

EIP



Obvious to try in all but name?

The applicability of the obvious to try question has been a thorny issue in UK patent law for some time, and the desire for a party seeking invalidity to apply this test has pervaded many recent pharmaceutical patent cases in the UK, particularly where the patent claims a single enantiomer and the prior art indicates that the racemate is pharmaceutically active, or more generally where the compound of the claim was previously disclosed as part of a larger group of potential compounds.

In Medimmune Ltd v Novartis Pharmaceuticals UK Ltd & Ors [2012] EWCA Civ 1234, the Court of Appeal of England and Wales made clear that whether a particular step was obvious to try (or not) was not a replacement for the statutory test of whether the invention was obvious. Indeed practitioners' use of this mantra instead of the statutory test came in for some specific criticism from Lewison LJ. However, the leading judgment of Kitchen LJ still acknowledges that an assessment of whether a particular approach was "obvious to pursue" with a "reasonable or fair expectation of success as opposed to a hope to succeed" can be an appropriate manner of assessing the statutory obviousness question.

This latter point is reiterated in the more recent judgment of the Court of Appeal in Novartis AG v Generics (UK) Ltd (t/a Mylan) [2012] EWCA Civ 1623, which shows that where the skilled person or team has multiple pathways to take from the prior art, one of which leads to a claimed invention, the court cannot seem to avoid having to ask whether that particular step would be obvious to take/try/attempt/pursue as part of the overall assessment of obviousness. Indeed a finding that it would be obvious to take a particular compound forward for development, and subsequently obvious to attempt to resolve the individual enantiomers of that compound, lead to the overall finding of obviousness under the statutory question.

The patent-in-suit claimed the (-) enantiomer of N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate for the treatment of Alzheimer's disease. The racemate had been disclosed in two prior publications as being one of several compounds proposed for the treatment of Alzheimer's disease. The question was whether it would be obvious to select this particular compound (RA7) from those in the prior art, resolve it, and use the (-) enantiomer as a medicinal product for the treatment of Alzheimer's disease. In answering these questions, the judge at first instance concluded that:

- there was nothing inventive in deciding to resolve and test RA7 to see if there were advantages or disadvantages associated with one of its enantiomers;
- the separation would only involve trivial chemistry; and
- a pharmaceutical composition for the treatment of Alzheimer's disease comprising the (-) enantiomer was conceptually obvious.

Having lost their patent at first instance, Novartis sought to argue on appeal that the first instance judge (Mr Justice Floyd) had incorrectly applied the test for obviousness.

Counsel for Novartis argued:

- a) that Floyd J had used the obvious to try test (in finding that it was obvious to try the individual enantiomer for a particular therapeutic purpose) but that in doing so he had failed to consider whether the skilled team would have had a fair expectation that the undisclosed chemical entity would successfully treat Alzheimer's disease; and,
- b) in any event that test was not applicable as it only applies where it is more or less self-evident that what is being tested ought to work.

The Court of Appeal compared the approach taken by Floyd J with the test in *Medimmune*, and found that:

“...the judge directed himself correctly as to the law and in a manner which is entirely consistent with the principles explained by this court in MedImmune... He then applied these principles to the facts of the case and assessed first, whether it was obvious to take RA7 into development; and second, whether it was obvious to attempt to resolve it. He answered both these questions in the affirmative. As for the former, it required no insight or invention to follow the teaching of Professor Weinstock, to take the compounds she disclosed as having promise and meeting her criteria for an improvement over physostigmine and to investigate whether that promise translated into a useful therapeutic effect. As for the latter, the skilled team would consider that resolution of the racemate might bring practical benefits and would see resolution as a routine step. The approach adopted by the judge reveals no error of law. To the contrary, he approached the matter entirely properly...” (emphasis added)

Limiting the application of its own judgment in Saint-Gobain v Fusion Provida & Electrosteel [2005] EWCA (Civ) 177, the Court of Appeal also rejected the submission that the court can only make a finding of obviousness (when considering whether it was obvious to try a particular test with a reasonable or fair expectation of success) when it is manifest that the test ought to work.

As can be seen from the highlighted terms in the passage from Novartis quoted above, the finding of obviousness was founded upon the judge concluding that particular steps were obvious to take/try/attempt/pursue. Thus despite Lewison LJ’s observation in Medimmune that “questions of the degree of expectation of success and the length of time thought to be needed to undertake a trial have taken on lives of their own” and desire to fall back to the statutory question, it seems that, for the time being at least, these are questions that the UK Courts are going to have to address one way or another. Although the ultimate question is whether a claim is obvious, and although use of the obvious to try test has been disclaimed as a replacement, in arriving at the answer to that ultimate statutory question it is apparent that for cases such as Novartis v Mylan, the underlying question will be whether the step was obvious to try/take/pursue/attempt (with a reasonable or fair expectation of success).

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