.21. In the case in question, as we have seen when rejecting the invalidity of the claims for lack of inventive step, we understand that the holder can rely on the technical effect of **apixaban** to justify its inventive step. Said effect consists of being a "*new factor* la *inhibitor* with *improved pharmacological properties".* Therefore, the expert would have no reason to rule out the claimed therapeutic effects, as the plaintiff acknowledges in paragraph 245 of the complaint, which are known thromboembolic disorders (...)-.

5. The appellate judgment has been appealed in cassation by the plaintiff, on the basis of four grounds.

SECOND. *First* ground of *the appeal in cassation*

1. Formulation of the plea. The plea is based on the infringement of articles 54.1 and 89 EPC, in connection with articles 87.1, b) EPC, 4.A.1 CUP and 4.2 CC. This infringement would have occurred because the judgment under appeal denies TEVA standing to challenge the lack of novelty of claims 1 to 6 of the EP'415 patent, by not allowing it to challenge its priority date, which is decisive to establish the relevant prior art, and, additionally, it considers the challenge as abusive (points 2.11-2.13).

In the development of the plea, it is noted that the lawsuit claims that the EP'415 patent cannot validly claim its priority date of September 21, 2001 under art. 87.1. b) EPC, in connection with art. 4.A.1 CUP, since its applicant, BMS COMPANY, was not the successor in title of the US'1ó5 application invoked as priority. Therefore, the relevant prior art is formed by everything made available to the public up to the application date (September 17, 2002), being, consequently, claims 1 to 6 of EP'415 invalid for lack of novelty based on patent application WO'681, which is

made available to the public after the priority date of the EP'4J 5 patent (arts. 89 and 54.1 EPC). And the appealed judgment denies TEVA's standing to sue because the nullity action provided for in art. 102.1,
e) LP corresponds only to the person entitled to obtain the patent or to his successor in title ex art.
10.1 SPA, so that the exception of art. 103.1 SPA would be applicable to the general rule that the nullity action is public (points 2.11 and 2.12).

Against this, the appeal argues that "it has never exercised the action of art. 102.1. e) SPA (art. 138.1, e) EPC), but the action of invalidity for lack of novelty of art. 138.1, a) in relation to 54.1 EPC (art. 102.1, a) SPA) and this action is public (art. 103.1 SPA)". It is understood that in order to analyze the novelty of a patent it is necessary to determine the relevant prior art and this prior art will consist of everything that has been made accessible to the public up to the date of application of the patent (art. 54.1 EPC) or, if it is complied with the
The Court considers that the "exercise of the right of priority", until the priority date (art. *89* EPC).

And it considers that by not recognizing TEVA as having standing to sue, it is prevented from determining the date to establish the relevant prior art, which is a necessary prerequisite for the novelty action ex art. 54.1 EPC.

Finally, to the above, he adds a consideration that refers to the abuse in asserting this objection:

"Finally, the abuse referred to in point 6.13 of the Judgment should also fail, since it is settled case law that "the person who makes normal use of his right does not abuse it" [Judgment of the Supreme Court (1st Chamber) 1203/2007, of November 19, 2007, FJ Quinto]. In fact, BMS based this argument on abuse on two cases that it described as preliminary in point 127 of its answer to the claim and that have not been supported by cases G 1/22 and G 2/22".

2. Decision of the court. The plea must be dismissed for the following reasons.

We have reiterated on many occasions that a ground that does not determine the alteration of the summary judgment cannot have effect in cassation The justification for this doctrine *can be* found *in judgments* b98/2019, of December 19, reiterated by judgment 652/2015, of November 20'.

"In application of the doctrine of equivalence of results and lack of useful effect of the appeal, a plea that does not determine an alteration of the appealed judgment cannot have effect in cassation. According to this doctrine, an appeal does not proceed when the eventual acceptance of the appellant's legal argument leads to the same solution contained in the appealed judgment [...], even when the doctrine followed by *the* challenged *judgment* is not correct *if* its acceptance does not produce an alteration of the ruling *[...}.* In accordance with this criterion, the appeal should not be upheld when, despite the merits of one of the grounds supporting it, the judgment must be upheld on other grounds".

This doctrine is applicable when the appealed judgment has decided an issue based on different legal grounds or reinforcement arguments and only one of them is contested in the plea or in the appeal, so that the eventual acceptance of the appellant's argument would prevent the appeal from being upheld, since the other legal grounds not contested would remain (orders of May 17, 2023 [rec. 2009/2021] and May 31, 2023 [rec. 6927/2021]).

The judgment under appeal rejects the claim for invalidity of claims 1 to 6 of EP'415 as it cannot benefit from the invoked priority date of the patent application US'1 or 5, for three different legal reasons: due to the lack of standing of the plaintiff by application of art. 103.1 PL in relation to art.
102.1.3 LP; for the extremely formal and abusive exercise of the different personality of two companies; and for not having proved a fundamental fact as required by art. 217 LEC.

With respect to this ruling, only the first of the legal grounds is contested. The heading of the first plea alleges infringement of arts. 54.1 and 89.CPE, in relation to arts. 87.1.b) CPE,
A.1 CUP and 4.2. A.1 CUP and 4.2. CC, and is aimed at challenging the decision of the judgment under appeal denying TEVA PHARMA's standing to challenge claims 1 to 6 of patent EP415 for lack of novelty.

The allegations made at the end of the development of the plea, relating to the statements of the contested judgment on abuse of rights, do not meet the formal requirements to be examined by the court. The development of the plea must refer exclusively to the infringements indicated in its heading (art. 481.5 LEC) and it is not admissible to mix matters relating to different legal issues (art. 481.2 LEC and Judgment 1621/23 of November 21). Therefore, the impugnation of the statements of the appealed sentence on abuse of rights could not be alleged without further ado, apart from the infringements mentioned in the heading of the plea and therefore without denouncing the infringed norm, and without reasoning the concurrence of the interest of the appeal, but should have been raised through the formulation of a plea, with an indication in its heading of the infringed norm, an adequate development and the accreditation of the interest of the appeal.

In such a way that the eventual acceptance of the thesis of the plea would prevent the cassation of the appealed sentence in the contested pronouncement, since the other two legal reasons would remain unchallenged. This supposes the concurrence of the cause of inadmissibility of non-compliance with the requirements of content of the brief of interposition of the appeal insofar as the infraction denounced is not relevant for the ruling (art. 481.3 LEC) due to lack of useful effect.

As we have recalled on other occasions, the existence of a cause of inadmissibility becomes a cause for dismissal of the plea (judgment 1418/2024, of October 28, and those cited therein) which does not prevent it from being admitted at the time, given the provisional nature of said initial admission, as it is subject to a definitive examination in the judgment (judgments 109/2017, of February 17, and 487/2018, of September 12).

THIRD. *Second and* third grounds *of appeal*.

1. *Formulation of the* grounds.Both grounds refer to the requirement of the plausibility of the intended technical effect in order to assess the inventive step, which is why we analyze them together.

1.1. The *second* plea alleges infringement of Arts. 56, 83 EPC, in conjunction with Arts. 54.1, 63.1 and 23.2 EPC, with regard to the plausibility of the claimed technical effect in accordance with the technical teaching of the patent application WO'652.

23.2 EPC, with respect to the plausibility of the intended technical effect according to the technical teaching of the patent application WO'652. This infringement would have occurred because the judgment understands that it cannot analyze the technical teaching of the patent application in order to accept the claimed technical effect, but must do so from the granted patent, which is supposed to have solved the problems of the application.

In the development of the plea, it states that "the *patent bargain, i*.e., the fundamental principle on which the patent system is based, is based on the granting of a time-limited exclusivity in exchange for disclosing an invention at the time of applying for the patent, so that it becomes accessible to the public for free use at the expiration of that period. This exclusivity is 20 years from the patent application date (art. 63.1 EPC), although it can be extended up to 25 and a half years taking into account the CCP and the pediatric extension, and as such it benefits from that date, which will come to form the relevant prior art to analyze the patentability requirements (art. 54.1 EPC)".

Therefore, he then adds, "it is contrary to the aforementioned precepts that a person who files an application on an embodiment or a group of embodiments, without sufficient information that the technical problem he discloses is effectively solved, can benefit from an exclusivity and prior art.

In such a way that "(.") if the applicant benefits from an application date to form the relevant prior art that may affect the validity of his patent, the solution to the technical problem must have been provided with the patent application. Otherwise, a benefit is obtained on an application date, but on a research filed after it". This leads him to conclude that the plausibility of the technical effect must refer to the content of the patent application, which in this case was extraordinarily broad, as it included millions of compounds:

"It is evident, therefore, that the plausibility of the technical effect must be referred to the content of that patent application which, in the present case, was ektraOrdinately broad, including millions of compounds, with potential activities on different inhibitors, without activity data, without knowing which compound or compounds potently and selectively inhibited factor Xa, if any (Fourth and Fifth Facts of the complaint and Fifth and Sixth Allegations of the opposition to the appeal). If on September 21, 200J (priority) BMS did not yet have the invention and, as can be seen from the application, tried to protect everything it could think of, it should have waited until it had it to file its patent application with the information it decided to provide to the examiner on January 18, 2008 on the technical effects of apixaban (Document No. 22 TEVA). If, on the other hand, as Mr. Torcuato, inventor of the patent, said, and BMS defends in these proceedings, he already had that information, his action was doubly serious, since he tried to exclude competition on other products, whose potential pharmacological activities would never be investigated, by deciding not to provide the information on the properties of apixaban".

He then explains that, in any case, the granted patent does not add information that makes the technical effect plausible and cannot be a pretext for not analyzing the application.

He reasons why the limitation of the claim to a single compound did not solve the problems of plausibility of the technical effect, and concludes that:

"the Judgment does not verify, because it cannot, the fulfillment of the claimed technical effect of apixaban based on the content of the granted patent, but based on the post-published evidence to the patent application (priority 2001): on the authorization of the product, which happened in 2011 (points ó.5 and 6.6), and on the experimental evidence provided by the applicant during the examination and which is neither in the so|icítud

neither in the patent application nor in the granted patent (...). Thus, it was not until January 18, 2008, 7 years after the priority and 6 years after the application, that BMS justified the factor Xa inhibitory activity of **apixaban** before the EPO (points 3.14-3.15).

"Therefore, in terms of technical teaching the grant of the patent cannot be a pretext for not analyzing such teaching from the patent application. This does not mean that it should be analyzed from the granted patent, since it is evident that it contains an indicator towards the product to which the invention has been limited (apixaban), when such information was not in the patent application. Consequently, using the granted patent to analyze the plausibility of the technical effect would presuppose accepting a retrospective analysis towards **apixaban,** when that was not the technical teaching of the application, and, therefore, based on information submitted subsequently, which is not correct according to paragraph I above".

Next, the appeal accepts the reasoning of the contested judgment that "the inventive step could not be defined according to how the patent was applied for, since articles 123.2 and 68 EPC would be infringed" (points 6.23 6.31); and, it tries to turn it around, stating that "if the technical effect derives from the granted patent and not from the application, as the contested Judgment indicates when recognizing the speculative nature of the application (points 6.3, 6.6), then, the granted patent would be null for addition of matter".

The last part of the development of the plea is dedicated to the plausibility of the technical effect as a presupposition inherent to the requirements of inventive step (art. 56 EPC) and sufficiency of the description (art. 83 EPC).

1.2. The third ground is based on the infringement o f art. 56 EPC in relation to the verification of the technical effect of the claimed invention. The infringement would have been committed because, according to the appellant, the appealed judgment "accepts the technical effect on apixaban without verifying whether the patent application had sufficient information to make said technical effect plausible (Fifth and Seventh FJ). With this, the sentence *tactfully* grants *a* monopoly without the patent holder having justified that a concrete technical problem is being solved. To do so, it says that it is based on Decision G 2/21, but, in reality, it applies a test that is not that of the said EBA Decision and not even that of Decision T 116/18, issued in the referral matter that motivated G 2/21 and that it claims to apply, since, incomprehensibly, it partially reproduces the point of T 116/18 on which it is based, to extract the test that it considers applicable. (...) the test applied in the application is consistent with that of Decision G 2/21, so that the Judgment should not have rejected the analysis".

In the development of the plea, after examining the content of G 2/21, it reiterates that "according to G 2/21 the Judgment infringes art. 56 EPC by having based the technical effect (...) exclusively on the post-published test, published by the applicant during the prosecution of EP'415, without analyzing the technical teaching of the patent application".

The appellant considers that the interpretation of G2/21 made by the Court is not correct and that the test used in the lawsuit is still correct:

"The contested Judgment points out that it does not agree that it is correct to apply the test of the EPO Decision in the dasatinib case, on which this party has relied. This is because Decision G 2/21 would have introduced a new test, which would mean that, although the results of the pre-G 2/21 decisions would have been the same applying the new test, as confirmed by G 2/21 itself, the arguments leading to those results would be different (point 5.19, Judgment)."

For the appellant, "when the "technical teaching" of the patent application is being analyzed, according to the common general knowledge of the person skilled in the art, to verify whether it presents sufficient information on a certain technical effect (the potent and selective inhibition of factor Xa) with respect to a certain compound (apixaban), what is being done is to verify whether that technical effect is incorporated in that teaching. This is what is done in the lawsuit, in the opposition to the appeal, on what has been practiced and, on the other hand, on what the contested Judgment does not wish to analyze. This analysis cannot be denied in accordance with G 2/21".

The appeal also complains that the Court has applied a test that is not the one contained in G 2/21, stating: "the High Court holds that for the owner to be able to rely on the claimed technical effect when assessing the inventive step it is necessary that an expert, on the basis of the information contained in the application and the common general knowledge, concludes, first, that said technical effect derives from the original technical teaching and, second, that it effectively implies a realization of the latter. By original technical education we mean the invention claimed in the application". The Court, "instead of basing this interpretation on EBA Decision G 2/21 and establishing its own interpretation, bases it on a Decision of a Board of Appeal, T 116/18, which interprets G 2/21. (...) and the problem is that the Judgment is partially copying point 11.11 of T 116/18.

T 116/18, but disregarding the passage that interprets the referred terms". Specifically, it omits that "it is a realization of the originally disclosed invention". And, in addition, this decision T 116/18, further on explains how the question should be posed: "In other words, the question to be asked can also be formulated as the respondent did: would the skilled person, taking into account the common general knowledge at the filing date, and based on the application as filed, have legitimate grounds to doubt that the claimed technical effect can be achieved with the claimed subject matter?" . Being a plausibility test (ab initio implausibility), it is not the only interpretation of G 2/21 and furthermore he considers it in some respects incorrect. And he cites some other different application, such as, for example, T 873/21.

2. Decision of the court. The plea must be dismissed for the *following* reasons.

It should be clarified that it is justified for this Supreme Court, as a court of cassation, to hear these grounds, insofar as the interpretation of some legal precepts is questioned, relating to the validity of the patent and specifically to the requirement of inventive step. Basically, art. 56 EPC and other concordant provisions for what is the object of the legal problem raised.

The plaintiff, now appellant, *questions* the validity of *patent* EP'415 for lack of inventive step. It understands that it does not meet the requirement of plausibility of the intended technical effect in accordance with the technical teaching of the application, which is an inherent presupposition of the requirement of inventive step (art. 56 EPC).

It is true that this requirement that the intended technical effect be plausible according to the technical teaching of the patent is not strictly speaking a legal requirement for patentability. According to the first paragraph of article 56 EPC, "an invention involves an inventive step if it does not result from the state of the art in a manner obvious to a person skilled in the art". But the analysis of this requirement of inventive step implies that the technical effect intended with the invention derives from its technical teaching.

3. In order to determine, in the light of the case in question, the scope of this requirement of plausibility of the technical effect in the analysis of the inventive step, on the occasion of a patent invalidity action, we start from *decision G* 2/2J of March 23, 2023, of the Enlarged Board of Appeal of the EPO (hereinafter, G 2/21), which, in answering the preliminary question raised by one of the technical appeal chambers, analyses this question and the extent to which evidence published after the date of the application can be taken into account.

Although we are not bound by the decisions of the High Chamber, like so many other national courts, we follow its opinion in view of its authority in the matter and the conviction of its reasoning.

The assessment of the inventive step must be made on the effective date of the patent and on the basis of the information contained in the application, together with the common general knowledge available to the skilled person at that time. And in this examination, among other aspects, when determining the technical problem, it must be possible to evaluate the technical effect pursued by the claimed invention in comparison with the closest state of the art.

In the first answer of the Upper Chamber in G 2/21 to the questions referred for a preliminary ruling, after an intermediate conclusion that "the extent of reliance on subsequently published evidence is much less in the case of sufficiency of description (Art. 83 EPC) than in the case of inventive step (Art. 56 EPC).... (77)", states that:

"Evidence submitted by the applicant or patentee to demonstrate uh technical effect invoked for the recognition of the inventive step of the claimed subject matter may not be disregarded merely because such evidence, on which the effect is based, had not been made public before the filing date of the patent in suit and was submitted after that date",

And, in relation to the second answer, it understands that "the relevant criterion for relying on an alleged technical effect when assessing whether or not the claimed subject matter involves inventive step relates to the question of what a skilled person, taking into account the common general knowledge, would understand at the filing date of *the* application as originally filed as the technical teaching of the claimed invention. The technical effect claimed, even at a later stage, must be comprised in that technical teaching and embody the same invention, because such effect does not change the nature of the claimed invention" (93).

It therefore concludes that "an applicant or patentee may rely on a technical effect for inventive step if the skilled person, having in mind the common knowledge and based on the application as originally filed, would consider that such effect is covered by the technical teaching and embodied by the same invention as originally disclosed" (94). And, in responding to the request, it states:

"II. An applicant or patentee may rely on a technical effect for inventive step if the skilled person, having in mind the common general knowledge, and relying on the application as originally filed, would derive such effect as encompassed by the technical teaching and embodied by the same invention originally disclosed."

4. This decision G 2/21 has been interpreted by the Board of Appeal which had referred the questions for a preliminary ruling, in decision T 116/18, that the examination of the requirement that the effect must be capable of deriving from the same invention originally disclosed, translates it into the following question: "would the skilled person, having regard to the common general knowledge at the filing date, and on the basis of the application as filed, have legitimate reasons to doubt that the technical teaching in question, i.e. the claimed technical effect, together with the claimed subject matter, is a realization of the originally disclosed invention, i.e. the broader teaching of the application as filed?".

Thus, as opposed to the doctrine of *plausibility ab* initio (based on the information contained in the patent application or common general knowledge, the person skilled in the art at the filing date of the patent application would have considered the effect plausible), it is understood that Decision G 2/21 is better aligned with *implausibility ab* initio (based on the information contained in the patent application or common general knowledge, the person skilled in the art at the filing date of the patent application would have seen no reason to consider the effect implausible).

This is the interpretation also assumed by this court of cassation. To which the Court of Appeals agrees when it states that "the requirement of plausibility as it has been raised by the plaintiff throughout these two instances is not enforceable", insofar as TEVA relies on another understanding of the plausibility requirement, proper to *plausibility ab* initio, contained in the Decision of the Board of Appeal T 488/13, prior to G 2/21, which it considers has not been modified.

This does not preclude that, as the appellant points out in the appellate judgment, it should be examined whether in this case the intended technical effect was covered by the technical teaching and embodied by the originally disclosed invention itself.

5. In our case, as the appealed judgment warns, the intended technical effect was to inhibit factor Xa in a sufficiently effective and specific manner for its therapeutic purpose (useful as anticoagulants for the treatment or prevention of thromboembolic disorders, with improved pharmacological properties).

Although the patent application referred to very many compounds in claim 1, following objections by the examiner that it was not credible that all of these compounds possessed any degree of factor Xa inhibitory activity, the patent applicant limited it to a single compound, apixaban. This limitation does not appear to have involved any addition of new matter. For this reason, the examination of the plausibility of the intended technical effect should be limited to apixaban, without prejudice to the disclosure contained in the patent application.

As stated in the judgment under appeal, the patent application disclosed the compounds listed in examples 1 to 140, including one relating to apixaban (example 18). These examples showed the skilled person how to synthesize the disclosed compounds, among which 74 could be distinguished as most preferred, which had a Ki (potency) value in the nanomolar range. It is understood that they were preferred, in that they were mentioned by their common chemical designation in claim 8, which was the first dependent claim to mention compounds by name, one of which was apixaban. This compound appears on p. 225, lines 6-8, of the application.

If we also take into account that, as the judgment under appeal also records (when it reviews the common general knowledge of the expert in this case), it was part of the common general knowledge the importance of the anticoagulant candidates inhibiting factor Xa, which is the main technical effect highlighted in the patent application; the expert would know based on his common general knowledge and the information provided by the patent application, that the factor Xa inhibitory ability of these preferred compounds, in particular apixaban (ultimately the only compound protected by the patent}, as well as the selectivity could be verified by tests that were described in the application and were part of the respected common knowledge.

Thus, as the appellee argues, it is *logical to* conclude *that* the skilled person would have had no *reason* to doubt that the inventors had prepared the disclosed compounds, had lested them and had specifically protected in claim 8 the compounds for which they had obtained the best Ki value. And, applying the G 2/21 test, it could be concluded that the skilled person, based on his common general information and that provided by the patent application, would consider e] technical effect of apixaban (factor Xa inhibitor) comprised in the technical *teaching* of the application and also embodied by the same invention

originally disclosed, as the only compound protected in the patent (after limitation), apixaban, was explicitly disclosed in the application (in that it was specifically prepared in example 18 and was one of the 74 most preferred compounds that were specifically protected in claim 8, as the patent was originally applied for}.

6. This is corroborated by the opinion of other national courts that have had to rule on the same issue. Thus, the Court of Appeal of The Hague, in its judgment of August 15, 2023, on the occasion of the review of precautionary measures affecting the same patent now being prosecuted, also questioned the requirement of plausibility when analyzing inventive step. This decision records the opinion of two judgments, one from a French court (Judgment of the Court of Paris, 3^ Chamber, 1st section, of June 8, 2023, paragraphs 54-60, translation provided as document 52 of the answer to the application) and another from a Norwegian court (Judgment of the Oslo District Court of May 22, 2023, pp. 28 and 29 of the translation provided as document SJ of the response), according to which it was deductible to the expert from the application, using his general knowledge common at the date of priority, that an improved factor Xa inhibitor was sought compared to the factor Xa inhibitors already disclosed in WO 131, that the single substance apixaban disclosed in that application was the most promising candidate for it (...), that there was no reason for the expert to doubt that the objective (finding a factor Xa inhibitor) could be achieved with apixaban, and that it is not necessary to include proof thereof in the application.

In line with this criterion, the Hague Court of Appeal, within the interim prosecution, also understands that "it was deductible to the skilled person, using his common general knowledge at the priority date, from the application that the objective of finding a compound with improved factor Xa inhibition, selectivity and pharmacological properties compared to the already known factor Xa inhibitors can be achieved with apixaban. This meets the test requirements of G 2/21 (in the context of assessing inventive step) that the claimed technical effect is within the technical teachings of the application and embodies the same invention disclosed in the application. (...) The substance apixaban claimed in EP'415 was also individually disclosed in the application, both in example 18, and in claim 8."

The opinion of the judgment of the High Court of England and Wales of 7 April 2022, ratified by a judgment of 4 May 2023 of the Court of Appeal, which appreciates the nullity for lack of plausibility, is not taken into account because, in addition to excluding the criterion established by G 2/21, it applies the test of descriptive sufficiency established by the Supreme Court of the United Kingdom in Warnef Lambeft.

FOURTH. *Fourth ground of appeal*

1. Formulation of the plea. The ground of appeal is based on the infringement of art. 83 EPC in relation to the non-application of a plausibility criterion.

The infringement would have been committed because "the Judgment dismisses the challenge for insufficiency of the description of claims nos. 5-29 of patent EP'415 (FJ Octavo) on the grounds that plausibility cannot be analyzed by reference to the patent application (points 8.5-8.7); because the challenged claims would not be of second medical use (points 8.12-8.19}; and because the technical effect would have been accepted for the analysis of the inventive step and, in any case, the therapeutic effect would be known (points 8.20-8.21)".

In the development of the plea it is noted that "the plausibility test to be applied in relation to the sufficiency of the description is found in point 77 of Decision G 2/21 and, as can be seen, it is not limited to the claims being of second medical use, but to "the therapeutic effect" being "claimed"". Therefore, item 77 of G 2/21 should not cease to apply because Claims 5-29 of the EP'415 patent are of first use.

The appeal complains that the test of point 77 of G 2/21 is not the one applied by the appealed judgment, since it considers that the expert should have accepted the claimed technical effect with respect to apixaban to the extent that he would have accepted it with respect to the inventive step. And in relation to the test of point 77 the appeal states:

"The ratio of this test derives from the fact that in these cases we are analyzing whether the information in the application is sufficient with respect to the specific purpose claimed, while the protection of the product per se is broader. Transferred to the specific case it could have been made plausible the potent and selective inhibition of factor Xa, but not its use in therapy, since for use in therapy it is not sufficient only the potent and selective inhibition of the enzyme, factor Xa (points 192-197 and 223-224 of the Complaint). In other words, if the technical effect for inventive step is not plausible, all claims of the patent will be invalid. There is no need to look any further. But, on the other hand, the fact that it is plausible does not mean that it

is the therapeutic effect *necessary* for the sufficiency of the *description* (points 127-J 29 and 596 opposition to the appeal). Note that G 2/21 does not say that the test of sufficiency and inventive step are different, but that]the reliance on post-published evidence is lower with respect to sufficiency, and proof of therapeutic effect must be provided in the patent application. The difference would not reside, therefore, in the test, but in the intended technical effect on which it is applied".

2. Decision of the court. The plea must be dismissed for the following reasons.

The plea questions the interpretation and application of art. 83 EPC, which requires that "the invention must be described in the European patent application in a sufficiently clear and complete manner for a person skilled in the art to be able to apply it".

This precept correlates with one of the grounds for nullity of the patent, established in art. 138.1 EPC:

"The European patent may only be declared null and void, with effect for a Contracting State, in the following cases.
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"b) when the European patent does not describe the invention in a sufficiently clear and complete manner for a person skilled in the art to be able to carry it out".

Specifically, it is questioned that the appealed judgment did not assess the insufficiency of the description of claims nos. 5-29 of the EP'415 patent, it is complained that it did not apply the test provided for in paragraph 77 of Decision G 2/21.

3. The Court considered that these claims 5-29 were of first medical use, and not of second medical use (as the court had considered with respect to claims 7-29). They are first medical use because the active ingredient, apixaban, was first claimed in the same patent in which the medical use now contained was also claimed.

This question is now peaceful, since the appellant also starts from this consideration. And it is relevant in view of the reason or basis of his challenge to the appellate judgment. The appeal bases its challenge on the fact that the Court of Appeal did not apply the test contained in paragraph 77 of G 2/21.

It is true that the purpose of Decision G 2/21 was not to analyze the scope of the examination of the plausibility of the technical effect pursued by the patent in relation to the requirement of the sufficiency of the description, but in relation to the requirement of inventive step. But it is also true that it starts from an intermediate conclusion in which it contrasts the scope of the tests carried out subsequent to the application according to the sufficiency of the description or the inventive step:

"The reasoned conclusions of the Boards of Appeal in the above-mentioned decisions make it clear that the extent of reliance on subsequently published evidence is much less in the case of sufficiency of description (Article 83 EPC) than in the case of inventive step (Article 56 EPC). In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, proof of the claimed therapeutic effect must be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the person skilled in the art that the therapeutic effect has been achieved. A deficiency in this respect cannot be cured by post-publication evidence" (77).

Although this paragraph 77 does not distinguish between first and second medical use, it is very significant, as the respondent argues, that the findings of the Boards of Appeal, referred to in the first indent of this paragraph, refer to second medical use claims, as is evident from paragraph 74:

"Although the questions of sufficiency of description (Article 83 EPC) and inventive step (Article 56 EPC) and their assessment must clearly be dealt with separately, as correctly stated by the referring chamber in point 13.3.1. of the statement of reasons for the order for reference, the High Court is aware of the case law, in particular, concerning second medical use claims where the concept of "plausibility" has been used. In the case of such claims, the question of reliance on post-published evidence of an alleged technical effect arises in particular in the context of sufficiency of description.

"Indeed, a technical effect, which in the case of, for example, a second medical use claim is usually a therapeutic effect, is a feature of the claim, so that the question of whether this effect has been shown to be achieved is a question of the sufficiency of the description under Article 83 of the EPC,

"Therefore, since the subject matter of second medical use claims is usually limited to a known therapeutic agent for use in a new therapeutic application, it is necessary that the patent at the date of filing makes it credible that the known therapeutic agent, i.e., the product, is suitable for the claimed therapeutic application. The Enlarged Board explained the legal and historical background of the patentability of additional medical uses in its decision G 2/08".

Thus, the conclusion reached in paragraph 77 ("proof of the claimed therapeutic effect must be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the person skilled in the art that the therapeutic effect has been achieved"), on which the fourth ground of appeal relies, refers to claims for second medical use, without necessarily extending to claims for first use.

This has been understood in subsequent decisions of the appeal chambers interpreting G 2/21. For example, in Decision T 2037/22, in rejecting the application of paragraph 77 of G 2/21 to claims that are not second medical use', the Court of Appeal has held that 'the application of paragraph 77 of G 2/21 to claims that are not second medical use'.

"However, as can be extracted from point 77 of the Reasons for Decision G 2/21 ("proof of the claimed therapeutic effect must be provided in the application as filed") and points 74 76 above, the EBA's analysis of the case law on descriptive sufficiency was made in relation to second medical use claims where the technical effect is normally a therapeutic effect. In such a case, because the subject matter of second medical use claims is normally limited to a known therapeutic agent for use in a new therapeutic application, it is necessary that the patent at the filing date makes it credible that the known therapeutic agent, i.e., the product, is suitable for the claimed therapeutic application (item 74)".

4. In any case, one of the presuppositions of the rule contained in the provisional conclusion of paragraph 77 of G 2/21 is that, in the absence of experimental data in the application as filed, it is not credible to the person skilled in the art that the intended therapeutic effect has been achieved. Bearing in mind that, as expressed in Decision T 853/22, it could be sufficient to rely on "a theoretical or mechanistic explanation" or to rely on "on common general knowledge":

"(...) The board agrees with the appellant that decision G 2/21 in its obiter dictum on sufficiency of disclosure, in particular with regard to further medical use claims, did not consider experimental evidence mandatory. However it stated in Reasons 77 that "the proof of a claimed therapeutic effect has to be provided in the application as filed, in particular if, in the absence of experimental data in the application as filed, it would not be credible to the skilled person that the therapeutic effect is achieved™ and that "[a] lack in this respect cannot be remedied by post-published evidence". The board interprets this statement by the Enlarged Board as meaning that if there is no experimental data in the application as filed (as in the case in hand), a different proof of the claimed therapeutic effect has to be provided in the application as filed, e.g. by way of a theoretical *or* mechanistic explanation or by relying on common general knowledge".

In our case, we assume that the first use claims, for which the sufficiency of the description is questioned, are protected in the patent together with the product itself (apixaban). Moreover, as argued in the response to the appeal, at the time of the patent application, it was common knowledge that factor Xa inhibitors were useful for treating thromboembolic disorders due to their good anticoagulant activity. This, it must be understood, contributed to the credibility for the expert that a factor Xa inhibitor such as apixaban could be used in therapy to treat these disorders.

FIFTH. ***Costs***

Having dismissed the appeal, the costs generated by *the* appeal must be imposed on the appellant, in application of the criterion established in art. 398.1 LEC, with the loss of the deposits made for the appeal, in accordance with Additional Provision 15.

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In view of the foregoing, in the name of the King and by the authority conferred upon it by the Constitution, this Court has decided as follows

1. To dismiss the appeal filed by Teva Pharma, S.L.U. against the judgment of the Provincial Court of Barcelona (Section 15) of July 18, 2024 (roll 240/2024), which heard the appeal of the judgment of the Commercial Court No. 4 of Barcelona of January 15, 2024 (ordinary trial 573/2022).

2. "Impose on the appellant the costs generated by its appeal.

3. To order the forfeiture of the deposit made for the appeal.

Send the corresponding certification to the aforementioned Hearing. Notify the parties of this resolution and insert it in the legislative collection. So agreed and signed.