

# Kluwer Patent Blog

## Clarity on Plausibility

Brian Cordery (Bristows) · Tuesday, November 17th, 2015

Mr Justice Carr has only been sitting as a full time judge for just over a month and yet in his decision of 16 November 2015, he has already produced what this author considers to be a sensible, but thought-provoking judgment that is readable and comparatively concise.

The case involved a challenge by the well-known generics company, Actavis to a patent owned by Eli Lilly with Swiss type claims to the use of tomoxetine in the manufacture of a medicament for treating attention-deficit/hyperactivity disorder (ADHD). Tomoxetine is the active ingredient in Lilly's Strattera medicine which is commercially successful in the UK. The patent was challenged on numerous bases including lack of inventive step over two cited pieces of prior art, lack of plausibility leading to a finding of obviousness or insufficiency on the basis of lack of technical contribution and lack of entitlement to priority plus intervening prior art.

Ultimately, the Judge dismissed Actavis' challenge and found the patent valid. Lilly's counterclaim for threatened infringement succeeded.

Carr J's discussion on the issue of inventive step is noteworthy. The Judge reminded himself of the fact that the assessment of this issue is multi-factorial and that attention must be focused on the claimed invention. He added a colourful quotation from Jacob LJ in the Ultraframe case from 2005 that: "*Before the court gets to the examination room it has to do some swotting: to get into its mind the relevant knowledge of the skilled man. For how a document will be understood depends on the reader.*" Carr J also commented on the so-called "obvious to try" test and its significant limitations. Overall, it was considered that the cited prior art did not render the invention obvious.

Although the discussion on inventive step over the prior art was interesting, it was eclipsed by the commentary on plausibility. On this issue, the relevant facts were that Lilly's patent under challenge disclosed for the first time that tomoxetine was effective in the treatment of ADHD. It disclosed the mechanism of action of tomoxetine as a norepinephrine reuptake inhibitor and cited a relevant paper in support. However no data were present in the patent to support the assertions of safety or efficacy.

Actavis contended that there was a squeeze between lack of inventive step and lack of plausibility. It alleged that the patent contained no more than a bald assertion that tomoxetine was effective and safe for the treatment of ADHD. It claimed that insofar as the patent disclosed a theory to support that assertion, it was known from the prior art. Such a line of attack has become increasingly common in the English Patents Court and on some occasions, the challenges have been successful. However, Carr J took the opportunity to emphasise that plausibility challenges must be kept under

control. He noted:

*“There is no requirement in the EPC that a patent should contain data or experimental proof to support its claims. The reference in **Salk** (T609/02) to the provision of experimental tests to support the claimed therapeutic use was by way of example. In respect of claims to therapeutic applications which are of wide scope, such experimental tests may well be required. In the case of narrow claims, they may not be.*

*In my judgment, the policy considerations underlying plausibility for sufficiency are different from those underlying fair expectation of success for obviousness, which indicates that the standard for assessment of plausibility is not the same as assessment of obviousness. For obviousness, a fair expectation of success is required because, in an empirical art, many routes may be obvious to try, without any real idea of whether they will work. The denial of patent protection based upon the “obvious to try” criterion alone would provide insufficient incentive for research and development in, for example, pharmaceuticals and biotechnology, and would lead to the conclusion that a research program of uncertain outcome would deprive a patent of inventive step. The reason why the court requires that the invention of a patent should be plausible is different. It is to exclude speculative patents, based on mere assertion, where there is no real reason to suppose that the assertion is true.*

*The cases on which Lilly relies (to which I have referred above) establish that the test of plausibility is a threshold test which is satisfied by a disclosure which is “credible”, as opposed to speculative. That disclosure may be confirmed or refuted by further evidence obtained subsequent to the priority date. If it is subsequently shown that the invention does not work with substantially all of the products or methods falling within the scope of the claim then the scope of the monopoly will exceed the technical contribution and the patent will be invalid. This indicates why plausibility is only a threshold test. A plausible invention may nonetheless be shown to be insufficient. In my judgment the standard for assessment of plausibility is not the same the standard for assessment of expectation of success in the context of obviousness.”*

In the author’s personal view, this clarification is to be welcomed. There was a danger of plausibility taking on a life of its own and assuming a level of importance that was probably not intended by the House of Lords in **Conor v Angiotech** [2008]. Carr J’s approach is much more aligned with the EPO approach as demonstrated in e.g. T578/06 (Ipsen) and makes it clear that the assessment for plausibility is not the same as that for expectations of success in obviousness – the former is a much lower hurdle.

As noted at the start of this short commentary, this is one of the first judgments from the English Patents Court’s most recently appointed judge. Let’s hope it is a taste of what is to come.

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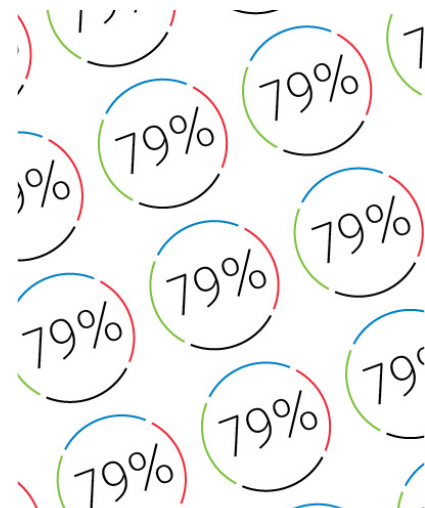
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