# Plausibility and the flotilla: have the English courts drifted from the commodore's approach to the evidential requirement for patent validity, and if so, is this divergence justified?

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**Summary**

"Plausibility" refers to an evidential requirement that asks whether the patent's specification demonstrates that the claimed invention's purported technical contribution is achievable. While both the terminology and the evidential requirement that plausibility represents may have their critics, a plausibility assessment has become an entrenched concept in analysing patent validity at the EPO and English courts. This essay identifies a divergence between the two decision-making bodies in their approach to plausibility's evidential standard.

The English courts have settled on the higher "positive obligation standard"[1] rather than the EPO's lower "substantiated doubt standard"[2]. The English courts adopting the higher standard lacks cogent justification as the standard neither reflects a balance between the competing objectives of the patent system nor limits a plausibility assessment to its targeted mischief. Instead, the flexibility inherent in the substantiated doubt standard should be preferred.

Absent legislative reform to clarify the status of plausibility, and with the emergence of technology that entails inventing without the need for classical experimenting, the frequency of cases involving a plausibility assessment is only likely to increase. With at least one forthcoming UK Supreme Court hearing that will again navigate plausibility's waters, it is hoped that plausibility's evidential standard will be brought in line with one that is balanced and proportionate.

**Introduction**

> "The term 'plausibility'…does not amount to a distinctive legal concept or a specific patent law requirement under the EPC...It rather describes a generic catchword seized in the jurisprudence of the boards of appeal, by some national courts and by users of the European patent system".[3]

What "plausibility" represents at its most basic level is an evidential requirement that asks whether the patent's specification demonstrates that the claimed invention's purported technical contribution[4] is achievable.[5] The evidential requirement applies even if the invention can be shown to work after the patent's filing date. It is trite to say that the requirement is not a ground for patent invalidity separate from the statutory criteria found in the Convention on

[1] The patentee is always obliged to provide evidence in their application to support their assertions about the claimed invention's purported technical contribution.
[2] The patentee is only obliged to provide evidence in their application to support their assertions about the claimed invention's purported technical contribution if there would be substantiated doubt about the patentee's assertions.
[3] G02/21 *SUMITOMO/Insecticide compositions* (unreported, 23 March 2023), [92].
[4] I.e., what the claimed invention adds to the state of the art. This is often framed as a technical effect, such as treating a particular disease.
[5] Alison Slade, 'Plausibility: A conditio sine qua non of Patent Law?' (2020) 3 IPQ 180, 180.

the Grant of European Patents[6] (EPC) and the United Kingdom's (UK) legislation implementing the EPC—the Patents Act 1977 (PA 1977).

Despite the above-quoted admonishment of the term by the European Patent Office's (EPO) Enlarged Board of Appeal (EBA), "plausibility" (or at least the requirement that the term represents) has been seen as a useful tool by both the EPO and the courts of England and Wales (English courts) in tackling speculative patenting (applications based on mere assertions about an invention's efficacy)[7] and overly broad claims.[8] It has been described as a "court-invented"[9] concept designed to address gaps in the statutory validity criteria found in the EPC.[10] As Floyd LJ explains, the aim is to prevent so-called "armchair inventors" (the notional individual who patents mere ideas) because such inventors have not contributed to the stock of technical knowledge through the patent specification in a way that justifies legal protection.[11] The plausibility requirement is classically justified under the "patent bargain" – i.e., disclosure is the price a patentee pays for their patent monopoly.[12] The courts have equated the absence of any evidence that an idea in a patent will work to "the absence of a description",[13] thus forming the foundation for the enforcement of plausibility in patent law under the EPC.

Plausibility issues most often (though not exclusively)[14] arise in the context of pharmaceutical or biotechnology (collectively, life science) patents. In the field of life sciences, proving the effectiveness of drugs requires rigorous clinical trials.[15] However, if patent protection could only be obtained after the completion of these trials, many drugs would be left unprotected as their existence and potential use would have already been disclosed.[16] To strike a balance, patent protection can be obtained by demonstrating plausibility of the drug's effect.[17] However, what standard of proof (i.e., evidential standard) strikes the right balance between protecting (and promoting) innovation in this sector and ensuring adequate disclosure to satisfy the patent bargain? This question has been the subject of considerable debate, resulting in plausibility reaching the UK Supreme Court twice and a recent EBA decision. Issues concerning the appropriate evidential standard will only become more frequent with the increasing use of computational biology to identify novel gene and protein sequences for

[6] of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.
[7] *Actavis v Eli Lilly* [2015] EWHC 3294 (Pat), [2016] RPC 12, [177].
[8] Richard Arnold, 'IP in the English Court System' in Hayleigh Bosher and Eleonora Rosati, *Developments and Directions in Intellectual Property Law: 20 Years of The IPKat* (OUP 2023), 20.
[9] *Warner-Lambert v Generics (UK) t/a Mylan* [2018] UKSC 56, [2018] RPC 21, [192].
[10] Paul England, *A Practitioner's Guide to European Patent Law* (2/e, Hart 2022), 383-384.
[11] *Warner-Lambert v Generics (UK) t/a Mylan* [2016] EWCA Civ 1006, [2017] RPC 1, [46].
[12] Matthew Fisher, 'Extracting the Price of a Patent: Enablement and Written Description' (2012) IPQ 262, 287-288.
[13] *Prendergast's Application* [2000] RPC 446 (Pat), 448.
[14] For example*, Optis Cellular Technology v Apple Retail UK* [2020] EWHC 2746 (Pat).
[15] England (n 10), 383; Slade (n 5), 196; Patrick Kelleher, *Life Sciences and Intellectual Property* (Thomson Reuters 2020), [7.234].
[16] ibid.
[17] *Warner-Lambert* (n 9), [29]; T609/02 *SALK INSTITUTE/AP-1 complex* (unreported, 27 October 2004), [9].

therapeutic use (referred to as bioinformatics).[18] Inherent in identifying drugs in this way is the absence of initial therapeutic efficacy data that may otherwise have been available had the drugs been identified through traditional "wet lab" methods.[19] A further compounding factor that will also likely bring plausibility to the fore with increasing frequency is the emerging use of generative artificial intelligence to identify novel drugs.[20] Therefore, courts must have a clear and consistent approach to assessing plausibility, with an evidential standard that best reflects a balance between the competing objectives of the patent system.

Plausibility was conceived through the EPO's interpretation of EPC provisions and imported into the UK under the English courts' obligation to "have regard to the decisions of the [EPO] on the construction of the EPC".[21] Member States of the EPC have been likened to a flotilla of ships with the EPO, the commodore, attempting to lead the ships to sail in the same direction.[22] However, whether the English courts are sailing in the same direction as the EPO in their respective approaches to applying plausibility is questionable. While EPO decisions are not binding on English courts, they are of great persuasive authority.[23] Therefore, any drift from the EPO's approach to plausibility should be predicated on cogent reasons.

In Part 1, this essay will examine the EPO and English courts' approaches to plausibility, identifying the divergence in the applicable evidential standard. Part 2 assesses whether the English courts are justified in applying a higher evidential standard than the EPO when assessing plausibility and whether this high standard is a proportionate response to the mischief plausibility aims to resolve. With at least one forthcoming Supreme Court hearing that will again grapple with plausibility,[24] it is to be hoped that the English courts will be steered to sail towards waters that best reflect a balance between the competing objectives of the patent system.

## Part 1: Approaches to plausibility at the EPO and the English courts.

### A. From herbicides to insecticides: the EPO sets sail.

Plausibility's story starts in 1995 with T939/92 *AGREVO/Triazole herbicides*.[25] The decision concerned a broad chemical compound claim, with the description asserting that the compounds were to be used as herbicides. The Technical Board of Appeal (TBA) held that for compounds *per se* to possess an inventive step, the claim "must not be arbitrary but must be

[18] *Eli Lilly v Human Genome Sciences (HGS)* [2008] EWHC 1903 (Pat), [2008] RPC 29, [5]-[6].
[19] ibid.
[20] International Association for the Protection of Intellectual Property (AIPPI), 'Plausibility 2019 Study Question Resolution' (18 September 2019), [2]. For example, Gopal Ratnam, 'Congress ponders whether AI should have the power of the patent' (Roll Call, 13 June 2023) <https://rollcall.com/2023/06/13/congress-ponders-whether-ai-should-have-the-power-of-the-patent/>.
[21] *Merrell Dow Pharmaceuticals v HN Norton* [1995] UKHL 14, [1996] RPC 76, [12].
[22] *Eli Lilly v HGS* [2010] EWCA Civ 33, [2010] RPC 14, [39].
[23] *Merrell Dow* (n 21), [12].
[24] On appeal from *FibroGen v Akebia Therapeutics* [2021] EWCA Civ 1279, [2022] RPC 7.
[25] [1996] EPOR 171.

justified by a hitherto unknown technical effect which is caused by those structural features which distinguish the claimed compounds from the numerous other compounds".[26] This reasoning was premised on the legal principle that "the extent of the patent monopoly should correspond to and be justified by the *technical contribution* to the art".[27] Accordingly, the patentee had to rely on the purported use of the compounds as herbicides. This use as herbicides, the TBA found, had not been made "credible" by evidence in the patent application.[28] Therefore, without a credible technical contribution, a technical problem had not been solved for the EPO's problem/solution approach to assessing inventive step.[29] Consequently, the patent was held invalid for obviousness.

*AGREVO*'s reasoning has permeated subsequent EPO decisions, requiring a patent to contain "plausible" evidence of an invention's purported technical contribution under an inventive step,[30] sufficiency,[31] or industrial applicability[32] analysis—the common denominator being that all of those statutory validity criteria "reflect the basic principle of the patent system that exclusive rights can only be granted in exchange for a full disclosure of the invention".[33] However, despite the EPO recognising the requirement for full disclosure as the basis for a plausibility assessment, other than for the three aforementioned validity criteria, the Boards have consistently refused to extend plausibility to other validity grounds that also rely on analysing the adequacy of disclosure.[34] No principled reason appears to have been provided for this refusal.[35]

What has lacked consistency is the evidential *standard* the EPO applies for plausibility. Put simply, after a patent application has been filed, if the claimed invention is subsequently factually demonstrated to have the technical effect asserted in the application, can the patentee only rely on this fact if they actively provided in the application plausible evidence to support the assertion?[36] Alternatively, would it suffice that a reader of the patent would have no substantiated doubts that the assertion was true?[37] Two alternative evidential standards arise—(i) a "positive obligation" standard, where the patentee is always obligated

[26] ibid, [2.5.3].
[27] ibid, [2.4.2] (emphasis added).
[28] ibid, [2.6], [2.7].
[29] ibid.
[30] T1329/04 *JOHN HOPKINS/Factor-9* [2006] EPOR 8, [11]-[12].
[31] *SALK* (n 17), [8], [10].
[32] T898/05 *ZYMOGENETICS/ Hematopoietic cytokine receptor* [2007] EPOR 2, [5], [27].
[33] ibid, [6].
[34] T903/05 *GEMVAX/Telomerase peptides* (unreported, 30 August 2007), [11], [12]; T824/06 *STORK PMT/Method and device for preserving the meat of a slaughtered bird* (unreported, 9 December 2008), [3.5].
[35] There does not appear to be a literal or conceptually un-problematic way to incorporate the plausibility assessment into the existing statutory framework. For critique of plausibility's legislative legitimacy, see Robin Jacob, 'Plausibility and Policy' (2020) 17(6) BSLR 223. If plausibility is to be viewed as an aspect of disclosure (to legitimise plausibility's inclusion in the patent system), there appears to be no cogent rationale for the EPO refusing to apply a plausibility assessment under other statutory validity criteria that also involve an analysis of disclosure. Nor is there any cogent rationale for the EPO apparently applying differing plausibility evidential standards between sufficiency and inventive step (see *SUMITOMO* (n 3), [77]).
[36] For example, *SALK* (n 17), [9]; T1791/11 *NOVOZYMES/Subtilase variants* (unreported, 7 April 2016), [3.2.5]-[3.2.7].
[37] For example, T1797/09 *UNILEVER/Dish-wash composition* (unreported, 8 February 2012), [2.7]; T2340/12 *LEE/Space energy implosion unit* (unreported, 15 March 2018), [3.5].

to provide evidence in their application to support their assertions and (ii) a "substantiated doubt" standard, where an obligation only arises if there would be substantiated doubt about the patentee's assertions. This question was the subject of a recent referral to the EBA in the context of insecticide compositions and inventive step.[38] The TBA referred to the two standards as "*ab initio* plausibility" and "*ab initio* implausibility", but this essay refers to them as the positive obligation standard and the substantiated doubt standard, as these terms are more descriptive of how the standards operate in evidential terms. In addition to the two above-mentioned standards, the TBA also provided a third option in the referral—"no plausibility".[39]

The EBA's decision was unsatisfactory in clarifying the applicable standard. The Board concluded that an invention's technical effect could be relied on if, using the common general knowledge and filed patent application, the skilled addressee "would derive said effect as being encompassed by the technical teaching and embodied by the same originally disclosed invention".[40] While stating this test should suffice for decision-making bodies to adjudicate such matters,[41] it appears that the decision does nothing to clarify how the test should operate. What is meant by "derive said effect" and "technical teaching"? The original question persists—is the patentee always under a positive obligation to provide evidence in the application, or does such an obligation only arise if there would be substantiated doubt about the asserted technical effect? This ambiguity is confirmed by the fact that different entities interpreting *SUMITOMO* have arrived at different conclusions on the applicable standard, stating that the EBA is describing the higher (positive obligation),[42] lower (substantiated doubt),[43] or no plausibility requirement[44]. This essay takes the view that *SUMITOMO* likely ascribes the lower standard for the following five reasons.

Firstly, subsequent TBA decisions have interpreted *SUMITOMO* as ascribing the substantiated doubt standard,[45] as have some national courts.[46] Secondly, other than in a single English decision (albeit by an esteemed IP judge sitting in the Court of Appeal),[47] there does not appear to be any other global commentary that has interpreted the EBA's decision as endorsing a positive obligation standard. Thirdly, an EBA communique (non-binding) preceding oral proceedings appeared willing to respond positively to the substantiated doubt

[38] T116/18 *SUMITOMO/Insecticide compositions* (unreported, 11 October 2021).
[39] ibid, [13.6].
[40] *SUMITOMO* (n 3), [93]-[94].
[41] ibid, [95].
[42] *Sandoz and Teva v Bristol-Myers Squibb (BMS)* [2023] EWCA Civ 472, [94].
[43] For example, 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>.
[44] For example, Cyra Nargolwalla, 'Plausibility Doctrine Found Implausible' (AIPPI, 12 May 2023) <https://www.aippi.org/news/plausibility-doctrine-found-implausible/>.
[45] For example, the subsequent decision of the referring Board: T116/18 *SUMITOMO/Insecticide compositions* (unreported, 28 July 2023), [12], [17.4.4], and [17.5].
[46] For example, The Hague Court of Appeal, *Sandoz et al v BMS* (15 August 2023, Case numbers: 200.327.532/01 and 200.328.173/01), [6.32].
[47] *Sandoz* (EWCA) (n 42), [94].

standard.[48] Nothing in the decision directly opposes this view. Fourthly, the EBA observed that the evidential requirement it ascribes would not change the outcome in all the conflicting cases that the TBA cited in its referral.[49] If the EBA's ascribed test can truly achieve this, it can only be because it utilises the substantiated doubt standard, as that is the only one of the two standards that can operate with flexibility. Fifthly, principled reasons point to the lower standard. The fourth and fifth points are discussed in further detail in Part 2 of this essay.

In summary, while there may be some ambiguity about the applicable evidential standard, the EBA in *SUMITOMO* has likely selected the substantiated doubt standard.

**B. Adoption and divergence: the English courts drift.**

Plausibility was imported into the UK from the EPO under the English courts' obligation under section 130(7) PA 1977.[50] Like the EPO, the English courts have justified using a plausibility assessment on the need for full disclosure.[51] However, the English courts' approach to plausibility's evidential standard appears to have diverged from the EPO.

Plausibility has made it to the UK Supreme Court on two occasions.[52] In *Human Genome Sciences (HGS)*, plausibility was assessed in the context of a gene sequence claim and industrial applicability.[53] The Court held that to satisfy a plausibility assessment in this context, a "'reasonably credible' claimed use, or an 'educated guess', can suffice".[54] Given this terminology, this essay views *HGS* as a UK authority for the substantiated doubt standard, particularly given that the Court applied *ZYMOGENETICS* in making the quoted statement. *ZYMOGENETICS* is unambiguously an authority for the substantiated doubt standard.[55] However, a subsequent Supreme Court decision appears to have raised the evidential standard in UK patent law. In *Warner-Lambert*, a case concerning the plausibility of a second-use claim in the context of sufficiency, the majority, without distinguishing, departing from, or even considering *HGS*, alighted on the positive obligation standard, requiring evidence to be explicitly provided in the specification, either in the form of experimental data or "*a priori* reasoning" in support of the claimed therapeutic effect.[56] In contrast, the minority (Lords Hodge and Mance) considered the positive obligation standard too high a burden on the patentee and instead favoured the substantiated doubt standard, disagreeing with the majority's interpretation of the relevant EPO case law.[57]

[48] EPO, 'Communication from the Enlarged Board of Appeal pursuant to Articles 13 and 14(2) of the Rules of Procedure of the Enlarged Board of Appeal' (13 October 2022), [16].
[49] *SUMITOMO* (n 3), [72].
[50] Slade (n 5), 190.
[51] *Warner-Lambert* (n 9), [17].
[52] ibid; *HGS v Eli Lilly* [2011] UKSC 51, [2012] RPC 6.
[53] *HGS* (n 52), [1].
[54] ibid, [107].
[55] *ZYMOGENETICS* (n 32), [27].
[56] *Warner-Lambert* (n 9), [37].
[57] ibid, [181], [195].

Given that the Supreme Court has observed that the "principal conditions of validity, novelty, inventive step, industrial application and sufficiency are all, in one way or another, directed to satisfying the [patent bargain]",[58] it is difficult to reconcile the differing evidential standards for plausibility in *HGS* and *Warner-Lambert*. Considering that both the *Warner-Lambert* Supreme Court and the EPO have highlighted that a plausibility assessment is context-dependent,[59] there may be a cogent argument that standards espoused in such judgments extend no further than the specific context of those cases.[60] Therefore, it could be argued that the lower evidential standard espoused in *HGS* did not apply in *Warner-Lambert,* as the *HGS* Court's reasoning could only be applied in the context of gene sequence patents. This essay finds the argument unpersuasive for two reasons. Firstly, Lord Hope in *HGS* clarified that the standard that the Court applied "must in principle be the same for patents in the bioscience industry as for those in other fields".[61] Secondly, the lower courts have applied the evidential standard espoused in *Warner-Lambert* outside the context of second-use claims and sufficiency, stating that the case is binding on them even in those different contexts.[62] Therefore, because *HGS* is still good law, it is difficult to understand why the lower evidential standard applied in *HGS* has not similarly been embraced by the English courts outside the context of gene sequence patents and industrial applicability. Nevertheless, English courts have consistently held that the positive obligation standard for plausibility is the one to apply in UK patent law.[63]

## Part 2: The case against the English courts' positive obligation standard.

### A. Economics and plausibility: framing the evidential standard based on the patent system's objectives.

As outlined in Part 1, the English courts have settled on the positive obligation standard for plausibility. This diverges from what is likely to be the EPO's preference, the substantiated doubt standard. To assess whether the English courts are justified in their divergence, it is pertinent first to examine how a plausibility assessment sits within the competing objectives of the patent system and arrive at an informed conclusion on the appropriate evidential standard.

Traditionally, the economic rationale for granting patents has been based on incentive/reward and disclosure theories.[64] Under these theories, patents are seen as necessary to incentivise innovation and early disclosure of inventions to the public because without the incentive of a

[58] ibid, [17]. See also *ZYMOGENETICS* (n 32), [6].
[59] *Warner-Lambert* (n 9), [37]; *SUMITOMO* (n 3), [95].
[60] For example, Christopher Floyd, 'Plausibility: where from and where to?' (2021) GRUR 185, 187; UK Intellectual Property Office, 'Manual of Patent Practice' (3 April 2023), [14.72.1].
[61] *HGS* (n 52), [142].
[62] For example, *Sandoz and Teva v BMS* [2022] EWHC 822 (Pat), [72]; *Gilead Sciences v NuCana* [2023] EWHC 611 (Pat), [341].
[63] For a recent post-*SUMITOMO* example, see *Teva v Grünenthal* [2023] EWHC 1836 (Pat), [342].
[64] John Duffy, 'Rethinking the Prospect Theory of Patents' (2004) 71 U Chi L Rev 439, 439.

monopoly, innovators would resort to secrecy to protect the costs they have sunk into inventing.[65] Professor John Duffy refers to such theories as backwards-looking objectives of the patent system, as such objectives "protect the investments in innovation made *prior to* patenting".[66] The patent bargain appears to sit comfortably within these backwards-looking objectives, as a system based on these objectives would only confer a monopoly over that which was made before patenting. Therefore, it may be argued that pure adherence to the bargain and backwards-looking objectives would favour the positive obligation standard for plausibility.

While fulfilling the patent bargain may be viewed as the bedrock of the modern patent system,[67] pure adherence to backwards-looking objectives comes with problems. Such pure adherence would not account for the practical difficulty of demonstrating functional efficacy at the point that patent applications in practice have to be made in the life sciences sector (the context in which plausibility often arises).[68] There are eye-watering sums involved in bringing a new drug to the market (average cost $1.3 billion).[69] Clinical trials and other regulatory processes might render the product unpatentable if a patentee had to wait for such data to satisfy the patent bargain.[70] Cumulatively, these factors appear to have the potential to disincentivise innovation in the life sciences sector. Professor Sir Robin Jacob argues that this is why pre-EPC UK patent law moved away from the requirement for an "oven-ready" invention before a patent could be granted.[71] Consequent to firms taking such lengthy and expensive regulatory steps post-patent, the public would, in fact, get back more in the bargain than just that disclosed in the specification once a pharmaceutical patent expires.[72] Therefore, while a pure view of the patent bargain and backwards-looking objectives may support a positive obligation standard for plausibility, the risk to innovation in the life sciences sector appears to point away from such a strict application when framing the evidential standard.

Several theories have been proposed to address the gaps in the backwards-looking objectives. Examples include prospect and commercialisation theories.[73] Professor Duffy refers to such theories as forward-looking objectives, as they embody the notion that "the patent system is to encourage investment in a technological prospect *after* the property right has been granted".[74] This is done largely by conferring broad patents on initial inventors.[75] Under

[65] See, generally, Richard Levin and others, 'Appropriating the Returns from Industrial Research and Development' (1987) 1987(3) Brookings Papers on Economic Activity 783.
[66] Duffy (n 64), 440.
[67] Fisher (n 12), 287–288.
[68] *Warner-Lambert* (n 9), [29]; *SALK* (n 17), [9].
[69] Olivier Wouters and others, 'Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018' (2020) 323(9) JAMA 844.
[70] Slade (n 5), 196.
[71] Jacob (n 35), 227, 230.
[72] ibid, 232.
[73] See, generally, Edmund Kitch, 'The Nature and Function of the Patent System' (1977) 20 J L & Econ 265.
[74] Duffy (n 64), 440.
[75] Richard Nelson and Roberto Mazzoleni, 'Economic Theories About the Costs and Benefits of Patents' in National Research Council, *Intellectual Property Rights and Research Tools in Molecular Biology* (National Academy Press, 1997), 22-25.

forward-looking objectives, innovation is seen more as a continuum than an event, as firms often must take several necessary commercial and administrative steps for inventions to be useful to the public.[76] Under these forward-looking objectives, the patent system incentivises firms to take the necessary steps past the initial invention.[77] When contrasted with the backwards-looking objectives, it becomes apparent that the substantiated doubt standard (and possibly even no plausibility assessment) would be favoured under a patent system that caters more to such forward-looking objectives.

One of the key assumptions made by forward-looking objectives is that the person who applies for the patent is in the best position to commercialise and improve on the invention.[78] Therefore, under a pure forward-looking system, patents may be susceptible to abuse by Patent Assertion Entities—entities, such as so-called "patent trolls", that have "no direct connection to the invention protected [by the patent]…with their business model dedicated to conducting licensing programs under the threat of an infringement action".[79] Indeed, from the perspective of the plausibility assessment, it is argued that "the patenting of unjustified claims risks creating monopolies over important scientific information a practical application for which has yet to be identified".[80] However, such a view does not accommodate two possibilities that may not constitute an abuse of the system. The first is where small firms, faced with significant development costs, rely on possessing patents on their inventions (speculative or otherwise) to seek development financing to make their invention marketable.[81] The second possibility is a scenario recognised by the United States Supreme Court whereby "university researchers or self-made inventors, might reasonably prefer to license their patents, rather than undertake efforts to secure the financing necessary to bring their works to market themselves".[82]

Forward-looking objectives may, in certain circumstances, hinder innovation. Take, for example, patents on gene sequences acquired during the early days of the Human Genome Project, where it was felt that patents were needed if private companies were to be induced to use those sequences to achieve commercial products.[83] Given that this led to the development of firms whose business model was predicated purely on discovering and patenting sequences and subsequently licensing to development firms, pharmaceutical companies argued that consequent to associated transaction costs in this specific context, progress was stifled due to costlier end products.[84] Therefore, it appears that much depends on what is assumed about the degree of transaction costs associated with patent licenses.

[76] ibid.
[77] ibid.
[78] ibid.
[79] Bertrand Sautier, 'Trolls, Sharks, and Privateers: Twenty Years of Patent Assertion Entities' in Hayleigh Bosher and Eleonora Rosati, *Developments and Directions in Intellectual Property Law: 20 Years of The IPKat* (OUP 2023), 512.
[80] Slade (n 5), 181.
[81] Nelson and Mazzoleni (n 75), 22.
[82] *eBay v Mercexchange*, 547 US 388 (2006), 393.
[83] Nelson and Mazzoleni (n 75), 25-26.
[84] ibid.

Ultimately the public bears the associated cost, and if the price is perceived to be too high to purchase, there is no incentive for development firms to pursue the project.[85]

The point of the above analysis is to demonstrate that no one set of objectives appear better than the other in developing a fair and efficient patent system. While there may be some overlap between the theories, there are also significant ideological differences. Therefore, a balance must be struck between forward-looking and backwards-looking objectives in determining the appropriate evidential standard for a plausibility assessment.

So, where does the evidential standard currently sit within this theoretical framework? There appears to be a propensity for the courts to adopt a more backwards-looking lens when framing the evidential standard. For example, in *Warner-Lambert,* Lord Sumption (with whom the majority agreed) almost exclusively limited the theoretical foundation on which to base the appropriate evidential standard to securing the patent bargain.[86] Therefore, it is unsurprising that the majority arrived at the positive obligation standard.[87] In contrast, Lord Mance (with whom Lord Hodge agreed) appeared to recognise the limits of such backwards-looking objectives by taking a minimalist view of the evidential burden and thus arrived at the substantiated doubt standard.[88]

The risk, as noted by Professor Jacob, is that if the evidential standard is set as high as that applied by the majority in *Warner-Lambert,* it may be perceived as a return to the old law "oven-ready" requirement—a requirement that was specifically departed from to accommodate innovation in sectors such as the life sciences.[89] This essay posits that the extent to which such a high standard could be justified (as opposed to accommodating more forward-looking objectives) depends on two pragmatic factors. Firstly, to what extent are Patent Assertion Entities a feature of the life sciences sector, and to what extent do such entities raise transaction costs in the sector? If such transaction costs do indeed stifle innovation, then this factor would favour the high standard set by the *Warner-Lambert* majority. Without such empirical data, the minority's minimalist view of the standard should be favoured. Secondly, which standard proportionately addresses the mischief the plausibility assessment aims to resolve?

## B. Mischief and plausibility: framing the evidential standard to address deficiencies in the patent statute.

Looking now at the targeted mischief, the plausibility assessment has been observed to be "patent law's primary response to speculative patenting".[90] However, the premise that all speculative patenting is undesirable has been questioned. For example, as observed by

[85] ibid.
[86] *Warner-Lambert* (n 9), [17].
[87] ibid, [37].
[88] ibid, [180], [192]-[193].
[89] Jacob (n 35), 230. See also, *HGS* (n 52) [97]-[102], [130], [141], [171].
[90] Arnold (n 8), 20.

Pumfrey J in *Cipla v Glaxo Group*,[91] "a perfectly valid patent may be written by a person who does not stir from his armchair…and does no experiments to confirm his hunch".[92] Additionally, as argued by Professor Jacob, "[i]deas, even unsubstantiated, can be valuable", particularly given that if the idea does not work, nothing will be lost by the speculative patent, as it would have no commercial value.[93] However, such arguments lose strength in certain scenarios, particularly in the case of second-use patents (new use of a known compound).[94] With such patents, given that the compound is already known, the skilled addressee already knows how to make the compound from the prior art.[95] Therefore, in contrast to a claim for a new compound, it is significantly easier for the patentee to satisfy the statutory sufficiency requirement (disclosure to enable carrying out/performing the invention) with little more than an assertion such as "compound X for use in treating disease Y".[96] Similarly, an assertion of novel use may not be obvious to the skilled addressee, thus satisfying the statutory inventive step requirement.[97] In the context of second-use claims, it is argued that speculative patenting is an abuse of the system given that "the knowledge which made the identification of the new purpose inventive need not be disclosed at all".[98] Similarly, plausibility is seen as a useful tool to curtail overly broad claims.[99] It appears that this rationale is less clear given that the English courts have demonstrated an ability to combat excessive claim breadth without relying on a plausibility assessment.[100] Nevertheless, the point is that plausibility is a court-invented assessment (with questionable legislative legitimacy)[101] constructed to tackle specific mischief arising from deficiencies in the patent statute.[102] Outside the confines of this mischief (e.g., a novel single chemical compound claim), provided the invention actually works, it becomes difficult to argue that the patentee has not contributed to the state of the art just because they have not provided evidence to make the invention's purported technical contribution plausible.[103] Consequently, this essay takes the view that the appropriate evidential standard for a plausibility assessment is one that possesses adequate flexibility not to capture scenarios falling outside of the mischief that gave rise to the need for plausibility in the first place.

Turning to the two evidential standards, both the Supreme Court and the EPO have observed that the content of a plausibility assessment is "inevitably influenced by the legal context" or "influenced by the technical field of the claimed invention", respectively.[104] However, it

[91] [2004] EWHC 477 (Pat), [2004] RPC 43.
[92] ibid, [116].
[93] Jacob (n 35), 232.
[94] *Warner-Lambert* (n 9), [19]-[20].
[95] Floyd (n 60), 187.
[96] ibid.
[97] Slade (n 5), 181.
[98] *Warner-Lambert* (n 9), [19].
[99] Arnold (n 8), 20.
[100] For example, *Regeneron Pharmaceuticals v Kymab* [2020] UKSC 27, [2020] RPC 22.
[101] See fn35 above.
[102] *Warner-Lambert* (n 9), [192]; Floyd (n 60), 187.
[103] Floyd (n 60), 187.
[104] *Warner-Lambert* (n 9), [37]; *SUMITOMO* (n 3), [95].

appears that a positive obligation standard cannot operate in such a flexible fact-dependant manner. For example, *Sandoz v BMS* involved a novel single chemical compound *per se* claim.[105] This is the kind of claim that the *Warner-Lambert* majority determined would give rise to a "correct" assumption that the invention has been sufficiently disclosed if the specification enables it to be carried out/performed.[106] Despite this observation by the Supreme Court, as noted by Arnold LJ, such claims cannot circumvent a plausibility assessment.[107] As a matter of logic, this essay agrees. The *existence* of a requirement that an invention be plausibly demonstrated to work cannot disappear just because of a change in the type of claim. However, it appears that such flexibility (applying the plausibility assessment differently for different types of claims) can be accommodated based on the evidential *standard*.

If a positive obligation standard applies (as in *Sandoz*),[108] then it appears that the patentee will always be under a positive obligation to include evidence in the specification that makes plausible the invention's purported technical contribution, irrespective of the type of claim. In contrast, there is greater scope for flexibility under the substantiated doubt standard, as the level of underlying substantiated doubt about an invention and its technical effect *can change* for different types of claims.[109] As a broad illustration, take two EPO cases where the patentee relied on a technical effect of the same compound—dasatinib's inhibitory activity on various protein tyrosine kinases.[110] The first case involved a broad chemical compound claim, while in the second case, the claim was specifically for dasatinib. Although the patents in the respective cases contained no experimental evidence in support of the purported technical effect, the Boards arrived at different decisions regarding plausibility. In the first case, given the nature of the invention (i.e., a broad compound claim), the technical effect relied on was not "self-evident", and the specification should have included evidence supporting the purported effect.[111] In contrast, in the second case, given the specificity of the claimed invention, there were "no substantiated doubts that the claimed concept can be put into practice", so supporting experimental evidence did not have to be included in the specification.[112]

While flexibility is beneficial, the substantiated doubt standard does appear to have a flaw. As noted by Meade J in *Gilead v NuCana*, inherent in its flexibility is a degree of uncertainty regarding how the assessment operates.[113] However, this essay takes the view that this flaw should not detract from the principled benefits of this standard when compared to the

[105] *Sandoz* (EWCA) (n 42), [1].
[106] *Warner-Lambert* (n 9), [19].
[107] *Sandoz* (EWCA) (n 42), [91]-[93].
[108] ibid, [94]-[95].
[109] Rose Hughes, 'Plausibility demystified - a review of EPO case law before G 2/21' (IPKat, 24 February 2023) <https://ipkitten.blogspot.com/2023/02/plausibility-demystified-review-of-epo.html?m=1>.
[110] T488/16 *BMS/Dasatinib* [2019] EPOR 24; T950/13 *BMS/Dasatinib* (unreported, 3 February 2017).
[111] T488/16 (n 110), [4.9].
[112] T950/13 (n 110), [3.6].
[113] *Gilead* (n 62), [342].

alternative, namely, its ability to go no further than the purpose for which plausibility was conceived—tackling speculative claims where they are an abuse of the patent system.

## Conclusion

While both the terminology and the evidential requirement that plausibility represents may have their critics, a plausibility assessment has become an entrenched concept in analysing patent validity at the EPO and English courts. This essay has identified a divergence between the two decision-making bodies in their approach to plausibility.

The English courts have settled on the higher positive obligation standard rather than the EPO's lower substantiated doubt standard. The English courts adopting the higher standard lacks cogent justification as the standard neither reflects a balance between the competing objectives of the patent system nor limits a plausibility assessment to its targeted mischief. Instead, the flexibility inherent in the substantiated doubt standard should be preferred.

Three areas of further research will assist in arriving at a more conclusive answer to some of the issues identified in this essay. Firstly, a large part of framing aspects of the plausibility assessment is predicated on assumptions made about speculative patenting. To this end, empirical data is required, such as the prevalence of Patent Assertion Entities in the life sciences sector and associated transaction costs. It is only fair that the need for a patentee to provide evidence should itself be evidence-based. Secondly, it will be informative to thoroughly examine how other jurisdictions (both EPC and non-EPC states) combat speculative claims identified as an abuse of the patent system and what lessons can be learnt and adopted in the UK. The Resolution from a 2019 plausibility study is a good starting point for this analysis.[114] Finally, there are aspects of plausibility that are hotly debated (e.g., the date plausibility is assessed[115] and the appropriateness of using so-called "prophetic" examples[116]) that were beyond the scope of this essay to examine in any detail. Consensus on these contentious matters will no doubt have a bearing on the appropriate direction of travel for some of the issues identified in this essay.

Absent legislative reform to clarify the status of plausibility, and with the emergence of technology that entails inventing without the need for classical experimenting, the frequency of cases involving a plausibility assessment is only likely to increase. With at least one forthcoming UK Supreme Court hearing that will again navigate plausibility's waters, it is hoped that plausibility's evidential standard will be brought in line with one that is balanced and proportionate.

[114] AIPPI (n 20).
[115] Floyd (n 60), fn6.
[116] AIPPI (n 20), [3]: "description which does not describe experiments that have actually been performed but which rather predicts that a specific experiment will prove a technical effect".