

Highlights from the UK Patents Court 2022: Validity

It is almost invariably the case that a standard patent dispute should entail the question of infringement and validity. Leaving the updates on Infringement to fellow IP Federation associate Alex Calver of WilmerHale, we will focus on validity.

Obviousness

The principles governing the assessment of obviousness have been looked at by the courts in some depth in recent years. Fundamentally there is a single question. Is it obvious? Aside from the question as to whether it is possible to infer the nature of the skilled person from what the specification assumes about his/her abilities (Meade J said no in *Optis v Apple*, Mellor J said yes in *Alcon v AMO*), we have a fairly extensive and consistent body of case law explaining the law on obviousness and illustrating its application. The attribution of the characteristics of a skilled person is an important point though, as noted by Birss J (as he was then) in the Illumina case: "It would be wrong and unfair to the public to define a team so widely that that their common general knowledge is so dilute as to make something seem less obvious than it really was". Defining the attributes of a skilled person would equally impact the assessment of sufficiency, as noted by Mellor J in *Alcon v AMO*.

Novelty

The same goes for novelty. We all know that to anticipate, the prior art disclosure must 'plant the flag', and that still holds true. Perhaps it is worth adding that Mellor J reminded us that "...the notion that one cannot strip out inconvenient detail from the prior art applies also/especially in the context of anticipation" in *CommScope Technologies v SOLiD Technologies*.

Sufficiency

In recent years, in keeping with the rapid developments in the case law, the UK Patents Court has focused in some detail on the state of play with respect to sufficiency. There is an outstanding point, on the date at which sufficiency is to be assessed, which remains ripe for review by the higher courts, but nothing significant has happened on that issue in 2022. Instead, judgments in 2022 indicate that the governing principles have largely settled too, but for the purposes of this publication, we have cherry-picked a couple of interesting judgments worth raising in relation to *Classical Insufficiency* and *Biogen Insufficiency*.

Classical Insufficiency

Classical insufficiency arises when the directions in the patent are inadequate to enable the person skilled in the art, using their common general knowledge (CGK), to perform the invention without undue burden.

In *Saint-Gobain Adfors v 3M*, the case about 3M's patent to dish-shaped abrasive particles with a recessed surface area, Michael Tappin QC illustrated the application of the classical type of insufficiency as it now stands. Saint-Gobain's challenge was that the skilled person could not, without

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undue burden, produce particles with an average 'Tc/Ti' ratio at the upper end of the claimed range. Michael Tappin QC held that the claimed range of 1.25–5.00, for the average ratio, was a relevant range, so, the patent would be insufficient if it did not enable a skilled person to make, without undue burden, abrasive particles *at both the upper and lower end of the claimed range*.

In the context of the undue burden challenge, 3M sought to rely on a cross-reference to a US patent contained in 3M's patent. The document explained that, depending on process parameters, the same identical production tooling could produce abrasive particles of the requisite character. However, the judge said that the *"fundamental problem"* for 3M was that none of this was addressed by its expert in his reports, nor put to Saint-Gobain's experts in cross-examination. The judge stated:

"My understanding is that in order for a skilled person to consult a document for a particular purpose, it must be made clear that the skilled person should consult a document for that purpose. Further, in my judgment, the question of what a skilled person would do, when faced with a cross-reference and the document cross-referred to, is one on which expert evidence is admissible, and indeed required if a party wishes to establish that the skilled person would alight on particular text and find it of assistance in a particular way."

It follows, for 3M to have succeeded on this point, evidence would have been needed that the skilled person would have alighted on the passages relied upon and would have appreciated that they would provide a solution to the problem, namely of making dish-shaped abrasive particles with an average Tc/Ti ratio towards the upper end of the claim. The judge said that the *ability to make particles at the top of the range needed to be "abundantly clear*".

Excessive claim breadth / Biogen / lack of plausibility insufficiency

The '*Biogen'* / 'excessive claim breadth' / lack of plausibility type of insufficiency is met where the extent of the monopoly claimed exceeds the plausible technical contribution to the art made by the invention as described in the specification. The question of whether the specification adequately discloses the invention is one of degree. It is permissible to define an invention using general terms provided the patent discloses a principle of general application in the sense that it can reasonably be expected the invention will work with anything falling within the scope of these terms. This '*reasonable prediction*' test is approached by adopting a three-step test

- First, identify what it is which falls within the scope of the claimed class
- Second, determine what it means to say that the invention works what is it for?
- Third, determine whether it is possible to make a reasonable prediction that the invention will work with substantially everything falling within the scope of the claim?

In 2022, in *Sandoz v BMS*, Meade J concluded that BMS' patent to apixaban was invalid for lack of plausibility. The judge said that, *in order for a patent not to be insufficient for excessive claim breadth*, it must be possible for the person skilled in the art to make a reasonable prediction (i.e.: plausible or credible) *that the invention will work with substantially everything falling within the scope of the claim*. What it means for the invention to "work" is to be determined from the specification where the claim is not explicit (although the patentee is not restricted to the most ambitious assertion made).

When considering insufficiency the court is addressing a patent which has been granted and is required to start from a presumption of validity – the burden should be on the challenger to prove that the patent is invalid. However, it seems that the burden of proof seems to have been placed on the patentee in this case.

Page 3 of 3

Summary and conclusions

While the recent jurisprudence relating to insufficiency has largely settled UK law in this area including by reference to principles developed in the European Patent Office, some aspects of the law present challenges for patent owners seeking patent protection at a relatively early stage of R&D. In 2022, a patent supposedly protecting a medicament that does, in fact, "work" has been found invalid for lack of plausibility in the disclosure of the specification. Indeed, there is a downside for a patentee in seeking early protection – the patent expires sooner. However, the opportunity to acquire enforceable monopoly rights is at the heart of the patent system and stimulates technical progress. This area of patent law may yet benefit from being revisited by the Supreme Court in 2023.

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Some of the content within this article is covered in more detail at Gowling's annual patents review, <u>A Slightly Slippery Slope</u>.