Kluwer Patent Blog

Leo Roars Again

Brian Cordery (Bristows) · Friday, August 7th, 2015

The end of July always brings a flurry of decisions from English Patents Courts at all levels as the Judges, understandably, seek to clear their desks before the summer vacation. This year was no exception with at least half a dozen judgments concerning patents being handed down in the space of two weeks. Among them was a gem from the Court of Appeal in the **Teva v Leo** [2015] EWCA 779 case in which the substantive judgment was given by Sir Robin Jacob with whom Kitchin and King LJJ agreed.

One of the most pleasing aspects of the decision is its length – a mere 9 pages including the cover page. It is also easy to read with Sir Robin, in customary style, deploying short sentences, colourful English idiom and short extracts from the first instance proceedings to aid readability.

In overturning the finding of Birss J that Leo's patents to an ointment consisting of two active ingredients (calcipotriol and betamethasone), a base and the solvent Arlamol E were obvious, the Court of Appeal touched on two central concepts of the assessment of inventive step in the English Courts. The first was in relation to expectations of success. Sir Robin underlined that an invention will only be held to lack inventive step when it was not only obvious to try but also where there was a fair expectation of success. In this case, the skilled person would know that to formulate the two active ingredients it would be necessary to use a non-aqueous solvent but it was not established that any non-aqueous non-toxic solvent would work. Birss J had found that the skilled formulator would try about 10-20 different solvents but it was not proven that there was a good expectation that one of the 20 would be suitable. In these circumstances, the use of the solvent Arlamol E, which was not used significantly in topical pharmaceuticals, and which did not form part of the common general knowledge of the formulator, was not obvious. Birss J's decision amounted to a finding that the idea of including Arlamol E as part of a research project amounted to obviousness. As Sir Robin pointed out, the obvious to try standard requires a higher expectation of success than that.

The second point of importance, which is related to the first, is that the Court of Appeal emphasised that for the assessment of inventive step, the skilled person is imbued with the real prejudices and practices of those working in the field. So just as the bag-ridden mindset of the skilled person helped Dyson succeed in its case against Hoover in 2002, so Sir Robin held the skilled formulator's strong preference to work with compounds that he or she was familiar with was an important consideration which the Judge had been wrong to overlook.

Having established that the first instance court had made an error of principle, the Court of Appeal

revisited the question of obviousness de novo and, relying on, among other things, the long-felt want for the product and that no explanation of why the solution had not been made when it could have been, held that this was "*the classic sort of case where the courts have found invention over the years*". The added matter and insufficiency allegations were quickly dismissed.

So Leo have their patents and must be very pleased with the result – the second time that they have had a successful outcome in the English Courts in recent years – the last time being in 2009 when Jacob LJ (as he then was) upheld a Leo patent to a crystalline form of calcipotriol in the face of an obviousness attack.

It is not uncommon to see one or two Patents Court decisions handed down in August and September although things will inevitably quieten down in this period. A lot of activity is expected at the start of October, not least the decision of Arnold J in the Lyrica (pregabalin) case concerning second medical use and skinny label issues. One suspects that this judgment will not be written in fewer than 10 pages…

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