The best things in life are unexpected because there were no expectations (Eli Khamarov)

Kluwer Patent Blog
July 2, 2015

Brian Cordery (Bristows)

Please refer to this post as: Brian Cordery, 'The best things in life are unexpected because there were no expectations (Eli Khamarov)', Kluwer Patent Blog, July 2 2015, http://patentblog.kluweriplaw.com/2015/07/02/the-best-things-in-life-are-unexpected-because-there-were-no-expectations-eli-khamarov/

Apart from the enthralling Lyrica saga which began in earnest back in January, and the main trial of which recently began before Arnold J, 2015 has not witnessed many significant pharmaceutical patent decisions from the UK patents courts. Thus, three cases in this field which, rather like London buses, arrived almost simultaneously, have provided welcome food for thought to life sciences patent enthusiasts.
The three cases were **Smith & Nephew v Convatec** (24 June 2015) and **Eli Lilly v Actavis** (25 June 2015) from the Court of Appeal and a decision from Arnold J in **Hospira v Genentech** (24 June 2015), part of the on-going campaign to clear the way in respect of certain Genentech patents relating to Herceptin.

We will report on the Court of Appeal cases later in the week but this first review will look at Arnold J's decision which although, at a mere 30 pages, is short by the standards of England's Senior Patents Judge, contains a number of interesting points.

On this occasion Hospira challenged Genentech's patent to the use of the antibody, trastuzumab (the active ingredient in Herceptin) in combination with a taxane in the treatment of HER2-positive breast cancer. Taxanes are a class of chemotherapeutic agents which include paclitaxel and docetaxel.

Hospira alleged that Genentech's patent was either anticipated or obvious over a single piece of prior art referred to as "Baselga 97". Baselga 97 was a paper describing, among things, "positive" and "encouraging" results in a Phase II clinical study using a combination of trastuzumab in combination with doxorubicin and paclitaxel and the fact that a Phase III was on-going.

Before assessing the allegations of invalidity, Arnold J considered several points of construction. Two are of particular interest: the first, relatively settled, point was that a second medical use claim imported clinical efficacy as a functional technical feature of the claim. This followed a long line of decisions from the EPO and several UK authorities including the UK Court of Appeal in **Regeneron**. Secondly, following the guidance of the Court of Appeal in the Lyrica case, Arnold J held that "for" in a second medical use claim imported a mental element namely that it was known to, or reasonably foreseeable by, the manufacturer that the antibody would be intentionally administered in combination with a taxane for the relevant therapeutic purpose.

Having dealt with the construction issues, Arnold J then looked at novelty and obviousness in turn. Starting with novelty, the Judge first noted that there are two requirements – disclosure and enablement but that only disclosure was in play in this dispute.

On the question of the novelty of a claim including a specified therapeutic effect, Arnold J followed a long line of jurisprudence from the EPO starting with **T158/96** that the prior disclosure of the existence of clinical trials does not anticipate a claim which includes the specific therapeutic effect revealed by the results of that clinical trial unless the therapeutic results can be derived directly and unambiguously from the prior disclosure.

Arnold J then looked at purpose limited claims and, following the leading House of Lords authority of **Synthon** held that such claims could be anticipated by either (i) disclosure of the invention, or (ii) disclosure of subject matter which, if performed, would necessarily infringe the claim under attack (so-called "inevitable result" anticipation). On the facts before him, Arnold J did not think that the invention was disclosed by Baselga 97. Turning to the inevitable result attack, the Judge described this as "more persuasive" but considered that the mental element of the claim was missing – one could not intend to administer the combination of trastuzmab and a taxane to achieve increased efficacy in the treatment of breast cancer unless one knew that the clinical benefit would be obtained.

So far, so good for Genentech. However in relation to obviousness, Hospira persuaded Arnold J that Genentech's patent lacked inventive step over Baselga 97. Arnold J's summary of the law was clear and relatively uncontroversial – noting that the issue of obviousness is multifactorial and explaining that what was required was a "fair expectation of success" on the part of the skilled person if he were to pursue a particular approach – was the glass half full or half empty as the Judge put it? Arnold J set out his findings on many issues which played a role in his assessment of obviousness, including motivation, the nature of the work and the effort involved, the alternative routes which could be pursued and any "lions in the path" (i.e. perceived prejudices which would deter a skilled person from pursuing the route taken by the inventors). Taking into account the evidence from both experts, including the fact that Genentech's expert had, upon reading the Investigator's Brochure for the Phase III trial which contained equivalent information to Baselga 97, decided to participate in the trial and to enrol his patients in it, the Judge considered that there was a fair expectation of success and thus the patent was obvious.

It is not yet known if Genentech will appeal the finding of obviousness or if Hospira will appeal the ruling on lack of novelty. In the author's view, the ruling on anticipation accords with a long line of similar cases at the EPO and common sense – the essence of a second medical use invention is in the clinical efficacy which will only be known once at least preliminary data are available. It seems that the issue of obviousness was more finely balanced but ultimately Arnold J considered that the skilled person would have had a fair expectation of success based on all evidence before him. Such a factual finding may not be easy to overturn.