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Sandoz v BMS – Court of Appeal grapples with plausibility again

Sandoz Limited v Bristol-Myers Squibb Holdings Ireland Unlimited Company; Teva Pharmaceuticals Industries Limited v Myers Squibb Holdings Ireland Unlimited Company [2023] EWCA Civ 472

The Supreme Court in Warner-Lambert v Actavis confirmed the principle that a patent specification must render plausible, at the filing date of the application, that the technical effect embodied in the claimed invention can be achieved. This has become treated in English cases as a free-standing requirement for "plausibility", whereas it is better understood as referring to a threshold of evidence which, if not met, will lead to a finding of lack of inventive step and/or enablement.

As we reported in a prior post, the Enlarged Board of Appeal of the European Patent Office in its decision G2/21 decided that, contrary to what has been stated in many prior Technical Board of Appeal decisions, plausibility is the wrong way to think about this issue. Rather, it should be considered whether a technical effect relied on is one which the skilled person would derive "as being encompassed by the technical teaching and embodied by the same originally disclosed invention". However, this decision was limited to inventive step, and in particular whether the technical effect could then be evidenced by later-filed data. It was explicitly conceded that in relationship to enablement, the relevant test might be different.

Following this, English courts are faced with binding Supreme Court precedent stating that plausibility is a requirement for a valid patent, and an Enlarged Board of Appeal decision stating that it is not. The Court of Appeal was faced with how to reconcile the two.

The case related to a patent EP(UK)1427415 with a compound claim for apixaban.

Apixaban is used as a blood thinner. The main question at issue was whether the patent rendered it plausible that the compound was an effective factor Xa inhibitor, and hence a useful therapeutic for thromboembolic disorders. The patent application disclosed no specific data, stating only "a number of compounds of the present invention were found to exhibit a Ki of <10 μM, thereby confirming the utility of the compounds of the present invention as effective Xa inhibitors".

Arnold LJ, giving the judgment of the court, had a chance to distinguish the Supreme Court decision of Warner-Lambert v Actavis, which related to a second medical use claim, but instead ruled that "the underlying principles [of the requirement for plausibility] are applicable as much to claims to single chemical compounds as to claims to classes of compounds and second medical use claims." He therefore considered the Court of Appeal was bound by the majority decision in Warner-Lambert v Actavis.

It was therefore not necessary, strictly, to attempt to reconcile that decision with G2/21, but Arnold LJ nevertheless grappled with the apparent divergence. He equated the tests of "ab initio plausibility"[1] and "ab initio implausibility"[2], which were considered and both rejected as being the relevant consideration by G2/21, as in essence corresponding to the tests espoused by the majority and minority decisions, respectively, in Warner-Lambert v Actavis. Nevertheless, he considered that the test established in G2/21 "is as a matter of substance much closer to the former than to the latter."

Having held that the plausibility standard remained unaltered, Arnold LJ found that the first instance judge had applied it correctly. The patent application "gives the skilled team no reason for thinking that there is a reasonable prospect that the assertion [that apixaban is a factor Xa inhibitor] will prove to be true. It is therefore speculative." Accordingly the appeal was dismissed and the finding of invalidity of the patent was upheld.

Darren Smyth, Head of Knowledge

[1] According to which post-published evidence could be taken into account if, based on the information in the application and the skilled person's common general knowledge, the skilled person would have considered the technical effect plausible

[2] According to which post-published evidence could be taken into account if, based on the information in the application and the skilled person's common general knowledge, the skilled person would not have considered the technical effect implausible