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Article

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Balancing Disclosure and Protection: Plausibility after G 2/21

This article examines the evolving doctrine of plausibility in European patent law following the Enlarged Board of Appeal's decision in G 2/21 (Reliance on a purported technical effect for inventive step (plausibility)). Plausibility, an implicit requirement ensuring that a patent's technical contribution is commensurate with the scope of protection granted, originates from Technical Boards of Appeal (TBA) decisions to curb speculative claims, particularly in pharmaceuticals. G 2/21 emphasises free evaluation of evidence and a context-dependent assessment: a technical effect must be encompassed by the application's technical teaching and embody the original invention. For product patents, it tilts toward *ab initio* implausibility, easing reliance on post-published data and potentially enabling earlier or less developed filings. In contrast, second medical use claims demand that the technical effect be made plausible at filing (*ab initio* plausibility), with limited post-published support to prevent overbroad protections for known compounds. Drawing on European litigation, the article analyses national courts' interpretations, revealing divergences, and evaluates the implications of G 2/21 for the fundamental balance between disclosure and protection in patent law.

I. Introduction

Few doctrinal patent law issues evoke as much disagreement as plausibility: the condition that the technical problem behind a patent application must at least be plausibly solved at the effective filing or priority date.[1] Judges, practitioners, and academics diverge in their opinions on whether plausibility is needed,[2] whether the concept even exists,[3] and, if so, where the bar lies[4] and, indeed, should lie.[5]

This is perhaps unsurprising when plausibility is not a statutory requirement. It originates from decisions of the Technical Boards of Appeal ('TBA') of the European Patent Office ('EPO'). Observing that applicants were filing broad claims with little evidence, the TBAs began requiring data to support the claim – first with product patents and then second medical use patents.[6] The requirement is anchored in the patent bargain – the notion that to be awarded a patent, patentees must make a technical contribution.[7] Recognising that plausibility represents a way to help preserve this patent bargain, but faced with the issue that the European Patent Convention ('EPC') makes no mention of plausibility anywhere, the TBAs took matters into their own hands. They inserted the concept under other patent requirements, such as inventive step and sufficiency of disclosure, depending on the type of claim.[8] By so doing, plausibility

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1 The plausibility requirement is often traced back to T 939/92 *Agrevo/Triazoles* [1996] EPOR 171, but the word itself first appeared in T 1329/04 *Johns Hopkins/Growth differentiation factor-9* [2006] EPOR 8; for a detailed overview, see Paul England, 'Patents and plausibility' (2014) 9 JIPLP 22, 23 and Andrew JK Wells, 'Technical contribution and plausibility: the approach of the European Patent Office and the courts of England and Wales' (2019) 14 JIPLP 784.

2 Compare eg Markus Ackermann, 'No Need for 'Plausibility' in German Patent Law' [2021] GRUR International 3 and Alison Slade, 'Plausibility: a route to stronger and more robust patents?' in Duncan Matthews and Paul Torremans (eds), *European Patent Law* (De Gruyter 2023) 43-58.

3 The EBA appears to dismiss plausibility as a concept in G 2/21; others also question whether plausibility even has a legal basis, see The Rt. Hon. Professor Sir Robin Jacob, 'Plausibility and Policy' <https://discovery.ucl.ac.uk/id/eprint/10116755/1/Plausibility%20and%20Policy%20-%20final%20author%27s%20draft.pdf> accessed 20 October 2025 ('If one actually looks at the words of the EPC, a purist would say it is straining the meaning of words beyond breaking point to get plausibility out of them – positively Humpty Dumpty-ish').

4 See eg the differing views by UK Supreme Court judges in *Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Anor (rev 1)* [2018] UKSC 56.

5 ibid.

6 For a discussion, see *Warner-Lambert* (n 4) [23] (Lord Sumption).

7 Slade in Matthews and Torremans (n 2) 43.

8 This article focuses on inventive step and sufficiency, but it is important to note that plausibility is also relevant for industrial applicability, see eg *Human Genome Sciences Inc (HGS) v Eli Lilly & Co* [2011] UKSC 51. For a discussion, see eg Timo Minssen and David Nilsson, 'The industrial application requirement for biotech inventions in light of recent EPO & UK case law: A plausible approach or a mere "hunting license"?' (2012) 34 EIPR 689.

emerged as an implicit, but especially important part of the requirements for patentability and validity.

In recent years, plausibility has assumed even greater significance, particularly in the pharmaceutical field. It is at the forefront of patent challenges,[9] and likely plays a role in a shift in patent litigation. Previously generic/biosimilar companies predominantly challenged second medical use patents standing in the way of market entry, shying away from product patents. That is no longer the case. Generic/biosimilar companies now more frequently challenge product patents and Supplementary Protection Certificates ('SPCs') on the basis of plausibility.[10] More importantly, they are successful when doing so, causing key patents to be struck down. This highlights the need to examine plausibility closely.

Yet, despite its importance, plausibility remains without an explicit statutory basis, causing its function and existence to not only remain under attack, but its treatment through the case law of the EPO boards to be inconsistent. Various TBAs have been left to interpret and apply plausibility in practice. This has led to different plausibility standards,[11] in turn creating legal uncertainty in the field. In light of these developments, the Enlarged Board of Appeal ('EBA') handed down its long-awaited decision in G 2/21.[12] The EBA held that post-published evidence can generally be taken into account for inventive step, provided the effect is derivable from the application as filed by the skilled person. Unsurprisingly, the current test remains subject to debate.[13]

This article examines what G 2/21 means for plausibility. While the EBA noted that plausibility is not a distinct legal concept,[14] prompting some to question its centrality in the decision,[15] we take the view that G 2/21 has important consequences for plausibility going forward. Indeed, it not only sets the bar for plausibility, but enables broader claim scope based on less evidence, which is especially advantageous for patentees in a first-to-file system.

Section II elucidates the plausibility requirement in European patent law, tracing its origins in TBA decisions and emphasising its role in ensuring that patent protection corresponds to a genuine technical contribution while preventing speculative claims. Section II.1 examines the role of post-published evidence, illustrating through key cases how divergent approaches have emerged, including *ab initio* plausibility (requiring initial proof of the technical effect) and *ab initio* implausibility (presuming plausibility unless doubts are substantiated), leading to inconsistencies in evidentiary burdens and standards. Section II.2 shows how G 2/21 moves the plausibility test towards *ab initio* implausibility for product patents, while maintaining a higher standard for second medical use patents. Section III then assesses the implications of G 2/21 for plausibility, evaluating its impact on the evidentiary standards for product patents and second medical use patents, while examining national courts' interpretations through the lens of the *Apixaban* patent disputes.

II. Plausibility as a non-statutory requirement: Origins, divergence, and G 2/21

1. The plausibility doctrine from TBA decisions to EBA clarification

To obtain patent protection for an invention, applicants must demonstrate that 'the technical problem underlying the invention was at least plausibly solved at the filing date' of the patent application.[16] Merely disclosing an invention is, in other words, not enough. The technical contribution must be plausible. This is a '*conditio sine qua non*', according to the TBA of the EPO,[17] and is otherwise known as the plausibility concept, requirement or test.[18] Plausibility is thus a mechanism ensuring that the scope of protection conferred by a patent aligns with the patentee's technical contribution to the art.[19] As Slade states, '[i]t seeks to discourage monopolies on things that do not work, and also over claims for which the patentee has not provided adequate justification at the date of filing'.[20] That is the reason and justification behind the requirement: it aims to prevent speculative claims.

Plausibility is notably not an explicit statutory requirement. It originates from EPO Board decisions.[21] Observing that patentees were filing overly broad claims, the Boards started requiring evidence to back them up – first with claims to chemical classes, i.e. a family of chemicals sharing a similar structure; then claims to individual chemical compounds (product claims) and second medical use claims, i.e. claiming protection for an existing substance on the basis that a new therapeutic 'use' for it has been discovered. Plausibility is a matter of inventive step when patentees rely on a specific technical effect to support inventive step, but where the technical effect is not expressed in the claim, as is the case for product patents. If the technical effect is expressed in the claim, such as with second medical use claims, then plausibility is assessed as a matter of sufficiency.

In T 939/92 *Agrevo*, the TBA found that the applicant bears the burden of proof and must demonstrate that the purported technical effect is achieved.[22] Using a Markush claim formulation,[23] the patent application claimed a class of chemical compounds. However, the

9 See eg *Sandoz Ltd v Bristol-Myers Squibb* [2023] EWCA Civ 472; *Generics (UK) Ltd & Ors v AstraZeneca AB* [2025] EWCA Civ 903.

10 ibid.

11 For a discussion see: Slade in Matthews and Torremans (n 2) 48.

12 G 2/21 of 23 March 2023 – *Reliance on a purported technical effect for inventive step (plausibility)*.

13 See eg *Generics v AstraZeneca AB* (n 9) [37] (Richard Arnold LJ) ('What is less clear is whether the test it laid down differs in substance from one of plausibility, and if so how. There is a substantial dispute as to how that test is to be understood and applied').

14 G 2/21 (n 12) [92].

15 Rose Hughes, 'Clarity on the interpretation of G2/21 from the referring Board (T 0116/18)' (*IPKat*, 27 November 2023) <https://ipkitten.blogspot.com/2023/11/clarity-on-interpretation-of-g221-from.html> accessed 15 December 2025.

16 T 488/16 of 1 February 2017, [4.9] – *Dasatinib/BRISTOL-MYERS SQUIB*.

17 ibid.

18 See eg Alison Slade, 'Plausibility: a conditio sine qua non of patent law?' (2020) 3 IPQ 180.

19 *Warner-Lambert* (n 4) [23].

20 Slade (n 18) 181.

21 For a discussion, see *Warner-Lambert* (n 4) [23] (Lord Sumption).

22 *Agrevo/Triazoles* (n 1).

23 A Markush formula or grouping is a claim to a generic formula, eg ABCD, where each letter represents a member of a certain class.

application, as filed, only shared test data for certain compounds, yet claimed that all compounds had herbicidal activity, causing the examining division to refuse the application. The applicant maintained that all compounds had herbicidal activity, but alleged in the alternative that the inventive step analysis 'did not provide a basis for limiting the subject-matter of claims such as those of the present application to compounds having any activity or indeed any technically useful property'.[24] With this in mind, the applicant argued that selecting the claimed compounds from 'an unlimited number of possibilities' was inventive, albeit arbitrary.[25] This was to no avail. The TBA found that 'the selection of such compounds, in order to be patentable, must not be arbitrary but must be justified by a hitherto unknown technical effect caused by those structural features which distinguish the claimed compounds from the numerous other compounds'.[26] Substantially all selected compounds must produce the technical effect, and the submitted evidence and/or common general knowledge must show that this is the case.[27] If not, the claim is *AgrEvo* obvious.

Plausibility under inventive step therefore involves an assessment of whether the patentee has shown that the claimed solution in fact solves the objective problem across the breadth of the claim, whereby merely synthesising further chemical compounds is not considered a technical contribution to the art. The second part of the assessment considers whether the patent makes it *plausible* that the claimed solution solves the relevant objective problem.[28]

In T 1329/04 *John Hopkins*, the TBA reaffirmed that the burden of proof lies with the applicant when asserting a technical effect.[29] The application claimed a molecule that allegedly belonged to the transforming growth factor-ß (TGF-ß) family, but was refused for lack of an inventive step. The claimed molecule was structurally different from other TGF-ß family members and the application included no evidence showing that the claimed molecule had functional similarities to other TGF-ß members. As such, the TBA decided that 'there is not enough evidence in the application to make at least plausible that a solution was found to the problem which was purportedly solved'.[30] Nor could post-published evidence come to the rescue. The TBA ascertained that:

> '[t]his approach would be in contradiction with the principle that inventive step, as all other criteria for patentability, must be ascertained as from the effective date of the patent. The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves the problem which it purports to solve'.[31]

These decisions indicate that plausibility requires applicants to show that what they assert bears some truth.[32] When and how that should be achieved is, however, debated, especially when it comes to post-published evidence, as will now be discussed.

2. Post-published evidence: Balancing first-to-file incentives and disclosure obligations

Post-published evidence, patentees argue, is especially important in a first-to-file patent system.[33] In a first-to-file patent system, actors are incentivised to file patent applications early. Failure to do so risks another inventor claiming the invention first, meaning one's time and efforts were for nothing. However, early patent filings may entail less-mature patent applications. The inventor may not have delineated the full scope of the invention or have sufficient data ready at the stage of filing. They might also not grasp what the best embodiment of the invention is. In the pharmaceutical field, for example, it is common practice to first file an originator patent protecting a family of molecules.[34] This is because at the time of filing, the entire class might seem promising, but patentees may not have narrowed down the particular molecule showing the most promise. Together this provides an incentive to file patent applications with broad claims to ensure all subject-matter relating to the invention is covered, in turn preventing competitors from using any part of the invention. But this in turn runs the risk that the submitted evidence cannot back up the claim, thus the reason why post-published evidence is important for patentees. It allows an applicant to secure protection first and generate the necessary data later.

This is also why post-published evidence is controversial. A too-lenient approach to post-published evidence may enable patentees to protect solutions for problems they have not necessarily solved at the date of filing. Such an outcome would arguably contravene the principle that one should only receive protection for what one has actually invented. Nothing more, nothing less. When assessing plausibility, the TBAs must therefore keep these two competing interests in mind and attempt not only to strike a fair balance but remain consistent in their approach. This may be easier said than done. Indeed, the question of whether and how applicants may rely on post-published evidence to support the asserted technical effect has given rise to several, diverging decisions by various TBAs prior to G 2/21.[35]

24 *Agrevo/Triazoles* (n 1) [V].
25 ibid [2.5.2].
26 ibid [2.5.3].
27 ibid [2.5.4]-[2.6.2].
28 For a helpful discussion, see Wells (n 1) 787.
29 *Johns Hopkins* (n 1).
30 ibid [11].
31 ibid [12].
32 Note, however, that certain decisions take another view, as is discussed in later sections.
33 As argued in eg *Johns Hopkins* (n 1) [V], [10].
34 Or 'originating patents', see eg *I.G. Farbenindustrie A.G's Patents* (1930) 47 RPC 289, 321; see also Dmitry Karshtedt, Mark A Lemley and Sean B Seymore, 'The Death of the Genus Claim' (2021) 35 HJLT 1.
35 When referring its questions to the EBA, the referring TBA noted these different approaches, as discussed in G 2/21; however, some refute that these different strands of plausibility exist, including the EBA itself, see: G 2/21 (n 12).

For example, in T 609/02 *Salk Institute/AP-1 complex*, the TBA found that post-published evidence could not be relied upon to support the purported technical effect.[36] The patent contained claims to a method for identifying certain compounds that were useful to treat abnormal cells. All but one of the contested claims were deemed valid by the Opposition Division. The patentee appealed and filed a new request which included *inter alia* a revised claim. The revised claim was to hormones identified using the method outlined in the other claims of the patent for the treatment of certain diseases linked to AP-1 (a protein). However, the patent failed to provide any data demonstrating this effect. It merely included a written reference noting this was possible.[37] The applicant argued the invention was sufficiently disclosed because the post-published evidence confirming the asserted technical effect had been achieved using patent's teaching.[38] The TBA disagreed. The Board stated that:

> '[s]ufficiency of disclosure must be satisfied at the effective date of the patent, ie on the basis of the information in the patent application together with the common general knowledge then available to the skilled person. Acknowledging sufficiency of disclosure on the basis of relevant technical information produced only after this date would lead to granting a patent for a technical teaching which was achieved, and, thus, for an invention which was made, at a date later than the effective date of the patent. The general principle that the extent of the monopoly conferred by a patent should correspond to, and be justified by, the technical contribution to the art, has to be kept in mind'.[39]

In T 488/16 *Bristol-Myers Squibb/Dasatinib*, the TBA likewise rejected that post-published evidence could be used to demonstrate the alleged technical effect for the patent in question.[40] The patent application, as filed and granted, claimed a large chemical class based on a generic formula; however, following opposition, BMS sought to only maintain protection for the compound dasatinib. BMS alleged dasatinib had 'protein tyrosine kinase (PTK) inhibitory activity' and so could be used to treat various diseases, such as cancer, and that it was an improved PTK inhibitor compared to other compounds disclosed in the prior art.[41] But BMS failed to support this assertion with any data. The application, as filed, did not adduce any activity data for any of the compounds.[42] It only contained a statement that '[c]ompounds described in the following Examples have been tested in one or more of these assays and have shown activity'.[43] Accordingly, the TBA affirmed that:

> 'it is not acceptable to draw up a generic formula, which covers millions of compounds, vaguely indicate an "activity" against PTKs and leave it to the imagination of the skilled reader or to future investigations to establish which compound inhibits which kinase and is therefore suitable to treat the respective diseases associated therewith'.[44]

Although the TBA acknowledged that experimental data are not *per se* required, the applicant must show that the relevant technical problem was at a minimum plausibly solved when filing the application.[45] Since this was not the case, BMS also could not rely upon post-published evidence. Such evidence may, the TBA stated, only be relied upon if 'it is already plausible from the disclosure of the patent that the problem is indeed solved'.[46]

However, in T 578/06 *Ipsen*, the TBA allowed the patentee to rely on post-published evidence to support the asserted technical effect.[47] The patent application in question was a second medical use patent. It claimed the use of somatostatin (a specific hormone) for a specific therapeutic use. The examining division refused the application for lack of inventive step, finding it was not plausible that the problem had been solved at the date of filing. The applicant did not submit any experimental data along with the application, nor did the post-published evidence use applicable test methods, according to the examining division. Taken together the evidence failed to demonstrate the asserted technical effect. This proved fatal, the examining division found, as the applicant bears 'the burden of proof for facts in his favour' in *ex parte* proceedings.[48] The patentee appealed. Deciding in favour of the patentee, the TBA observed that the examining division failed to substantiate why the invention was not plausible and, moreover, 'saw no reasons to doubt the usefulness of somatostatin to attain the claimed effect'.[49] As there were no doubts relating to plausibility, the applicant could rely on post-published evidence.[50]

The TBA similarly deemed post-published evidence admissible in T 0536/07 *Co-expression* despite the application, as filed, containing no working examples or preferred embodiments relating to the claimed invention, i.e. an alternative co-expression system.[51] The TBA stated, '[T]here is *a priori* no reason for the skilled person to consider it not to be a plausible solution to the above mentioned technical problem', further recognising that the post-published evidence showed that the proposed solution was feasible.[52] The TBA also found that this case differed from T 1329/04 *John Hopkins*. Unlike T 1329/04 *John Hopkins*, where the skilled person had reason to believe that the claimed molecule was not a member of the TGF-ß family, the skilled person had no reason to doubt

36 T 0609/02 of 27 October 2004 – *AP-1 complex/SALK INSTITUTE*.
37 ibid [5].
38 ibid [7].
39 ibid [8].
40 *Dasatinib/BRISTOL-MYERS SQUIB* (n 16).
41 ibid.
42 ibid [4.5] ('No further information is provided. No individual values or range of values are given. No information as to whether the observed "activity" is suitable for the intended use, ie the treatment of a number of diseases and disorders, is provided').
43 ibid [4.5].
44 ibid [4.9].
45 ibid [4.9].
46 ibid [4.2].
47 T 0578/06 of 29 June 2011 – *Pancreatic cells/IPSEN*.
48 As recognised by the TBA in ibid [V].
49 ibid [12].
50 ibid [17].
51 T 0536/07 of 14 October 2008 – *Co-expression soluble PACE/GENETICS INSTITUTE*.
52 ibid [9].

that the claimed solution could be carried out, thus post-published evidence could also be considered.[53]

These (and other) TBA decisions are commonly bifurcated into two camps: *ab initio* plausibility and *ab initio* implausibility.[54] *Ab initio* plausibility entails that the applicant must give the skilled person reason to believe that the underlying technical problem has been plausibly solved at the date of filing, and only then may the applicant rely on post-published evidence. In contrast, *ab initio* implausibility means that the technical effect is deemed plausible from the start and so post-published evidence may always be considered, *unless* the skilled person has substantiated doubts at the date of filing. As such, the evidentiary burden shifts depending on which approach is applied. This in turn may also influence the final decision on the validity of a patent, whereby the decision may be entirely different if viewed through the lens of *ab initio* plausibility or *ab initio* implausibility. It is in response to this uncertainty that G 2/21 was decided.

3. G 2/21: Reframing plausibility through free evaluation and contextual assessment

Although plausibility is especially important for the pharmaceutical field, EP2484209 – the disputed patent in G 2/21 – did not concern pharmaceutical compounds; rather, it concerned insecticide compositions. The individual compounds and their insecticidal activity were known, but the patentee alleged the claimed insecticides combinations produced an improved synergistic effect compared to the individual compounds and submitted post-published data showing said effect for two types of moths. Syngenta, the opponent, disagreed. In their view, EP2484209 lacked, *inter alia*, an inventive step,[55] and the patentee could not rely upon post-published evidence to demonstrate the asserted technical effect. After Syngenta failed in the opposition division, they appealed to the TBA, which found that specific data submitted as post-published evidence was crucial in deciding the patent's validity, but the Board was uncertain whether the post-published evidence was admissible.

The TBA observed that previous TBAs diverged in their approach to post-published evidence, and thus it referred three questions to the EBA, namely:

> 'If for acknowledgement of inventive step the patent proprietor relies on a technical effect and has submitted evidence, such as experimental data, to prove such an effect, this evidence not having been public before the filing date of the patent in suit and having been filed after that date (post-published evidence):
> 1. Should an exception to the principle of free evaluation of evidence (see e.g. G 3/97, Reasons 5, and G 1/12, Reasons 31) be accepted in that post-published evidence must be disregarded on the ground that the proof of the effect rests *exclusively* on the post-published evidence?
> 2. If the answer is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have considered the effect plausible (*ab initio* plausibility)?
> 3. If the answer to the first question is yes (the post-published evidence must be disregarded if the proof of the effect rests exclusively on this evidence), can the post-published evidence be taken into consideration if, based on the information in the patent application in suit or the common general knowledge, the skilled person at the filing date of the patent application in suit would have seen no reason to consider the effect implausible (*ab initio* implausibility)?'

Firstly, regarding post-published evidence, the EBA found that such evidence, when used to support a technical effect for the purposes of inventive step, cannot be refused only because the evidence was not public at the date of filing and thus submitted later.[56] The EBA ascertained that 'principle of free evaluation of evidence … may not be used to disregard evidence *per se* insofar as it is submitted and relied upon by a party in support of an inference which is challenged as to its plausibility and is decisive for the final decision'.[57] Refusing such evidence, when admissibly filed, would contravene the principle of free evaluation of evidence and the parties' procedural rights.[58] Recognising that neither the EPC nor decisions by the Boards of Appeal stipulate formal rules regarding the evaluation of evidence,[59] the EBA noted that this principle is at the discretion of the Boards, taking into account the entire context.[60] In other words, the admissibility of post-published evidence depends on the skilled person, common general knowledge, and the patent application itself. It is a context-dependent analysis.

Secondly, on the question of the standard for relying on a purported technical effect for inventive step, the EBA found that it depends on what the skilled person derives from the patent application.[61] More specifically, the EBA affirmed that:

> 'a patent applicant or proprietor may rely upon a technical effect for inventive step if the skilled person, having the common general knowledge in mind, and based on the application as originally filed, would consider said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention'.[62]

In other words, the technical effect must: (i) be 'encompassed' by the patent's technical teaching, and (ii) embody the original invention as said effect 'does not change the

53 ibid [11].

54 For summary, see G 2/21 (n 12).

55 The opponents also attacked EP2484209 for lack of novelty, sufficiency and added matter, but the referring TBA found that the patent was novel and sufficiently disclosed, so inventive step was the subject of the referral.

56 G 2/21 (n 12) [I], [91].

57 ibid [90].

58 ibid [32].

59 TBA decisions have, however, developed certain principles which should be applied, as recognised by the EBA ibid [39].

60 ibid [29]-[30].

61 ibid [71], [93].

62 ibid [94].

nature of the claimed invention'.[63] This in turn means that patentees cannot rely on post-published evidence demonstrating a technical effect that is entirely detached from the patent application. Despite acknowledging the 'abstractness' of these criteria,[64] the EBA offered little guidance on whether the technical effect can be implied, or must be explicitly expressed, leaving it up to TBAs to decide on a case-by-case basis.

The EBA did, however, make it clear that a different standard applies for plausibility when assessed in the context of sufficiency of disclosure, paying special attention to second medical use claims.[65] For such claims, the EBA observed that applicants must prove the technical effect in a patent application, as originally filed, to satisfy the sufficiency requirement. As per the EBA:

'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'.[66]

Unlike in the case of inventive step, post-published evidence cannot come to rescue if this criterion is not satisfied.[67] The EBA therefore creates a distinction for product claims and second medical use claims, whereby the plausibility bar is set higher for the latter and one cannot be overly reliant on post-published evidence.[68]

Although G 2/21 includes 'plausibility' in the title of the decision, the EBA notably dismisses plausibility as a concept altogether, noting it is not a 'distinctive legal concept', or a specific patent law requirement. Rather, it is, the EBA states, 'a generic catchword' used by certain TBAs, national courts, and the like.[69] Nor do two branches of plausibility necessarily exist.[70] The outcome would likely be the same irrespective of whether one views it through the lens of *ab initio* implausibility or *ab initio* plausibility, according to the EBA. It all depends on the skilled person.

III. The post-G 2/21 landscape: Implications for product claims, second medical uses, and national application

G 2/21 has been met with mixed reviews. Some, such as Lambert, assert that, 'the approach that seems to be that advocated by the EBA is not logical, and could lead to abuse and degradation of the European patent system'.[71] Others argue G 2/21 changed nothing at all with respect to inventive step. It merely confirmed what was already known.[72] The following sections evaluate what G 2/21 means for product claims and second medical use claims, before discussing how several national courts have interpreted G 2/21.

1. Product claims and the risk of speculative patenting under *ab initio* implausibility

G 2/21 makes it clear that the plausibility test under inventive step now hinges on whether the technical effect was encompassed by the patent application's technical teaching and was embodied by the original invention. Moreover, that post-published evidence may be relied upon unless the skilled person had substantiated doubts at the date of filing. By so doing, G 2/21 moves the EPO's plausibility standard towards *ab initio* implausibility: the technical effect is deemed plausible from the start unless the person skilled in the art has substantiated doubts.

This is evident when the referring TBA subsequently upheld EP2484209, finding that the invention had an inventive step, even when the application at the time filed contained no direct data supporting the asserted technical effect,[73] and despite the opponent adducing data demonstrating that one of the insecticide combinations failed to produce the alleged synergistic effect against one of the moths used to support the claim. The TBA did so based on post-published evidence showing that the effect was achieved against another type of moth, which albeit mentioned in the application, was not supported by any of the original data.[74] Applying the EBA's reasoning in G 2/21, the TBA reaffirmed that experimental proof is not required to support an asserted technical effect.[75] Nor, the TBA found, does G 2/21 require applicants to provide a 'positive verbal statement' as to the technical effect in the application when filed.[76] Accordingly, the technical effect need not be explicitly stated. It must merely be encompassed in the technical teaching and embodied by the original invention. That does not, however, give applicants a free pass. The TBA stated:

> 'The Enlarged Board thus did not give patent applicants and proprietors "carte blanche" to be able to rely on a purported technical effect at any stage of the proceedings'.[77]

The TBA affirmed that the application itself and its filing date 'is intended to prevent the filing of applications directed purely to speculative (armchair) inventions made only after the filing date'.[78] Whether that is sufficient is subject to debate.

63 ibid [93].

64 ibid [95].

65 The referred questions concerned plausibility in the context of inventive step, not sufficiency of disclosure, but the EBA nonetheless took the opportunity to consider the latter, ibid [77].

66 ibid.

67 ibid.

68 As per the EBA, 'the scope of reliance on post published evidence is much narrower under sufficiency of disclosure … compared to the situation under inventive step', see ibid.

69 ibid [92].

70 ibid [70]-[72].

71 Justin Lambert, 'Must Assertions made in European Patents be Plausible, or is Invention a Question of Faith instead of Fact?' (2023) 6 Stockholm Intellectual Property Review 47, 48.

72 See eg Rose Hughes, 'To encompass and embody: Applying the abstract principles of G 2/21' (*IPKat*, 2 May 2023) <https://ipkitten.blogspot.com/2023/05/to-encompass-and-embody-applying.html> accessed 15 December 2025; Rose Hughes, 'G 2/21: Is the technical effect embodied by the invention as originally disclosed?' (*IPKat*, 24 March 2023) <https://ipkitten.blogspot.com/2023/03/g-221-did-invention-as-originally.html?_sm_au_=iVVN0TtD00rjkVNQpGsWvKttvN1NG> accessed 15 December 2025.

73 T 0116/18 of 28 July 2023 – *Insecticide compositions/Sumitomo*.

74 ibid.

75 ibid.

76 ibid [11.10], [11.13].

77 ibid [11.1].

78 ibid.

The plausibility bar set for product claims under G 2/21 may facilitate speculative patents at the EPO. By not requiring any data, the applicants may be incentivised to claim first, invent later. In other words, applicants may seek to protect hypotheses that have yet to be tested, but that they believe will be of commercial value in the future. If need be, relevant evidence can be obtained and supplied later in the form of post-published evidence, whereby said evidence must only somehow be related to the patent application.[79] The patent then functions more as a 'hunting license' than a right protecting an invention as applicants may not be in possession of the invention at the time of filing.[80]

Equally, G 2/21 may make it easier for patentees to conceal important information in broad claims. For example, which compounds are the most effective and commercially important within a larger claimed family. This issue arose in the recent English case of *Sandoz v Bristol-Myers Squibb*, where generic companies challenged the product patent protecting Eliquis (apixaban), an Xa inhibitor. BMS first filed patent application WO 00/39131 (granted as EP1140941) in 1999, which disclosed a class of factor Xa inhibitors using general formulas.[81] Apixaban was embraced within several embodiments of WO 00/39131, but was not individually disclosed, nor was 'it obvious that apixaban would be likely to be efficacious as a factor Xa inhibitor'.[82] Then, in 2002, BMS filed another patent application (granted as EP1427415), which claimed a class of factor Xa inhibitors.[83] The application, as filed, claimed the compounds using several generic formulas. No claim was directed at apixaban specifically.[84] Though apixaban fell within the scope of embodiment 8 – 'a novel compound selected from a list of 74 compounds, one of which is apixaban' – no embodiment pointed to apixaban directly.[85] Nor did the application contain any data inferring apixaban was one of the compounds with useful results, which proved fatal to the patent and SPC in English court proceedings, as is discussed further below. With this patent strategy in mind, Sandoz and Teva notably claimed that:

> 'there was a practice among big innovators at around the priority date of deliberately leaving out data from patent applications filed for compounds per se in order to achieve broad protection without giving away their commercial intentions or technical information useful to their competitors. They said that either that practice had led to the omission from '652 of testing data about apixaban or the applicant had not done any such testing'.[86]

Strategically concealing such information may be in the interest of pharmaceutical companies. It may allow them to first obtain a patent protecting a broad family of substances based on a technical effect and then another patent protecting an individual substance within that family based on another technical effect. Double product patent protection may, however, not have been possible if more data were required to render product claims plausible. The data could have made the subsequent invention obvious. Afterall, how can the skilled person assess whether the unknown or surprising technical effect relied upon to acquire another product patent is justified without any data?[87]

Data are especially important in fields like pharmaceuticals, chemistry and biotechnology. All three are considered the 'unpredictable arts'.[88] In these cases, unpredictability can be beneficial. As patent attorney Tostman observes:

> 'whenever a hitherto unknown (i.e., novel) substance is synthesised, typically a non-predictable effect or use can be ascribed to this substance. Generally, in this case the assumption is made that finding this substance (and its use) was not obvious to the skilled person, and hence, the statutory requirement of inventive step is met'.[89]

Unpredictability should then also mean that more, not less, data are required to ensure the unpredictable is not in fact predictable and push more information into the public domain. Requiring evidence may deter patentees from concealing 'important technical information from a patent application in order to maintain confidentiality and, thus, maintain an advantage over competitors'.[90] Equally, a lack of 'supporting data or examples' and 'undue patent scope' may, Seymore states, 'have a chilling effect on other scientists who are trying to elucidate how to make and use the claimed invention while the inventor does not know how to do so'.[91]

On the other hand, data requirements which are too stringent may affect innovation. Applicants may, for instance, not have such data at the stage of filing patent applications, but are incentivised to file early due to the first-to-file system. Critics also argue the standard should be set at *ab initio* implausibility.[92] If the invention works and the inventor tells you how to make it, why should it be invalid? That should be sufficient.[93]

79 Lambert (n 71).

80 For a discussion on patents and hunting licenses, see Minssen and Nilsson (n 8).

81 Du Pont Pharmaceuticals Company filed WO 00/39131, but BMS later acquired this business, see *Sandoz v Bristol-Myers Squibb* (n 9).

82 ibid [66].

83 ibid [2], [67]-[76].

84 ibid [76].

85 ibid [69]. Apixaban was an example of 140 synthesised compounds.

86 *Sandoz Ltd & Ors v Bristol-Myers Squibb Holdings* [2022] EWHC 822 (Pat) [22].

87 An unknown technical effect is required of selection patents, see *Agrevo/Triazoles* (n 1) [2.5.3] ('the selection of such compounds, in order to be patentable, must not be arbitrary but must be justified by a hitherto unknown technical effect which is caused by those structural features which distinguish the claimed compounds from the numerous other compounds').

88 Karshtedt, Lemley and Seymore (n 34) 9; Holger Tostman, 'Protecting Chemistry Inventions: The Double-Edged Sword of Being an Unpredictable Art' (2015) 6 ACS Medicinal Chemistry Letters 364, 365.

89 ibid 364.

90 Slade (n 18) 197.

91 Sean B Seymore, 'Heightened Enablement in the Unpredictable Arts' (2008) 56 UCLA L. Rev. 127, 130-31.

92 See eg Jacob (n 3); see also discussion at Twenty-Seventh Annual Conference International Intellectual Property Law & Policy, Session 2C, Fordham University School of Law (2019) <https://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=1006&context=ipli_conf_27th_2019> accessed 17 October 2025.

93 ibid.

Adopting *ab initio* implausibility for product claims also brings the EPO's plausibility standard closer to the USPTO's approach under 35 U.S.C. § 112(a) for enablement and written description. Indeed, in the US, the specification must demonstrate possession and enablement at the effective filing date but the system allows for assertions or prophetic examples in unpredictable fields like pharmaceuticals. Credibility is presumed unless the examiner substantiates doubts, and post-filing affidavits or data are permitted to overcome rejections during prosecution. This harmonisation could facilitate transatlantic patent strategies, reducing discrepancies in evidentiary thresholds and encouraging global innovation by aligning with US flexibility for early-stage disclosures without mandating exhaustive upfront proof.

Ab initio implausibility may be particularly beneficial for small biotechnology companies with limited resources, as they often rely on securing patent rights early to attract essential investment and funding for their research and development efforts. A lower plausibility threshold shifts the evidentiary burden to opponents, who must substantiate doubts regarding the implausibility of the technical effect, rather than placing the onus on patentees to prove plausibility affirmatively from the application as filed, thereby making patent protection more accessible for novel inventions in fast-evolving fields. Furthermore, in unpredictable arts like biotechnology and pharmaceuticals, where comprehensive clinical trials or extensive experimental data are often infeasible pre-filing due to time, cost, and ethical constraints, *ab initio* implausibility accommodates the realities of scientific development by presuming credibility unless proven otherwise, allowing post-published evidence to confirm initial hypotheses. In a way, early patent grants function like mineral claims, staking out unexplored technological territories to attract investment, coordinating research efforts around the patent scope of protection, and avoiding wasteful duplication among competitors, with the overarching goal of ultimately fostering greater innovation and funding for R&D.[94]

The EPO grant patents with claims encompassing potentially significant numbers of chemical substances, often based on assertions of their biological or chemical activity, without requiring supporting experimental data at the time of filing. When granting such broad claims, it remains essential that the invention delivers the purported technical effect to justify the scope of protection, and that the skilled person can evaluate whether this effect extends across the entire claimed scope. Evidence is therefore key to this determination. Although the EPO permits the use of post-published data to support claims, views differ on whether this adequately addresses concerns about speculative filings. Mandating a minimum level of relevant data at the filing stage could help ensure that applicants substantiate their inventions upfront, a consideration that might warrant consistent application across all patent types.

2. Second medical use claims: sustaining a higher plausibility threshold

G 2/21 clearly distinguishes between product claims and second medical use claims, whereby the plausibility bar is set higher for the latter. The EBA notably states that:

> 'because the subject-matter of second medical use claims is commonly limited to a known therapeutic agent for use in a new therapeutic application, it is necessary that the patent at the date of its filing renders it credible that the known therapeutic agent, i.e. the product, is suitable for the claimed therapeutic application'.[95]

The EBA's reasoning is thus based on the fact that second medical use claims concern known compounds, meaning something more is required for these types of claims.

Indeed, merely asserting that compound X can be used to treat disease Y is not sufficient to satisfy the requirement, but patentees need not adduce absolute proof of a substance's suitability, such as clinical trial results.[96] They also do not have to present human or animal test results. Unless there are no substantiated doubts about the invention's suitability to solve the formulated problem,[97] what is required is certain information, such as experimental tests, to underpin that:

> 'the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se. Showing a pharmaceutical effect *in vitro* may be sufficient if for the skilled person this observed effect directly and unambiguously reflects such a therapeutic application … or … if there is a "clear and accepted established relationship" between the shown physiological activities and the disease'.[98]

The submitted evidence and/or common general knowledge must thus show a link between the substance and its suitability for the claimed use to render it 'technically plausible for the skilled person that the claimed compounds can be applied for the claimed therapeutic use'.[99]

This link may, for example, be shown using experimental data, including *in vitro* tests (tests on cells, biological molecules and the like in a test tube), provided the patent evinces that the *in vitro* effect is relevant to the medical use, unless the skilled person knows this from the prior art.[100] That is not to say that any *in vitro* test will do. The TBA stated in T 1685/10: 'the conditions of the test must be carefully selected and should correspond as closely as possible to the *in-vivo* conditions', when it found that the *in vitro* test relied upon to demonstrate that RAS-inhibitors were effective in treating or preventing

94 For a discussion on patents function as such, see Edmund W Kitch, 'The Nature and Function of the Patent System' (1977) 20 Journal of Law and Economics 265.

95 G 2/21 (n 12) [74].

96 *Salk* (n 36) [9].

97 *Pancreatic cells/IPSEN* (n 47) [15]; See also T 1437/07 of 26 October 2009 – *Botulinum toxin for treating smooth muscle spasm/ALLERGAN*.

98 *Salk* (n 36) [9].

99 T 1599/06 of 13 September 2007, [6] – *Mycobacterium vaccinating agent/UNIVERSITY OF CALIFORNIA*.

100 *Salk* (n 36) [9]-[10]; T 1685/10 of 6 June 2011, [3.6]-[3.8] – *RAS-inhibitors/ARK THERAPEUTICS LTD., ET AL*.

stroke was inadequate.[101] This was due to the patentee using an inappropriate RAS-inhibitor, as well as heart muscle cells, not cells affected by a stroke, for testing. Another way of supporting a use claim is to supply data from pre-clinical animal models. Such tests are usually done *in vivo* with live animals, which are given the substance and then studied. As with *in vitro* tests, when using data from animal models, the model must be appropriate for the disease in question. In short, whatever test is used, it must be suitable. That is not much to ask for. It should be the expectation.

Setting a higher plausibility bar for second medical use claims is, on the one hand, understandable. These patents are directed at the *use* of a compound. This is important not only because the claimed therapeutic effect constitutes a functional feature of the claim,[102] but because novelty stems from the new use as the compound is known. It is only fair that such new use is supported with evidence. Without evidence, patentees could acquire protection for 'known compounds for the purpose of treating every conceivably relevant condition without having invented anything at all, in the hope that trial and error might in due course show that the product was efficacious in treating at least some of them'.[103]

Imposing a more stringent test for second medical use claims, i.e. claims with a narrower scope of protection is, on the other hand, questionable. The result is that, for product patents, patentees can acquire more protection with less disclosure. This may, as discussed above, facilitate speculative product claims and significantly impact innovation and competition. Indeed, it may enable applicants to protect compounds protecting every conceivable use without having invented anything. This then begs the question of why this is less of a valid concern for product patents than second medical use patents. Adopting a similar plausibility standard, with different data requirements, would perhaps strike a fairer balance between protection and disclosure for all types of claims. This is notably the approach taken by English courts, as will be discussed below.

3. National divergence in practice: The apixaban litigation saga

Just before the EBA handed down its judgment in G 2/21, several generic companies sought to clear the way for market entry and initiated legal proceedings to invalidate the Supplementary Protection Certificate ('SPC') protecting Bristol-Myers Squibb's ('BMS') drug Eliquis (apixaban). Eliquis (apixaban) treats thromboembolic disorders. It entered the market after receiving a market authorisation in May 2011. Since then, Eliquis has become a blockbuster drug, with sales totalling $20.7 billion in 2024.[104] Unsurprisingly, BMS protected Eliquis with several patents, including a product patent, multiple secondary patents,[105] and an SPC that expires in May 2026.[106] The SPC is based on EP1427415, which expired in September 2022. EP1427415 was a selection patent and protected several compounds, including apixaban, which are improved factor Xa inhibitors (the originator patent disclosed factor Xa inhibitors).[107] However, the patent application for EP1427415 only contained assertions as to the compound's technical effect. It did not explicitly state the improved technical effect, nor disclose direct data for apixaban or, indeed, any compound.[108] Keen to launch generic versions of apixaban, Sandoz and Teva challenged the validity of EP1427415 on the grounds that the application, as filed, did not render the invention plausible.[109] As G 2/21 was decided in March 2023, during these proceedings, the apixaban case presented several national courts around Europe with their first opportunity to interpret and apply G 2/21.

In the English case of *Sandoz v. Bristol-Myers Squibb*, Arnold LJ (with whom Nugee LJ and Warby LJ agreed) upheld Meade J's decision,[110] which found that EP1427415 and its corresponding SPC were invalid for lack of plausibility.[111] As above, EP1427415 merely contained assertions relating to technical effect, not directly relevant data. BMS argued such assertions are sufficient for claims to chemical compounds, provided said assertion 'is not manifestly speculative or wrong'.[112] Arnold LJ disagreed. Encouraging the skilled person to conduct the 'simple tests identified in the specification to confirm the efficacy of the claimed product even if carrying out such tests would indeed show that the product is likely to be efficacious' is not sufficient.[113] Although Arnold LJ considered G 2/21, he did not discuss G 2/21 extensively. Rather, he found that the court should apply the plausibility test laid down by the majority in the infamous *Warner Lambert* case, where said majority set the bar at *ab initio* plausibility.[114] BMS appealed the decision to the Supreme Court, which refused to hear the case, finding the appeal failed to raise an arguable point of law, thus rendering the revocation final.[115]

The Dublin High Court similarly found that EP14 27415 was invalid for implausibility.[116] When assessing

101 ibid [3.6].

102 ibid [9].

103 *Warner-Lambert* (n 4) [20] (Lord Sumption).

104 Brian Buntz, '2024's blockbusters: Top 50 drugs by sales' (*Drug Discover & Development*, 4 April 2025) <https://www.drugdiscoverytrends.com/2024s-blockbusters-top-50-pharmaceuticals-by-sales/> accessed 15 December 2025.

105 This includes four formulation patents which were subsequently invalidated in England, see *Sandoz Ltd & Ors v Bristol-Myers Squibb Holdings Ireland Unlimited Company* [2022] EWHC 1831 (Pat).

106 For facts, see *Sandoz v Bristol-Myers Squibb* (n 9).

107 For the patent see <https://patentimages.storage.googleapis.com/8a/0f/2b/1f2922b434af7d/EP1427415B1.pdf> accessed 15 December 2025.

108 As noted in *Sandoz Ltd v Bristol-Myers Squibb* [2022] EWHC 822 (Pat).

109 Note that in certain jurisdictions the generic companies also challenged EP1427415 on other grounds, including BMS' right to priority.

110 *Sandoz v Bristol-Myers Squibb* (n 108).

111 *Sandoz v Bristol-Myers Squibb* (n 9).

112 ibid [89].

113 ibid [95].

114 ibid [94]; *Warner-Lambert* (n 4); For a discussion see Edward Cronan, 'Plausibility after Warner-Lambert v Actavis: Fantastic Legal Tests and Where to Find Them' (2019) 14 JIPLP 552.

115 See UK Supreme Court, 'Permission to Appeal - September 2023' <https://supremecourt.uk/news/permission-to-appeal-september-2023> accessed 15 December 2025.

116 *Bristol-Myers Squibb Holdings Ireland UnLtd Company v Norton [Waterford] Ltd trading as Teva Pharmaceuticals Ireland* [2023] IEHC 744.

plausibility, Barrett J did not apply the test laid down by G 2/21. Rather, he applied the test laid down in the Irish decision *Boehringer*, which requires that 'in light of the teaching in the specification and the common general knowledge' there must be a real reason for supposing that the claimed invention will indeed have the promised technical effect'.[117] This is, however, understandable since BMS merely argued that the two tests were different. It did not argue that G 2/21's test should be applied at first instance. As with English courts, Barrett J found, *inter alia*, that the lack of any biological data relating to apixaban proved fatal to EP1427415.[118] BMS appealed and applied for an interim injunction. While the High Court refused BMS's application for injunctive relief, the Irish Court of Appeal later granted an interim injunction in June 2024, forcing Teva's generic off the market until the appeal on the merits was decided.[119] In November 2024, the Court of Appeal allowed BMS's appeal and remitted the case back to the High Court to be heard by another judge.[120] The Court of Appeal found that Barrett J either failed in making findings of fact or explaining the reasons behind his findings.[121] He also did not apply the correct test for plausibility. Indeed, the court ascertained that the correct test is the one laid down by G 2/21. The court also observed that the High Court judge did not give sufficient weight to other national decisions concerning EP1427415; instead, Barrett J appeared to rely too heavily on English judgments, where the adduced evidence notably differed from that presented to the Irish courts.[122] The outcome of the re-trial has yet to be published.

As the Irish Court of Appeal observed, national courts around Europe have taken a different approach as compared to English courts. Agreeing with a first instance decision, the Borgarting Court of Appeal in Norway upheld EP1427415 on 3 June 2024.[123] BMS notably argued G 2/21 lowered bar. The court disagreed. G 2/21 did not, it found, change how plausibility is assessed. Whether the relevant technical effect may be taken into account when assessing inventive step depends on whether the skilled person considers that the application, as filed, renders the technical effect plausible, as was the case pre-G 2/21, affirmed the court. Despite the lack of test data at the date of filing, the court held that the skilled person would find it credible and likely that apixaban was an effective factor Xa inhibitor based on common general knowledge and the application itself. Post-published data further confirmed that the patent had an inventive step, as observed the court. In Sweden, the Svea Court of Appeal likewise agreed with a first instance decision and upheld EP1427415.[124] As in the Norwegian case, Teva claimed, *inter alia*, that the technical effect was not plausible at the filing date and should not form part of the inventive step analysis, and that it was not plausible that the relevant compounds were effective factor Xa inhibitors. This was to no avail. The court upheld the first instance decision in full. The Danish Maritime and Commercial Court similarly ruled that EP1427415 was likely valid and infringed, and granted an interim injunction against Teva.[125] Applying G 2/21, the Danish court found that apixaban and its improved factor Xa inhibition was encompassed by the patent application's technical teaching and embodied by the invention, as disclosed at the filing date. It thus allowed BMS to rely on post-published data demonstrating apixaban's efficacy.

Although the Commercial Court No. 4 of Barcelona (a first instance court) found the patent invalid due to a lack of inventive step and insufficient disclosure, the Barcelona Court of Appeal reversed this judgment. The Court of Appeal clarified the EBA jurisprudence on plausibility (G 2/21) and noted that in order to determine that plausibility is not met, it is necessary to establish that there were reasons to doubt that the intended technical effect in conjunction with the claimed subject matter (i.e. apixaban and its capacity to inhibit factor Xa) does not constitute a concrete realisation of the invention as originally disclosed. On 24 April 2025, the Spanish Supreme Court upheld the appeal judgment in full and added that the 'decision G 2/21 is understood to be better aligned with the *ab initio* implausibility'.[126]

A Dutch first instance court initially refused BMS' application for an interim injunction against Sandoz in May 2022, finding that EP1427415 lacked an inventive step as it did not explicitly disclose an improved technical effect compared to the prior art.[127] After G 2/21 was decided, BMS returned to court, again requesting an interim injunction against several generic companies, which was initially refused, but later granted by the Court of Appeal.[128] The Dutch Court of Appeal found that there was a serious issue to be tried as EP1427415 and its SPC were likely valid. After the generic companies appealed the decision,[129] the District Court of the Hague proceeded with a trial on the merits, whereby the court reaffirmed that the SPC was valid.[130] The court found that the skilled person would find that

117 *Norton (Waterford) Limited t/a Teva Pharmaceuticals Ireland v Boehringer Ingelheim Pharma GmbH & Co. KG* [2022] IECA 58 [174]-[179], as quoted in ibid [824]-[825].

118 ibid [1153] ('In the absence of any theory based on e.g. its structure or any data in the specification, there is simply nothing in the application to support the assertion that apixaban is a factor Xa inhibitor, let alone a factor Xa inhibitor of sufficient potency to be useful in therapy').

119 *Bristol-Myers Squibb Holdings Ireland Company v Norton (Waterford) Ltd Trading as TEVA* [2024] IECA 143.

120 *Norton (Waterford) Ltd v Bristol-Myers Squibb Holdings Ireland UnLtd Company (Approved)* [2024] IECA 287.

121 ibid [2].

122 ibid [95]-[109].

123 Borgarting Court of Appeal (Norway), LB-2023-141798 – *Teva Pharmaceutical Industries Ltd. v Bristol-Myers Squibb Holdings Ireland Unlimited Company*; the Norwegian Supreme Court also refused to hear the appeal, rendering the Court of Appeal's judgment final.

124 Svea Court of Appeal (Sweden), PMT 14326-22 – *Teva Sweden v Bristol-Myers Squibb Holdings Ireland Unlimited Company*.

125 Maritime and Commercial Court (Denmark), BS-23475/2025-SHR – *Bristol-Myers Squibb Holdings Ireland Unlimited Company v Teva Denmark A/S*.

126 Supreme Court (Spain), Case No 7920/2024 – *Teva Pharma S.L.U. v Bristol Myers Squibb Holdings*.

127 Rechtbank Den Haag (Netherlands) – *Bristol-Myers Squibb Holdings Ireland Unlimited Comp v Sandoz B.V.* NL:RBDHA:2022:4385.

128 Gerechtshof Den Haag (Netherlands) – *Sandoz B.V v Bristol-Meyers Squibb Holdings Ireland Limited Company* NL:GHDHA:2023:1593.

129 Konstanze Richter, 'BMS scores another win against Sandoz and Teva over apixaban in Den Haag' (*JUVE Patent*, 6 November 2024) <https://www.juve-patent.com/cases/bms-win-against-sandoz-over-apixaban-eliquis/> accessed 22 October 2025.

130 Rechtbank Den Haag (Netherlands) – *Bristol-Myers Squibb Holdings Ireland Unltd. Comp v Sandoz B.V* NL:RBDHA:2024:17666.

improved factor Xa inhibition – the asserted technical effect – was encompassed and embodied by the application, as filed, and that the exemplified compounds show how the problem has been solved. Unlike Arnold LJ, the court also found that it was safe to assume that skilled person could synthesise and test the compounds for their ability to inhibit factor Xa. Satisfying the G 2/21 test, BMS could also, the court found, rely on post-published data showing that apixaban constituted an improved factor Xa inhibitor compared to compounds known from the prior art.[131]

The Swiss Federal Patent Court similarly upheld the validity of BMS's SPC.[132] Based on G 2/21, the court found that the asserted technical effect must not be explicitly stated in the patent application, nor must it be supported by experimental data. The technical effect must merely be encompassed by the teaching and embodied by the original invention. As the purpose of this test is to prevent abusive speculative claims, the bar should not, as the court affirmed, be set too high.[133] Doing so would prevent worthy inventions from receiving patent protection.[134] The court deemed these two criteria to be met and allowed BMS to rely on post-published data supporting that apixaban was an improved factor Xa inhibitor.

With the exception of the English courts and a few first instance decisions, which were later overturned, the national courts upheld the validity of BMS' SPC despite the patent application, as filed, not containing any test data, nor an explicit mention of the asserted technical effect. By so doing, the national courts strictly follow G 2/21 and push the plausibility bar towards *ab initio* implausibility for product patents. Only the English courts require *ab initio* plausibility for product and second medial use patents alike, thus differing from G 2/21.[135]

IV. Conclusion

G 2/21 represents a pivotal, albeit imperfect, milestone in the evolving jurisprudence on plausibility within European patent law. Key insights from this analysis underscore that G 2/21 effectively tilts the evidentiary balance towards *ab initio* implausibility for product claims, presuming the technical effect plausible unless substantiated doubts arise, thereby permitting greater reliance on post-published evidence. This approach acknowledges the realities of early-stage innovation in fields like pharmaceuticals, where data may be nascent at filing, potentially fostering inventive activity by reducing upfront evidentiary burdens. However, it raises legitimate concerns about enabling speculative or overly broad claims, which could undermine the patent bargain by granting patents with a scope of protection disproportionate to the actual technical contribution at the filing date.

In contrast, the EBA's reaffirmation of a higher threshold for second medical use claims in the context of sufficiency of disclosure – requiring evidence of suitability from the application as filed – serves as a safeguard against 'shotgun' patenting, ensuring that functional features tied to therapeutic novelty are not asserted without substantiation. This bifurcation aligns with the distinct policy imperatives of each claim type: encouraging broad protection for novel compounds while preventing undue extensions of exclusivity for second medical uses of already known substances. Yet, as illustrated by the *Apixaban* litigation, G 2/21 has not fully harmonised practice across Europe. National courts have interpreted the decision variably, with England adhering to a stricter *ab initio* plausibility standard leading to revocation, while courts in Norway, Sweden, Denmark, Spain, the Netherlands and Switzerland have upheld validity, often emphasising the absence of mandatory experimental data and the contextual role of the skilled person's perspective. Such divergences highlight persistent legal uncertainty, potentially exacerbating forum shopping and inconsistent outcomes in European disputes at the national level.

Looking forward, while G 2/21 attempts to clarify plausibility within European patent law, its abstract and open-ended criteria risk perpetuating rather than resolving legal uncertainty, particularly in failing to offer granular guidance on evidentiary standards – such as the type of data required for different claim types or the precise boundaries of 'encompassed' technical effects. This vagueness not only invites inconsistent application but may inadvertently encourage speculative filings, especially for product claims where the low plausibility bar could tilt the balance toward overly broad protections at the expense of genuine innovation. This leaves substantial room for further refinement by future Boards and courts, including the Unified Patent Court, which may play a unifying role if it can bridge the gaps left by the EBA. Ultimately, a balanced patent regime must weigh the incentives for early-stage innovation against the risks of over-protection, ensuring that patentability standards preserve the delicate equilibrium between private IP rights and public access to technological progress.

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131 For a discussion of the Dutch decisions, see Eveline Lots, 'Dutch District Court upholds BMS's apixaban patent' (*Kluwer Patent Blog*, 24 December 2024) <https://legalblogs.wolterskluwer.com/patent-blog/dutch-district-court-upholds-bmss-apixaban-patent/> accessed 6 December 2025.

132 Swiss Federal Patent Court, 5 March 2024, O2022_007 – *Mepha Pharma AG v Bristol-Myers Squibb Holdings Ireland Unlimited Company*; this ruling was appealed, but the appeal only concerned priority.

133 ibid [39].

134 ibid.

135 The Court of Appeal recently discussed G 2/21 again and followed the approach it took in *BMS v Sandoz*, see *Generics v AstraZeneca* (n 9).