Must Assertions made in European Patents be Plausible, or is Invention a Question of Faith instead of Fact?

by Justin Lambert

ABSTRACT

The concept of "plausibility" is used to test the quality of information that a patent application must contain to support valid claims. A significant divergence between the way the UK courts apply the concept, and the way the European Patent Office and Courts in other European jurisdictions may apply the concept, is looming on the horizon following the Enlarged Board of Appeal's opinion in G 2/21 (Sumitomo). The opinion opens the way for patentees to rely on information that is not contained in the patent application, nor the state of the art, to support assertions made in the application. Allowing patentees to rely on such additional information, equivalent to "added matter", is likely to negatively impact the credibility of the European Patent System.

Recent patent litigation in Europe about Bayer's multi-billion dollar anticoagulant drug, Apixaban (sold as ELIQUIS), has highlighted how important the concept of "plausibility" is to the European patent system.

Prior to the Apixaban litigation, a common perception was that plausibility was only important in "second medical use" cases for policy reasons. It was thought that second medical uses deserved special treatment because, on the one hand, it is desirable to encourage research into new uses of known drugs, but, on the other hand, clinical trials for testing whether the drug has an effective second use are very expensive and difficult to keep confidential until after a patent is filed.

However, in the Apixaban litigation, Bayer's patent was for the drug molecule *per se*. By the time of the trial there was no dispute that the molecule worked, the patent identified it clearly, and the skilled person would have no difficulty following the patentee's instructions on how to make it. Nevertheless, the UK trial judge concluded:

> "European Patent (UK) 1 427 415 B1, is invalid by reason of lack of plausibility."[1]

A comparison between the reasoning of the UK courts, such as that in the Apixaban litigation, and a recent opinion of the Enlarged Board of Appeal of the European Patent Office (**EBA**) foreshadows divergence between how the UK courts, the EPO, and courts in other European countries understand and deploy the concept of "plausibility". This is of particular concern, given its importance.

In the UK, "post published information" [2] cannot be used in an analysis of the technical information that a skilled person can derive from a patent application in support of an assertion that a claimed invention delivers an asserted benefit or technical effect. There is no debate. However, in the EPO there has been debate about when it is permissible to rely on post-published information in such an analysis. According to the EBA, post-published information can be relied upon to support an assertion of technical effect if the technical effect is "encompassed by the teaching" of the original application.

This article will explore the consequences of the divergence. It will start with a discussion of second medical use claims, so as to refresh readers' understanding of what they are, and their role in the development of plausibility.

Secondly, it will work through some cases and statements of principle selected from different areas of patent law, all relating to the quality of information that must be contained in a patent application in order to justify a claimed monopoly. These include cases relating to industrial applicability, added matter, priority, inventive step, and insufficiency. Readers that are familiar with all of these subjects may skip (or skim read) these sections.

1 Sandoz Ltd v Bristol-Myers Squibb [2022] EWHC 822 (Pat) (07 April 2022) at [257.1].

2 Information that was not available to a skilled person at the filing or priority date of a patent application, either because the information did not yet exist or was secret.

Thirdly, the article explores the proposition that patents are not religious texts. Courts and patent offices should not assume that the notional skilled person will read patent applications with faith in all, or any, assertions made therein. While the notional skilled person is not inventive, he or she is rational.

Fourthly, it explores plausibility in more detail, by reference to three relatively recent and important cases, namely Pregabalin[3], Sumitomo[4], and Apixaban[5]. Pregabalin is a judgment of the UK Supreme Court. Since the Supreme Court is the UK's highest court, the judgment sets out the position that all UK trial and Court of Appeal judges must follow. The decision is also important because it features in the reasoning of the Technical Board of Appeal (**TBA**) and the reasoning of the EBA in Sumitomo. Finally, both Pregabalin and Sumitomo were considered and compared by the UK Patents Court and Court of Appeal in Apixaban.

The article will end with some discussion and conclusions. In summary, in the author's opinion, the approach of the UK courts is logical. On the other hand, 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, including for the reasons given by Richard Arnold QC[6] (and accepted by the Court of Appeal) in relation to "added matter" in Vector Corp v Glatt Air Technologies[7]:

> "The applicant or patentee could gain an unwarranted advantage in two ways if subject-matter could be added: first, he could circumvent the "first-to-file" rule, namely that the first person to apply to patent an invention is entitled to the resulting patent; and secondly, he could gain a different monopoly to that which the originally filed subject-matter justified.

SECOND MEDICAL USE CLAIMS

The effects that a compound will have on a human body, and therefore its potential medical uses, are an inherent property of the compound. If an active pharmaceutical ingredient (**API**) is administered to a patient for the purpose of treating one medical condition, it may inherently treat another, without either the patient or the doctor intending or being aware of the second benefit. In that case the use of the API is uninformative, in the sense that it does not disclose information about its second use to the public.

If methods of medical treatment *per se* could be patented under the European Patent Convention (**EPC**), a second medical use patent might claim:

> A method of treating medical condition Y by administering compound X.

However, the EPC forbids the grant of patents claiming methods of treatment. Accordingly, "EPC 2000 form"[8] claims are used instead, and up until 2011 "Swiss form" claims[9] were used[10]. However, it is helpful to remember that these types of claims are a substitute for method of treatment claims. Both EPC 2000 and Swiss from claims require that the compound exhibits some degree of efficacy. Further, and importantly, the process of administering a compound to a patient for the purpose of **treating** a specific medical condition may be contrasted with simply administering a compound to a patient without any **intention** to improve the relevant condition. Accordingly, these claims are limited by (a) efficacy of the compound, and (b) a mental element on the part of the person using the compound. This mental element distinguishes the claimed method from prior, uninformative, uses of the compound that might have improved a patient's condition because of the compound's inherent properties.[11]

The issue of plausibility arises when prior art proposes or announces a clinical trial of the drug to treat a new condition, but no results of the trial have been published. Since a proposal does not disclose the efficacy of the drug, which is a technical feature of such claims, it will not anticipate them.[12]

Birss J explained the issue very clearly in Hospira[13]:

> The effect of these points is that such claims are generally regarded as novel over a mere proposal to administer the drug to patients in the manner claimed. That is because the mere proposal does not disclose that the treatment is indeed efficacious. If it was obvious that the treatment would be efficacious, or at least it was obvious to conduct a trial of the treatment which would involve treating patients, then the claim is likely to lack inventive step but that is another matter.
>
> One might say therefore that the patent specification must contain the results of a clinical trial in

3 Warner Lambert v Generics [2018] UKSC 56 (14 November 2018).

4 T 0116/18 and G 2/21.

5 Sandoz Ltd v Bristol-Myers Squibb [2022] EWHC 822 (Pat) (07 April 2022) and Sandoz Ltd v Bristol-Myers Squibb [2023] EWCA Civ 472 (04 May 2023).

6 As he then was, because he is now a Lord Justice of the Court of Appeal.

7 [2007] EWCA Civ 805, at [6].

8 "Compound X for use in treating medical condition Y".

9 Having the form "Use of compound X in the manufacture of a medicament for treating medical condition Y".

10 The EBA decided in G 2/08 that patent applications filed after 28 January 2011 could no longer contain Swiss form claims. Since EPC 2000 claims were introduced in 2007, both forms of claims existed in parallel during this period, and patents in force contain both types.

11 See for example the reasoning of Floyd LJ in *Warner-Lambert v Actavis* [2105] EWCA Civ 556 at [121].

12 Likewise, since the results of clinical trials cannot be predicted, an announcement will not always make a claim obvious.

13 Hospira UK Ltd v Genentech Inc [2014] EWHC 1094 (Pat) (10 April 2014) at [59] to [64].

> order to prove efficacy, since the claims contain this element as a feature. But to require that at least in all circumstances may cause another problem. Finding new treatments for disease is highly desirable. Clinical trials are a necessary but very expensive and complex part of that process. The existence of a patent (or application) may facilitate investment in the clinical trial which might not otherwise take place but that means that the patent has to be applied for before the results are known. So a rule which demanded clinical results could cause real difficulties.
>
> On the other hand, if all the patent contains is a mere proposal, then it has not made a contribution to the art in this example. One has now come full circle. A mere proposal is not a disclosure of the claim, properly construed. But the patentee can hardly argue, and the Court or Patent Office is unlikely to accept, that a mere prior proposal is not enough to invalidate the claim if all that is present in the specification of the patent is a mere proposal followed by a use claim.
>
> Moreover, it would be a recipe for abuse if all that was required in order to obtain a patent in this field was a proposal, without any basis, to use drug A to treat disease B.
>
> Patent law seeks to address these factors balancing the requirements for sufficiency of disclosure against the rules of novelty and inventive step**. But the conventional sufficiency test of asking whether the claimed invention works, does not help. The treatment does work but what if the patent does not say so**? [emphasis added]
>
> For these reasons the idea of "plausibility" as part of the law of sufficiency of disclosure has been developed both in the EPO (T609/02 Salk Institute) and the UK (Regeneron). The term "plausibility" has been coined to characterise what it is that a patent specification must provide in order to be sufficient, short of full clinical proof of efficacy.

The highlighted sentence, asserting that the conventional sufficiency test doesn't work in such scenarios, deserves further explanation. The Judge was considering a "Swiss form" claim. These types of claims cover any process for manufacturing a relevant medicament (i.e. one containing the API and which is suitable and intended for use to treat the relevant disease). In most cases, the skilled person won't have any difficulty with the manufacturing process. Indeed, the patent is likely to say that well known formulation techniques may be used. So, an argument to the effect that the claim is insufficient because the skilled person would face undue burden working out how to formulate the product could not succeed.

In Pregabalin, Lord Sumption explained the same point in the following terms:[14]

> Section 14 of the Patents Act and the corresponding provisions of the EPC assume that an invention will be sufficiently disclosed if the specification enables it to be "performed". In the case of a patent for a new product or process, that assumption is almost always correct. The skilled person will discover that it works by replicating it in accordance with the specification. But the assumption is not correct in the case of a second use patent. The invention is not the compound or the process of its manufacture. The skilled person already knows how to make the product from the prior art disclosed in the original patent. The invention consists in the new purpose for which the product is to be manufactured. If sections 14(3) and 72(1)(c) are read literally and as an exhaustive statement of the requirement of sufficiency, **all that needs to be disclosed is the new purpose, which is enough to enable it to be administered to a patient suffering from the relevant condition**. The skilled person does not need to know how or why the invention works in order to replicate it. The result would be that the knowledge which made the identification of the new purpose inventive need not be disclosed at all. [emphasis added]
>
> The main problem about this result is that it would enable a patent to be obtained on a wholly speculative basis. Without some disclosure of how or why the known product can be expected to work in the new application, it would be possible to patent the manufacture of 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.

If the sufficiency of such claims is considered in this way, it is easy to sympathise with an argument that a requirement that the patent also make it plausible that the API can be used to treat the disease is an impermissible addition to the statutory test, which has led to arguments about the role of plausibility in patent law.

However, in the author's view, there is another way to look at things. As mentioned above, in these cases the invention comprises new information about the drug's utility. Accordingly, the invention is not put into the skilled person's possession until he or she is provided with information that allows him or her to consider, on an objective basis, that administration of the drug will result in some form of treatment. Without such information, no rational skilled person could form the intention to treat the relevant disease by administering a medicament containing the relevant API. Since a mere assertion won't provide the skilled person with such information, such claims are not made sufficient by mere assertions. Considered in this way, the requirement that the patent contain sufficient information to make a treatment effect plausible is **not** an addition to the statutory test.

14 At [19] and [20].

INDUSTRIAL APPLICABILITY

An idea for something that is useful, but which is not enabled, is not an invention.

In Biogen Inc v. Medeva[15] Lord Hoffmann, explained:

> The idea of making HBV antigens by recombinant DNA technology was shared by everyone at the Geneva meeting of Biogen in February 1978 and no doubt by others working in the field, just as the idea of flying in an heavier-than-air machine had existed for centuries before the Wright brothers. The problem which required invention was to find a way of doing it.

The flip side of the above statement is just as important. That is, something that is enabled, but which is not useful, is not an invention either. This idea may be considered in the context of Article 57 of the EPC, which requires that a claimed invention be susceptible of industrial application.

The way in which this requirement applies to a patent for biological material was considered by the UK Supreme Court in HGS v Lilly[16]. Lord Neuberger considered that the following general principles could be distilled from TBA cases:

> (i) The patent must disclose "a practical application" and "some profitable use" for the claimed substance, so that the ensuing monopoly "can be expected [to lead to] some ... commercial benefit" (T 0870/04, para 4, T 0898/05, paras 2 and 4);
>
> (ii) A "concrete benefit", namely the invention's "use ... in industrial practice" must be "derivable directly from the description", coupled with common general knowledge (T 0898/05, para 6, T 0604/04, para 15);
>
> (iii) A merely "speculative" use will not suffice, so "a vague and speculative indication of possible objectives that might or might not be achievable" will not do (T 0870/04, para 21 and T 0898/05, paras 6 and 21);
>
> (iv) The patent and common general knowledge must enable the skilled person "to reproduce" or "exploit" the claimed invention without "undue burden", or having to carry out "a research programme" (T 0604/04, para 22, T 0898/05, para 6).

The overlap between issues that must be considered under this heading, and issues that must be considered under inventive step or sufficiency, is immediately apparent. Indeed, Eli Lilly conceded that, on the facts before the Court, the issue of industrial applicability and inventive step, more specifically "Agrevo obviousness", stood or fell together. It is therefore appropriate to say something further about Agrevo obviousness, and the problem-solution test that the EPO applies when determining inventive step, under this heading.

The EPO's "problem-solution" test involves the following stages:

> (a) determine the closest prior art;
>
> (b) compare the subject matter of the claim at issue with the disclosure of the closest prior art and identify the differences between them;
>
> (c) determine the technical effect or result achieved by and linked to these differences;
>
> (d) define the objective technical problem solved by the invention as achieving these effects or results; and
>
> (e) consider whether or not the skilled person would have suggested the differences in order to obtain the effect or result.[17]

The patent under consideration in Agrevo[18] claimed a class of compounds described by a Markush formula. The claims were to the compounds *per se* and not limited by any use, but the specification asserted that they were useful as herbicides. The Examining Division found that the skilled reader would not expect all the claimed compounds would have herbicidal activity. In relation to inventive step, the TBA explained:[19]

> [T]he appellant submitted that ... even on the basis of known starting compounds and known synthetic methods, a practically unlimited number of chemical compounds would have had to be considered, and that a particular selection from this unlimited number of possibilities should be regarded as inventive, even if it was arbitrary, unless there was a direct pointer to the preparation of just these very compounds in the state of the art.
>
> This argument must, however, fail, since in the Board's judgment the answer to the question as to what a person skilled in the art would have done, depends on the result he wished to obtain ...
>
> If this result is only to be seen in obtaining further chemical compounds, then all known chemical compounds are equally suitable as the starting point for structural modification, and no inventive skill needs to be exercised in selecting [some of them]. ... In other words, 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.
>
> ... [T]he technical problem which the present patent application asserts to solve is the provision of fur-

15 [1996] UKHL 18 (31 October 1996) at [49].

16 [2011] UKSC 51.

17 See G2/21 at [24].

18 T 939/92.

19 At 2.5.2 and 2.5.3.

> ther (alternative) chemical compounds with **herbicidal activity**.
>
> However, ... this technical problem could only be taken into account if it could be accepted as having been solved, that is, if, in deciding the issue under Article 56 EPC, it would be credible that substantially all claimed compounds possessed this activity.

The key reasoning is that, in relation to compounds that did not provide a new technical effect, the only technical contribution was providing "other compounds", which was not inventive. In other words, if the claim is for an arbitrary selection, it cannot be said to be inventive.

In this context, a new technical effect may be understood as a new concrete benefit, new use in industrial practice, or some improvement or advantage over the closest prior art. For the purposes of convenience, "utility" will be used as a catchall description.

Returning to the problem-solution approach, while steps (a) and (b) are easy to understand, steps (c) to (e) are not intuitive, because they involve looking for a solution before knowing the problem. They involve, respectively (c) searching the patent for a reason why the invention is delivers "utility" over the closest prior art, (d) if some utility can be found, defining the problem solved as how to deliver that utility, and (e) asking whether it would have been obvious to the skilled person to adapt the prior art in the way claimed in the patent in order to deliver it. The "utility" identified in step (c) defines the problem in step (d). If no utility can be found, there is no need to proceed to steps (d) and (e), for reasons given by the TBA in *Agrevo*.

ADDED MATTER

Article 123(2) of the EPC provides:

> A European patent application or a European patent may not be amended in such a way that it contains subject matter which extends beyond the content of the application as filed.

In G 1/93, the EBA explained that the underlying idea for the rule was "that an applicant shall not be allowed to improve his position by adding subject matter not disclosed in the application as filed, which would give him an unwarranted advantage and could be damaging to the legal security of third parties relying upon the content of the original application."

Whether or not an amendment "adds matter", is determined by the Court or patent office adopting the mantle of the skilled person reading and comparing the original and amended documents to see if any subject matter relevant to the invention has been added. Subject matter will be added unless it is "clearly and unambiguously disclosed" in the original application. New subject matter might be added by amendment to the claims, or amendment to the description.

In G 2/10, the EBA explained:

> [A]ny amendment to the parts of a European patent application or of a European patent relating to the disclosure (the description, claims and drawings) is subject to the mandatory prohibition on extension laid down in Article 123(2) EPC and can therefore, irrespective of the context of the amendment made, only be made within the limits of what a skilled person would derive directly and unambiguously, using common general knowledge, and seen objectively and relative to the date of filing, from the whole of these documents as filed.
>
> ...
>
> Therefore, as is the case for any other amendment, the test for an amendment to a claim by disclaiming subject-matter disclosed as part of the invention in the application as filed must be that **after the amendment the skilled person may not be presented with new technical information**. Hence, disclaiming subject matter disclosed in the application as filed can also infringe Article 123(2) EPC if it results in the skilled person being presented with technical information which he would not derive directly and unambiguously, using common general knowledge, from the application as filed. [Emphasis added].

Accordingly, if the claims of a patent application have a defect relating to lack of inventive step, or insufficiency, the applicant cannot fix that defect by an amendment (whether to the claims or to the description), which would result in the addition of technical information that a skilled person could not derive directly and unambiguously from the application as filed.

In Gilead v Nucana[20], Meade J considered a series of TBA and EBA added matter cases, in some detail, in the context of a patent for nucleoside analogues described by a Markush formula. The proposed amendments would have resulted in a significant narrowing of the Markush formula in the description and the claims. In this context Meade J explained:

> I do not see anything inconsistent in G2/10 with the notion that when asking whether an amendment adds matter, which is the fundamental question, it will be relevant to ask whether it presents a different invention, and that part of that inquiry may be whether it provides a new technical contribution. One is not inquiring whether there is a new technical contribution instead of asking whether there is added

20 [2023] EWHC 611 (21 March 2023).

> matter, but simply recognising it as a likely symptom of there being added matter.
>
> ...
>
> Given my reasoning above, the effect of an amendment, such as to allow a new argument on inventive step (as distinct from the motive for it) may also be relevant to added matter.

The Judge found that the effects of the proposed amendments was to define a new class of compounds, which was not disclosed in the original application. The purpose of the amendments was to restrict the claimed class to compounds that were active, which could be made, and which were not made obvious by prior art. The Judge observed that while there was nothing wrong with these motives, they were symptoms of an invention being put forward in the proposed amended patent that was different to the invention disclosed in the original application.

In summary, it is not permissible to amend a patent in order to bolster an inventive step or sufficiency case in a way that adds technical information that a skilled person could not derive directly and unambiguously from the original application.

PRIORITY

More than 30 years ago, the UK House of Lords in Asahi[21] decided that for matter in an application to be capable of supporting an invention it must contain an enabling disclosure.

In Unilin v Berry[22], the UK Court of Appeal explained:

> The approach is not formulaic: priority is a question about technical disclosure, explicit or implicit. Is there enough in the priority document to give the skilled man essentially the same information as forms the subject of the claim and enables him to work the invention in accordance with that claim?

In G 2/98, the EBA expressed the test for priority in the following way:

> The requirement for claiming priority of 'the same invention', referred to in Article 87(1) EPC, means that priority of a previous application in respect of a claim in a European patent application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole.

In Gemvax[23], one of the appellants submitted to the TBA that even though the wording of the claims could be derived from the priority document, the claims did not relate to the same invention since the priority document lacked any experimental data which made it plausible that the claimed invention worked. The TBA was nevertheless convinced that the claimed subject matter was "directly and unambiguously derivable from the priority document in the sense of opinion G 2/98":

> Since the enablement of the disclosure of the priority document has not been explicitly challenged by [the appellant], the Board does not consider it appropriate to doubt that the priority document discloses the invention in an enabling way. Beyond the issue of enablement, the Board sees no legal basis for imposing additional criteria such as the presence of experimental data in the priority document which make plausible the invention will work. The Board is furthermore convinced that the experimental data which are present in the patent and not in the priority document do not change the nature of the invention disclosed.
>
> [The appellant] submitted that in view of decision T 1329/04 of 28 June 2005, it would be necessary that the priority document contained experimental data which made plausible that the invention now claimed worked. However, said decision is concerned with the question of inventive step and is therefore not relevant for the present issue of entitlement to priority.

Gemvax was considered in Hospira. After explaining the role of plausibility in relation to second medical use claims (see above) the Judge extended his reasoning to priority:[24]

> Genentech submitted that the requirement for plausibility which is part of the law of sufficiency was not relevant in the context of priority and referred to [Gemvax] in which the Technical Board of Appeal rejected the suggestion that to be entitled to priority it was necessary for the priority document to contain data which made it plausible that the claimed invention worked (paragraph 11).
>
> ...
>
> Although I am reluctant to do so I disagree with the statement in Gemvax. The requirement for priority is that the earlier application must be in respect of the same invention as the patent. The establishment of priority includes a requirement for an enabling disclosure (Biogen v Medeva [1997] RPC at 48–49). In order to make an enabling disclosure of an invention it must be possible to make a reasonable prediction

21 Asahi Kasei Kogyo KK's Application [1991] R.P.C. 485.

22 [2004] EWCA Civ 1021.

23 T 093/05 (30 August 2007).

24 Hospira UK Ltd v Genentech Inc [2014] EWHC 1094 (Pat) (10 April 2014), at [147] and [149].

> that the invention will work (Regeneron v Genentech [2013] EWCA Civ 93, paragraph 100). In the context of an invention which includes the achievement of a therapeutic effect as one of its features, absolute proof is not required but the patentee must show that the therapeutic effect is plausible (Regeneron paragraph 103). It seems to me that this logic applies just as much to priority as it does to sufficiency of disclosure (see also Biogen on the relationship between priority and sufficiency). The alternative would be a recipe for abuse. A patentee could file a speculative priority application and obtain an earlier priority date, thereby stealing a march on the competition. I find that in law the test for priority includes the requirement for plausibility in a case like this one.

The above logic is compelling.

INVENTIVE STEP OR INSUFFICIENCY?

Article 83 of the EPC provides:

> The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

The test for insufficiency in the UK was summarised in Regeneron v Kymab Ltd:[25]

> It is a general requirement of patent law both in this country and under the European Patent Convention that, in order to patent an inventive product, the patentee must be able to demonstrate (if challenged) that a skilled person can make the product by the use of the teaching disclosed in the patent coupled with the common general knowledge which is already available at the time of the priority date, without having to undertake an undue experimental burden or apply any inventiveness of their own.

If there is nothing in the patent specification that would give the skilled person a basis on which to identify which products or processes are likely to "work", he or she may have to carry out their own research in order to find that out, which might involve an undue burden.

In the EPO, whether an attack based on the paucity of information in the patent is considered under inventive step or insufficiency depends on whether or not the claim in issue includes a utility requirement as a limitation.

In G 1/03, the EBA said:

> If … there is lack of reproducibility of the claimed invention, this may become relevant under the requirements of inventive step or sufficiency of disclosure. If an effect is expressed in a claim, there is lack of sufficient disclosure. Otherwise, i.e. if the effect is not expressed in a claim but is part of the problem to be solved, there is a problem of inventive step.

Agrevo has been discussed above. The claim was to a large Markush class of compound which the patent asserted had herbicidal activity. If the patentee had inserted a limitation into the claim, so that the claims only covered compounds of the Markush formula that had the relevant herbicidal activity, then the skilled person would have to do her own experiments to determine which compounds were within the claim, which would have involved an undue burden, and the claims would have been found insufficient.

In the UK, the quality of disclosure necessary to support an assertion of utility remains the same, whether it is considered under insufficiency or inventive step, so it doesn't matter under which heading "plausibility" is considered. This makes sense. If the test for inventive step were easier to satisfy than the test for sufficiency, the patentee would gain an artificial advantage by leaving any limitation to useful subject matter out of the claim, and the consequently broader claim would be harder to challenge than the narrow one.

FAITH

In the author's opinion, patents ought not be treated as religious texts, and what they teach the notional skilled person ought not be a question of faith in assertions contained therein. This is a fundamental point of this article and is consistent with everything said above. The notional skilled person (more accurately, a court or patent office adopting the mantle of the notional skilled person) has many roles, and is expected to apply a combination of common general knowledge and rational thinking when fulfilling them. This includes when bringing to bear his or her common general knowledge in order to: interpret words or phrases used in claims; consider the disclosure in the original application and whether any amendments to that disclosure result in the addition of new technical information; figure out how to implement a claimed invention in a sensible way; consider the teaching of prior art and how he might adapt the prior art to solve a technical problem, and so on.

For example, in relation to inventive step, the structured approach that is used in the UK to assess inventive

25 [2020] UKSC 27 at [2].

step (as originally set out in Windsurfing[26] and refined in Pozzoli[27]) involves the following steps:

> 1. Identify the notional "person skilled in the art" and the relevant common general knowledge of that person;
> 2. Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;
> 3. Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;
> 4. Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?

The patent in Pozzoli was for a case to hold two or more compact discs, with centres off-set, in a stepped arrangement. The patentee argued that the skilled person would be prejudiced against overlapping, by a fear that the CDs would be at risk from damage to their playing surfaces upon removal or replacement.

The Court of Appeal agreed that prejudice, if established, was relevant:

> Patentability is justified because the prior idea which was thought not to work must, as a piece of prior art, be taken as it would be understood by the person skilled in the art. He will read it with the prejudice of such a person.

In some cases, the closest prior art will be a patent. The recent UK case Mirabegron[28] is an example. In this case, the patent was for use of mirabegron to treat overactive bladder. At the priority date, the idea of using β3 adrenoreceptor agonists (**Agonists**) to treat overactive bladder had momentum. Some Agonists had been tested in clinical trials, but without success, and the reasons for failure were not clear.

The prior art patent (**288**) described a large number of compounds asserted to be Agonists, including six "best modes for conducting the invention". One of the six was mirabegron. However, 288 only contained limited test data for a single compound, which was not mirabegron. The trial judge explained:

> My overall conclusion is that the skilled addressee would think that no safe conclusion could be reached over what testing had been done other than the one data point for Example 6. That does not mean that they would think that the teaching could not usefully be progressed; they would have the hope that if they tested the six examples they might get some positive results, but they would have no expectation for any particular compound, other than perhaps Example 6 where it might be a bit more likely that selectivity had been tested, but from which no conclusion about other compounds could be drawn without testing.

The inventive step challenge based on 288 therefore failed. The judge noted that:

> [T]he central problem facing the claimants [for revocation] seemed to me to be the poor quality of the disclosure of 288 ... It could not be assumed that any β3-AR agonist would work, and it could not be predicted that the results for one would necessarily apply to another. ...
>
> This does not mean that the skilled addressee would positively think that mirabegron or the other Examples in 288 would not work, but it does mean that there would be a substantial degree of uncertainty.

If the problem-solution were used instead, with 288 as the closest prior art, the objective technical problem could have been defined as identification of an Agonist that was effective to treat overactive bladder. On the evidence before the Judge, the solution was not made obvious by 288 because it did not disclose to the notional skilled person that mirabegron was likely to be effective. This outcome should be uncontroversial.

However, imagine that instead the issue instead was whether or not a claim in 288 for mirabegron as an effective Agonist was valid? 288 **asserted** that mirabegron was an Agonist. If the skilled person were expected to have faith in that assertion, then the tribunal considering the validity of the claim would adopt the mantle of the same skilled person, read the same specification, and conclude that the claim was valid because the invention was disclosed in the specification.

This example illustrates how nonsensical outcomes would arise if a skilled person were to adopt a secular approach when considering the teaching of a patent specification when it is cited as prior art, but a religious, faith based, approach when its validity is in issue.

PREGABALIN

The case was about Warner-Lambert's patent for the use of pregabalin for the preparation of medicaments to treatment certain types of pain. As at the priority date, pregabalin was already known to be useful for treating seizure disorders. Claim 3 was for:

26 [1985] FSR 59.

27 Pozzoli SpA v BDMA SA [2007] EWCA Civ 588.

28 Teva v Astellas [2023] EWCA Civ 880 (25 July 2023).

> Use of [pregabalin] for the preparation of a pharmaceutical composition for treating neuropathic pain.[29]

As discussed above, a claim in this Swiss form requires that the compounds exhibits some degree of efficacy, though nothing in the claim could be taken as suggesting that the compound would need to meet the standards of efficacy and safety required for approval in a regulatory sense.[30]

The patent contained the results of an animal experiment, which suggested to a skilled person that pregabalin was effective in the treatment of inflammatory pain. It also referred to two well-known assays, designed by researchers Bennet and Kim, which could be performed to ascertain whether or not pregabalin was effective in the treatment of peripheral neuropathic pain (**PNP**). The patent did not say whether any of these assays had been performed.

The trial Judge found that:

> 1. A concept known as central sensitization was involved, at least as an amplifying mechanism, both in inflammatory pain and PNP.
> 2. If pregabalin was effective for the treatment of inflammatory pain because it overcame the problem of central sensitization, then it could also treat PNP since PNP was associated with central sensitization.
> 3. The patent accordingly made it plausible that pregabalin could treat PNP.

The Court of Appeal agreed that Warner-Lambert had done enough to make it plausible that pregabalin could be used to treat PNP. Floyd LJ explained:

> A test designed to prevent speculative claiming need go no further than requiring the patentee to show that the claim is not speculative: the specification does not need to provide the reader with any greater degree of confidence in the patentee's prediction than that.

Warner-Lambert argued in the Supreme Court that a patent needed some theoretical basis or experimental evidence in support of a second medical use claim only if the patentee's assertion that the compound was effective to treat the relevant medical condition was **inherently implausible**. The Supreme Court hearing the appeal was constituted by five law lords. The majority explicitly rejected this argument because, if it were accepted, it would follow that, if nothing was known either for or against the claimed therapeutic effect, then the patent would not need to contain any disclosure in support of it.

Lord Sumption, who gave the leading judgment of the majority, considered that the disclosure of the patent did not support a claim that pregabalin could treat PNP. He reasoned that, while it was known that central sensitization had a role in inflammatory pain and PNP, the experiment in the Patent did not show that pregabalin reduced inflammatory pain by influencing central sensitization. Further, the patent did not propose this as a theory. A skilled reader who closely read and considered the disclosure might well conclude that pregabalin worked for inflammatory pain because of its effect on a cause that was not shared with PNP.

In Lord Sumption's words:

> The rat paw formalin test, as I have said, models inflammatory pain. It shows a diminution of pain in the second phase, associated with the administration of pregabalin. But in the absence of anything in the specification about the effect of pregabalin on the mechanism of pain, there is no reason to suppose that the diminution of pain is associated with its effect on central sensitisation as opposed to its effect on any other agent of inflammatory pain.

So, while it remained **possible** that pregabalin could have an effect on PNP, the disclosure in the patent did not support any positive reason for supposing that it did.

> More generally, it cannot in my view be enough to justify a monopoly that it is "possible" *a priori* that a drug which was effective for inflammatory pain would also be effective for neuropathic pain, in the absence of any reason to suppose that the possibility had some scientific basis or that it was more than speculative. Everything is possible that is not impossible, but "not impossible" is very far from being an acceptable test for sufficiency. Plausibility may be easy to demonstrate, but it calls for more than that.

Warner-Lambert argued that the skilled reader would have been encouraged by the reference to the Bennett and Kim assays to carry out the tests, which could be done relatively easily, and thus establish that pregabalin did treat neuropathic pain. However, Lord Sumption considered that this submission just supported the conclusion that, while the patent posed a problem, it did not make any contribution to its solution.

In summary, Lord Sumption considered that "the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true". He thought that, as a matter of logic, this wasn't the case in Warner-Lambert's patent.

29 Neuropathic pain is pain sensation which arises by reason of something being wrong with the nerve itself as opposed to any external stimuli at the nerve ending.

30 Of course, it would be open for a claim to specify a minimum degree of efficacy and/or how efficacy is to be measured. See for example the discussion by the Full Court of the Federal Court of Australia in *AstraZeneca v Apotex* [2014] FCAFC [118] to [143], albeit in the context of entitlement. Method of treatment claims are permitted in Australia.

The minority of the Supreme Court thought that Lord Sumption's test could be read as "a requirement that the plausibility of the claim must appear to be established prima facie through scientifically cogent reasoning or experimental evidence set out in the specification", and was therefore a higher standard than EPO case law required. Lord Mance considered that EPO case law accepted:

> ... as sufficient a tailored claim which appears scientifically possible, even though it cannot be said to be even prima facie established, without for example testing or assays according to the state of the art. Only if a person skilled in the art would have significant doubts about the workability of the invention would it, in such a case, fail for insufficiency of disclosure.

Unfortunately, while the minority put the "plausibility" standard lower than the majority, they did not go on to explain why they thought claim 3 nevertheless failed to meet it.

In any event, the outcome of the case is that in order for a Swiss form claim to be valid in the UK, the patent must contain enough information to enable the notional skilled person to conclude, upon reading the patent application on the date it is filed, that the claimed product may well be useful as a treatment for the relevant medical condition. The test is not satisfied by a patent that contains merely assertion, but otherwise leaves the question open.

SUMITOMO[31]

The patent in Sumitomo is about insecticides. The relevant claim was originally for an insecticide composition comprising thiamethoxam (**T**) and another compound chosen from a class represented by a Markush formula. The Markush class covered approximately 10 million compounds.

Both T, and the Markush class, were separately known in the prior art as having insecticidal activity. However, according to the patent, the inventors had found that the claimed compositions were synergistic. The patent identified various species of insects which could be controlled by the compositions, including, among a long list, *Spodoptera Litura* (cotton leafworm), *Plutella xylostella* (cabbage moth), and *Chilo Suppressalis* (rice borer). The patent also contained two test examples, comprising a test of one composition against cotton leafworm, and another composition against cabbage moth, which were said to demonstrate a synergistic effect on the death rate of the pests. In both cases the two ingredients in the composition were present in equal amounts (a ratio of 1:1).

Since synergism was not a feature of the claims, the question of whether or not the effect was achieved across their scope was dealt with under inventive step.

During the opposition, the opponent filed experimental reports, showing compositions within the claims containing certain ratios of T and a compound within the Markush class (**C**), were not synergistic against cotton leafworm or cabbage moth, and at some ratios T and C were antagonistic. In response, the patentee filed an experimental report to show that a certain composition of T and C had a synergistic effect on the death rate of rice borer.

A key question for the TBA was whether the patentee's report (identified in the proceeding as D21) could be taken into account in relation to the assessment of inventive step. If not, based on the available evidence the compositions were not synergistic across the scope of the claim, and, in accordance with *Agrevo* "arbitrarily combining compounds known to have insecticidal activity to achieve an alternative insecticide composition does not require an inventive step."

On the other hand, if D21 could be taken into account, then, in the absence of any evidence from the opponent that compositions within the claims were not synergistic against rice borer, the TBA considered that "there was no reason not to acknowledge this synergistic effect against [rice borer] for other insecticide compositions covered by claim 1". Accordingly, "the objective technical problem would have to be [re-]formulated as the provision of an insecticide composition in which the insecticides act synergistically against [rice borer]", and an inventive step would have to be acknowledged.

The TBA reviewed numerous prior cases and identified conflicting approaches in them. A reference to the EBA was therefore appropriate. For the purpose of the reference, the TBA organised the cases into three categories:

> (a) Post published evidence can be taken into account only if, given the application as filed and the common general knowledge at the filing date, the skilled person would have had reason to assume the purported technical effect to be achieved. Examples of justification include experimental data or a scientific explanation in the application as filed (a*b initio* plausibility).
>
> (b) Post published evidence can only be disregarded if the skilled person would have had legitimate reasons to doubt that the purported technical effect would have been achieved on the filing date of the patent in suit. Such doubts may arise, for example, from the fact that either the application as filed or the common general knowledge on the filing date of the patent in suit give an indication that the purported technical effect can in fact not be achieved. In other words, post-published evidence must always be taken into account if the purported technical effect is not implausible (*ab initio* implausibility).
>
> (c) Plausibility is altogether rejected as a test for determining whether post published evidence of a beneficial effect can be relied on by the patentee (no plausibility).

31 T 0116/18 and G 2/21.

The TBA indicated in its reference to the EBA that the *ab initio* implausibility test was the right one.

Early in its reasoning, after setting out the problem solution approach, the EBA explained:

> The technical problem must be derived from effects directly and causally related to the technical features of the claimed invention. An effect could not be validly used in the formulation of the technical problem if the effect required additional information not at the disposal of the skilled person even after taking into account the content of the application in question.

This is another way of saying that the skilled person can't rely on "additional information", which is not contained in the patent, in order to identify how or why the invention is useful. The EBA then proceeded:

> According to the established case law of the boards of appeal ... it rests with the patent applicant or proprietor to properly demonstrate that the purported advantages of the claimed invention have successfully been achieved.

These paragraphs could be interpreted as the EBA squarely putting the onus on the patentee to include sufficient information in the specification to enable the skilled person to identify the invention's utility over the prior art, since he or she is not entitled to rely on "additional information" for that purpose.

However, there is another way of interpreting these paragraphs. In this alternative reading, the skilled person can rely on unsupported assertions in the patent about the claimed invention's utility, and then use those assertions in the formulation of the problem that the patent is said to solve. If the patentee is then called upon to demonstrate that the asserted utility is delivered, for example during opposition or examination proceedings, he can satisfy the onus by relying on post published information, which is, by definition, additional to that contained in the patent.

Such an interpretation would, however, be illogical. Why should the patentee be able to rely on technical information, not contained in the patent, about the synergy of the claimed compositions against rice borer, when the only experimental data was about cotton leaf worm and cabbage moth, and the opponent had already established, contrary to the assertion in the patent, that claimed compositions were not synergistic against them?

Nevertheless, the EBA's reasoning, particularly when distinguishing the role of "plausibility" in challenges to sufficiency compared with challenges to inventive step, and its critical conclusory paragraphs, leave open the possibility that this alternative, illogical, interpretation is the one that it intended to convey.

In relation to sufficiency, the EBA said:

> The reasoned findings of the boards of appeal in the decision referred to above make clear that the scope of reliance on post published evidence is much narrower under sufficiency of disclosure (Article 83 EPC) compared to the situation under inventive step (Article 56 EPC). In order to meet the requirement that the disclosure of the invention be sufficiently clear and complete for it to be carried out by the person skilled in the art, the proof of a claimed therapeutic effect has to be provide 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. A lack in this respect cannot be remedied by post-published evidence.

What role can post-published evidence have in inventive step cases, if it is not limited to bolstering an assertion that has already been made credible by information in the patent? The EBA's reasoning implicitly suggests that in inventive step cases, post published evidence can be relied on to bolster an assertion of utility that is not made credible by information in the patent.

As discussed above, whether an attack based on the paucity of information about the utility of an invention is considered under sufficiency or inventive step, depends on whether an integer requiring utility appears in the claims. In accordance with the EBA's reasoning, the patentee could be in a better position if he does not include such an integer in the claim. In other words, the quality of information in a patent application that is necessary to support a broad claim (susceptible to an inventive step challenge) might be lower than that required to support a narrow claim (susceptible to a sufficiency challenge).

The EBA then explained in its conclusionary paragraphs:

> Hence, evidence submitted by a patent applicant or proprietor to prove a purported technical effect relied upon for acknowledgement of inventive step of the claimed subject-matter may not be disregarded solely on the ground that such evidence, on which the effect rests, had not been public before the filing date of the patent in suit and was filed after that date.
>
> ...
>
> The relevant standard for the reliance on a purported technical effect when assessing whether or not the claimed subject-matter involves an inventive step concerns the question of what the skilled person, with the common general knowledge in mind, would understand at the filing date from the application as originally filed as the **technical teaching** of the claimed invention. The technical effect relied upon, even at a later stage, needs to be encompassed by that technical teaching and to embody the same invention, because such an effect does not change the nature of the claimed invention. [emphasis added]

In these paragraphs, the EBA's focus is on what the skilled person would understand to be the patent application's "technical teaching", and whether the invention's utility was "encompassed by that technical teaching", rather than whether or not the skilled person could derive the invention's utility without "additional information".

It seems likely that this change of language and emphasis was intentional. As a matter of language, it is more acceptable to describe a bare assertion in a patent that the invention has a particular utility as a "teaching", than as "information", about the utility.

Accordingly, these conclusionary paragraphs suggest that the EBA has adopted the abovementioned illogical interpretation of its own explanation of the problem solution approach.

Indeed, this is how the referring TBA has interpreted the EBA's opinion. In minutes of a hearing on 28 July 2023, which were published on 8 September 2023, the TBA held that the patentee could rely on D21. The minutes record:

> The parties were then heard on whether, in view of G 2/21, the [patentee] could rely on this synergism against [rice borer] shown in D21. The parties explained their understanding of order no. II of G 2/21 and the implications of that understanding for the facts of the case. ...
>
> After deliberation, the Chairman informed the parties that the Board – ... had concluded that the [patentee] could rely on the effect of synergism against [rice borer] shown in D21. ...
>
> After that, the Chairman explained that since the effect of synergism against [rice borer] shown in D21 could be relied upon, the objective technical problem could be formulated as the provision of an insecticide composition which acts synergistically against [rice borer], and in view of this an inventive step could be acknowledged, so that the main request was allowable.

Accordingly, the patentee has been permitted to rely on additional information, not disclosed in the application, nor derivable by the skilled person from the application, to establish inventive step. If the patentee had applied to amend the patent to include the information in D21, there is no doubt that the application would have been rejected, on the ground that the amendment would have added matter. Permitting the patentee to rely on the information in D21 without amending the application is equivalent to permitting added matter by the back door.

APIXABAN[32]

The patent in issue was for Apixaban *per se*. Apixaban is an anticoagulant, useful for the treatment of thromboembolic disorders. Thrombosis is the formation of a blood clot, and is one of the leading causes of death and disability in the world[33].

Claim 1 of the patent was for:

> A compound represented by formula 1 or a pharmaceutically acceptable salt thereof.

A purpose limited claim, was also discussed by the Court:

> A compound of claim 1 that is a factor Xa inhibitor for use in treating a thromboembolic disorder.

Apixaban is the only compound within formula 1.

The latter claim contains limitations relating to utility and purpose. However, according to the UK Court, it didn't matter which form of claim was in issue, and it didn't matter whether the validity challenge was considered under inventive step or insufficiency. In both cases, the asserted utility of the compound was as an anticoagulant, and the issue was whether or not the patent application contained information justifying that assertion to the skilled person.

It is worth pointing out, in order to illustrate how the approach in the UK differs from that in the EPO, that the trial judge (Meade J) made clear early in his judgment that post-published information was irrelevant to his assessment:

> [20] BMS emphasised that apixaban has proved to be a very important and widely used drug by virtue of being a potent and selective factor Xa inhibitor. Indeed its closing written submissions said that this was the "central" issue. BMS also relied on the researchers behind apixaban having been awarded the "Heroes in Chemistry Award" from the American Chemical Society.
>
> [21] I think those matters are irrelevant. I have to assess plausibility on the basis of the relevant specification for these purposes. Later findings about apixaban do not enter the picture. As to the award referred to, I am sure that it was merited, but I am equally sure that it was not given just for the work in [the relevant specification].

As at the priority date of the patent, it was common general knowledge that (a) a number of companies were actively searching for a synthetic Factor Xa inhibitor with sufficient potency, selectivity, and bioavailability to make it suitable for therapeutic use, (b) the structure of some promising molecules had been published, and, (c) for a Factor Xa inhibitor to be therapeutically useful, it needed a "nanomolar potency".[34]

32 *Sandoz v BMS* [2022] EWHC 822 (Pat) (Apixaban).

33 Blood clots cause heart attacks and strokes.

34 An IC_{50} value in the nanomolar range.

In a section headed "utility", the patent recorded:

> The compounds of this invention are inhibitors of factor Xa and are useful as anticoagulants for the treatment or prevention of thromboembolic disorders in mammals.

This statement was followed by descriptions of a relatively straightforward test for measuring the potency of factor Xa inhibitors, which was, in turn, followed by the following paragraph (at page 170):

> Compounds tested in the above assay are considered to be active if they exhibit [an IC_{50}] of ≤ 10μm. Preferred compounds of the present invention have [an IC_{50}] of ≤ 1μm ... Still more preferred compounds of the present invention have IC_{50}'s of ≤ 0.001μm. Using the methodology described above, a number of compounds of the present invention were found to exhibit IC_{50}'s of ≤ 10μm, thereby confirming the utility of the compounds of the present invention as effective Factor Xa inhibitors.

The patent also contained long lists of compounds, several Markush formula, and synthesis and characterizing data for 110 compounds. Example 18 of the patent described the synthesis of 3g of Apixaban, but no details of its activity were disclosed.

BMS submitted that the skilled reader would understand from the passage on page 170 that all (or at least most) of the 110 compounds synthesized had been tested, but accepted that the skilled reader would also infer that not all of the compounds tested were successful, and that some may have failed.

The Judge considered that it was impossible to draw any inference from the passage about the activity of a particular compound, whether apixaban or otherwise:

> In my view, the only statement of work actually done is that "a number of compounds" were tested and had [an IC_{50}] of 10 μM or less. The statements about lower IC_{50}'s for preferred/more preferred/still more preferred compounds are aspirational targets, and the statement that the utility of "the compounds of the present invention" was confirmed is an assertion that an inference can be drawn from the tests that were done. I understood that BMS accepted this.
>
> ...
>
> I note that there is no indication in this text itself of which or how many compounds were tested or with what specific result, and there is no reference to apixaban. BMS accepted this but said that the whole picture of the disclosure of `652 must be considered, and at that general level I agree. So, I must go on to consider the other later disclosure and the evidence before reaching any conclusion about this passage.

BMS therefore focused on Example 18, and emphasized that 3g was the largest amount of any of the compounds in the examples that was synthesized. However, the Judge thought that, of itself, didn't disclose anything more to the skilled person than, possibly, the patentee thought that apixaban could be promising. The skilled person would appreciate that there could be a number of reasons why a large amount was synthesized, for example it was easy to make and/or a useful intermediate in the synthesis of other compounds.

In any event, even if the arguments and evidence could have supported the proposition of Apixaban been active to the extent identified on page 170 (i.e. IC_{50} ≤ 10μM) it would not make it plausible that apixaban could be useful in therapy, because the skilled person would know that nanomolar potencies[35] were required for that.

Finally, the Judge was not impressed by the argument that simple tests were available to determine the potency and selectivity of the compounds of the invention. This was the equivalent to an argument that the Supreme Court had dismissed in Pregablin. That is, the argument

35 IC_{50} ≤ 0.001μM.

simply highlighted the absence of experimental information in the patent.

Accordingly, the Judge found the patent to be invalid.

BMS appealed. By the time of the appeal hearing, the EBA had published its opinion in Sumitomo. BMS submitted that the Court of Appeal was not bound to apply the test established by the majority of the Supreme Court in Pregabalin, because the claim was for a compound *per se*, rather than a second medical use, and therefore Pregabalin could be distinguished. Further, as far as possible the law in the UK should conform to that applied in the EPO, and the test advocated by the EBA in Sumitomo was more lenient than the Pregabalin test.

In response to these submissions, the Court of Appeal observed that many of the authorities considered by the Supreme Court were about patents for compounds. It decided that Pregabalin was binding.

The Court also observed that even if the appropriate test regarding the quality of disclosure was only designed to exclude speculative claims, it didn't understand how to determine whether or not a claim was speculative other than by assessing whether it was plausible. That is "[t]hey are two sides of the same coin."

In relation to whether or not the EBA's test was more lenient, the Court of Appeal set out the EBA's "concluding considerations" in full, and then explained:

> It is clear from these observations as well as the Enlarged Board's earlier reasoning that the fundamental consideration when a court or tribunal is considering whether a claimed invention involves an inventive step is whether the technical effect asserted by the patent applicant or proprietor is derivable by the skilled person from the application as filed read with the common general knowledge.

Later in the judgment the Court said:

> It is fair to say that the standard adopted by the majority [of the Supreme Court in Pregabalin] corresponds to the "ab initio plausibility" test identified in Sumitomo, while the standard espoused by the minority corresponds to the "ab initio implausibility" test. As discussed above, the Enlarged Board has taken the view in G 2/21 that the two approaches can be reconciled. I am bound to say that it seems to me that the divergence of opinion in the Supreme Court shows that the two approaches do not necessarily produce the same outcome. It also appears to me, however, that the harmonised approach adopted by the Enlarged Board, while eschewing the language of "ab initio plausibility" and "ab initio implausibility", is as a matter of substance much closer to the former than to the latter.

At the time of handing down its decision, the referring TBA in Sumitomo had not applied its understanding of the EBA' opinion to the facts before it. So, the Court of Appeal was not aware of the TBA's interpretation of the opinion.

In any event, for the reasons given above, while language used by the EBA early in its reasoning was consistent with the Court of Appeal's summary, the language in its concluding considerations was materially different. It shifted from whether or not the relevant technical effect could be derived by a skilled person from the application, to whether or not the technical effect was encompassed by the application's technical teaching. This leaves the door open for arguments in the EPO to the effect that skilled person is entitled to have faith in assertions made in patent specifications, and equate **unsupported assertions** of a technical effect to a **teaching** of that effect.

It is noteworthy that in addition to referring TBA in Sumitomo, the Court of Appeal of the Hague in the Netherlands interpreted the EBA's opinion in this way, in parallel litigation about Apixaban. For example, the Dutch Court of Appeal explained:

> According to Sandoz et al., the test formulated in G2/21 means that an alleged technical effect may only be invoked in the assessment of inventiveness if the average professional already understands from the patent application that the alleged effect is actually achieved by the invention and that the problem is actually solved, or at least that this is made plausible. That position is rejected.
>
> ...
>
> In this context, the EBA has in par. 77 of G2/21 considered that the possibility of relying on post-published evidence to demonstrate that the alleged effect actually occurs, compared to the assessment of inventiveness, is much more limited in the assessment of sufficiency of disclosure. In the case of an invention in which the technical effect achieved by it is included in the claim, such as the therapeutic effect in the case of a second medical indication claim, such evidence may only be taken into account if evidence of the alleged effect is already included in the application, in particular if, in the absence of experimental data, it is credible that the effect has been achieved. In the preliminary view, it is incompatible with that recital to interpret G2/21 in such a way that, in assessing inventiveness, the condition must be made that the alleged effect has always been demonstrated in the application, as advocated by Sandoz et al.
>
> ...
>
> Contrary to what Sandoz et al. argue, this interpretation of G2/21 by the court does not lead to a licence for speculative patents. Protection is granted on the basis of a purely speculative patent for an invention made only thereafter by requiring that the technical effect is already covered by the technical doctrine of the application and embodies the same invention revealed therein. Moreover, it is common ground that EP 415 does not constitute a speculative patent. BMS has undisputedly argued that the inventors had

> already experimentally established the favourable affinity and selectivity of apixaban prior to the filing of the patent application.[36]

The Dutch Court of Appeal decision is therefore a precedent for Courts in Europe, applying the EBA's opinion in Sumitomo, to consider that the "plausibility" test, which was intended to be generous for policy reasons to would-be patentees in second medical use cases, does not even have to be satisfied in other classes of cases.

The author would add that, while BMS may have established apixaban's favourable properties prior to filing its patent application, it kept that information secret and did not disclose it in the application. Of course, if it had subsequently applied to amend the patent application to include such information, there is no doubt that the amendment would have been rejected as "added matter".

CONCLUDING REMARKS

The requirement that assertions made in patents be plausible, simply reflects a requirement that a notional skilled person is expected to think rationally when assessing what is disclosed in the patent. Plausibility is not a ground of revocation, it is merely a convenient word against which to measure to the quality of information disclosed. Is the asserted utility plausible or not? The word "credible" could be used instead of "plausible".

Lord Sumption explained in Pregabalin, in the context of second medical use claims:

> The principle is that the specification must disclose some reason for supposing that the implied assertion of efficacy in the claim is true. Plausibility is not a distinct condition of validity with a life of its own, but a standard against which that must be demonstrated.[37]

Real researchers are more likely to read some journals than others, are more trusting of some resources than others, and, in some fields, may have technical prejudices. Real researchers think rationally, and do not have blind faith in assertions made in patent specifications[38]. In circumstances where the potential value of a patent monopoly provides significant temptation to would-be patentees to mischaracterise the work of their inventors and overstate their technical contributions, blind faith in assertions made in patent specifications would be a recipe for disaster.

Indeed, if it is not necessary for assertions made in patents to be supported by reasoning or results that make them credible or plausible, patents could cease to be a source of useful information. More and more patents will be filed containing assertions that may or may not turn out to be true. The potential value of the monopoly would be a sufficient justification for so called inventors to pay the patent office fees.

In the author's opinion, the EBA's reasoning and conclusions in Sumitomo comprise an invitation to use post published information in a way that is equivalent to allowing added matter by the back door. This is inconsistent with the fundamental principle, expressed in various ways across multiple areas of patent law, that in return for a monopoly a patentee must disclose an invention, not merely assert that he or she has made one.

36 Case number 200.327.532/01, at paragraphs 6.6, 6.9 and 6.12. This is not a professional translation of the passages. Rather, it is a rough translation of the passages into English facilitated by Google Translate.

37 At [36].

38 Just ask them!

Justin Lambert

Justin is of Counsel in Mishon de Reya's IP Disputes group. He is qualified as a solicitor in both Australia and the United Kingdom, and has over 20 years of experience in intellectual property matters in these jurisdictions. He has a background in science, having studied chemistry and pure maths, and focusses on contentious patent matters.