Kluwer Patent Blog

Court of Appeal confirms revocation of Herceptin formulation patents

Brian Cordery (Bristows) · Wednesday, August 3rd, 2016

The end of July traditionally brings a flurry of patents judgments from the English Courts. This year was no exception, hence the large number of posts in the last few days. Among this year's flurry was a decision handed down by the Court of Appeal on 27 July 2016 in **Hospira v Genentech** ([2016] EWCA Civ 780) which concerned two formulation patents for the monoclonal antibody trastuzumab (Herceptin®). Genentech had appealed the decision by Birss J in November 2014 that the patents were invalid for obviousness and added matter. In the lead judgment by Floyd LJ, the Court of Appeal dismissed the appeal, finding that Birss J had not fallen into any error of principle which would justify the Court of Appeal interfering with his decision on obviousness, and therefore the added matter point did not need to be considered.

Hospira's case on obviousness relied on prior art which disclosed trastuzumab was in phase II clinical trials for the treatment of breast cancer. Hospira argued that the prior art would motivate the skilled person to develop a lyophilised formulation of the drug which, using the skilled person's common general knowledge (CGK), would lead to the solution claimed in the patents. In accepting this argument, Birss J held that although it could not be said that the skilled team would arrive at the patented formulation without undertaking a screening programme, arriving at the formulation using the CGK would not have involved any inventive effort.

In dismissing the appeal, Floyd LJ considered the could/would approach to inventive step, and said that he did not consider it necessary in every case for the court to conclude that the skilled person acting only on prior art and the CGK would arrive without invention at the precise combination claimed. In this case, the skilled team would have conducted the screening programme with the expectation that they would identify a suitable formulation, and to require the team to predict in advance which precise combination would be successful was "wholly unrealistic". This was a case where the skilled person would expect some good results and some bad ones from the screening process and, the fact that the skilled person could not say which ones would be good in advance did not prevent a finding of obviousness. Floyd LJ did note, though, that in many cases the fact that routine screening could be carried out will not be enough to render a patent obvious

This case was distinguished from last summer's judgment from Sir Robin Jacob in **Teva v Leo Pharma** ([2015] EWCA Civ 779), where Birss J's decision on obviousness had been overturned, Floyd LJ stating in this case that the facts were very different. Floyd LJ noted that he was reminded of a citation from an old case, **Savage v Harris and Sons** (1896) 13 RPC 364, which stated that "*cases, so far as regards the law, are most useful, but when they are applied to particular facts,*

they, as a rule, are of little service. Each case depends on its own particular facts and the facts of almost every case differ".

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