# What about plausibility and post-filed data? UK Patent Court has ruled on the matter.

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Until now, a patent could not be invalidated for lack of plausibility as such. However, the last UK Patent Court decision on this matter was handed down by Mr. Justice Meade on 7 April 2022 and in relation to Bristol Myers Squibb's (BMS) European patent No. EP1427415 (EP'415) and corresponding supplementary protection certificate (SPC).

As you might know, we are awaiting for the Enlarged Board of Appeal response on the question referred by the Board of Appeal of the European Patent Office on the relevant plausibility standards for European patents[1]. But in the meantime, the UK court has ruled on this burning issue, taking a position on the matter.

[1] See Referral to the Enlarged Board of Appeal – G 2/21

The answer to this question is not trivial, as it will serve to establish the criteria to determine what evidence a patent applicant must include in the patent application when filing it, and to what extend post-published date support claims made about the inventiveness of the process or product covered by the application.

This is certainly difficult to balance, as patent applicants want to obtain protection for potentially valuable inventions at the earliest possible date, but also need to ensure that the disclosure (rather through data or prior reasoning) is good enough to make the scope of the claimed invention plausible.

Turning to Mr Justice Meade's decision, it has revoked the afore mentioned EP'415 for "*Lactam-containing compounds and derivatives thereof as factor Xa inhibitors*". The invalidity action was brought by Teva and Sandoz on the grounds that the PCT application did not make it plausible that apixaban would have factor Xa binding to any useful degree

No reference to apixaban was done whatsoever. Hence, no prediction could be made based on the basis of its structure alone and, although it would have been difficult to test apixaban to prove its factor Xa inhibitory activity there was an absolute absence of making some showing. This translate into it not being made plausible.

Consequently, the patent was revoked due to the lack of plausibility because it was considered even though "a factor Xa inhibitor" purported to be included to remedy the lack of plausibility was formally allowable, it does not cure it.

Thus, in the UK Patents Court case the criteria is that an actual contribution by the patentee is required. That is, that the specification must be sufficiently disclosed, as the contribution of post-filing data would be strictly limited. This twist by the English courts definitely puts some pressure on the company to apply for patent protection and could increase the requirement to meet the plausibility threshold. Although, given the circumstances, this decision would, in all likelihood, be appealed.

In the case of the European Patent Office and the level of disclosure required for medical use, the most commonly applied approach is indeed that the technical effect is "plausible" from the original application or patent. To fulfil the requirement of Art. 83 EPC, the patent has to disclose the suitability of the product to be manufactured for the claimed application. Thus, the therapeutic application may be proven by any kind of evidence as long as it reflects the therapeutic effect on which the therapeutic application relies. In the case of a claim to a second medical use, the requirement of sufficiency of disclosure is considered as fulfilled with respect to a claim to a second medical use if the disclosure in the patent or the common general knowledge enable the skilled person to obtain the compound to be applied and to apply it, and if there is evidence that the intended therapeutic effect can be achieved.

Following this approach and UK Patents Court's decision, it would be surprising if the Enlarged Board of Appeal were to consider that the requirement can be relaxed and that, although not specifically include on the content of an application, post-filed date could be taken into account. Anyhow, this does not mean that the opponent can submit data in any circumstances to show that a technical effect is not plausible from a patent application, nor may the patentee use their own date if the "plausibility" requirement is not met by the content of the original application.

It should be borne in mind that, so far, from UK's point of view (as well as in Spain), plausibility was not an independent ground of objection to the patent validity. Rather, it was generally regarded as an element of "sufficiency" at the date of the application. A condition that can be met by a credible disclosure, the aim of which is to avoid filing speculative patent applications without disclosing a real contribution to the art.

In any event, many cases stay until the questions are answer by the Enlarged Board of Appeal. Whether or not they will follow the UK Patent Court's approach is still an unknown, but it seems that the approach to plausibility is increasingly homogeneous among the most relevant patents courts.