Kluwer Patent Blog

Biotech patent fails for insufficiency – Eli Lilly and Company v Janssen Alzheimer Immunotherapy – 25 June [2013] EWHC 1737

Brian Cordery (Bristows) · Friday, July 19th, 2013

It could be argued that 2013 is proving to be somewhat unkind to UK patentees when it comes to the issues of sufficiency and priority. On 25 June 2013, in a typically comprehensive judgment running to some 90 pages, Arnold J held that Janssen's patent was invalid for insufficiency.

The relevant facts were as follows: Janssen is the owner of EP (UK) 1 994 937 (the "Patent") entitled "*Prevention and treatment of amyloidogenic disease*". The Patent discloses and claims pharmaceutical compositions comprising an antibody to ?-amyloid peptide (a type of protein plaque that builds up in Alzheimer's disease patients' brains – the theory being that an antibody to ?-amyloid peptide might serve to reduce the plaque deposits and ameliorate the symptoms of Alzheimer's disease). Lilly sought an order for revocation of the Patent (on grounds of added matter, lack of novelty, obviousness and insufficiency) and a declaration that dealings in pharmaceutical compositions comprising an antibody called solanezumab (which Lilly currently has in Phase 3 development for the treatment of Alzheimer's disease) would not infringe the Patent.

Lilly argued that claim 1 of the Patent was anticipated by an international patent application from 1996 ("Konig"). However Janssen argued that Konig did not disclose an antibody to the specific isotype of the ?-amyloid peptide covered by claim 1. Further, it argued that Konig does not disclose use of a "pharmaceutical composition comprising" the antibody in preventing or treating a disease characterised by amyloid deposit. Arnold J agreed with Janssen and also dismissed the allegations of added matter.

On the obviousness attack, Arnold J relied on the dictum of Kitchin LJ in *MedImmune v Novartis* [2012] (previously reported on this blog at http://kluwerpatentblog.com/2012/10/30/the-final-word-on-obvious-to-try/):

"*Ultimately the court has to evaluate all the relevant circumstances in order to answer a single and relatively simple question of fact: was it obvious to the skilled but unimaginative addressee to make a product or carry out a process falling within the claim*".

Arnold J added: "*The primary evidence as to obviousness is that of properly qualified experts and secondary evidence needs to be kept in its place*". Lilly relied on Konig and a further piece of prior art but these arguments were rejected together with an Agrevo-type obviousness objection. The

latter was rejected on the basis that the judge considered that the issue should be classified as an insufficiency objection.

So far so good for Janssen – it had cleared three of the Lilly hurdles. However, the Patent fell flatly at the fourth. On sufficiency, Arnold J said, "*It remains to be considered whether the Patent makes it plausible that any antibody to A? (provided it is of IgG1 isotype) will be effective to prevent and/or treat a disease characterised by amyloid deposit*". After considering the evidence, the judge concluded that "*…the disclosure of the Patent does not make it plausible that any antibody to A? (provided it is of the IgG1 isotype) will be effective to prevent and/or treat a disease characterised by amyloid protein. It only makes it plausible that N-terminal antibodies will be effective. It follows that the Patent is insufficient.*" And Arnold J continued, considering two further questions, "*Can the invention be performed without undue burden?*" (often referred to as "classical insufficiency") and "*Is the claim of excessive breath?*" (sometimes referred to as "Biogen insufficiency"). Deciding that the Patent was bad in both respects he concluded, "*…the Patent does no more than invite the skilled team to perform…a "very significant research project with a high prospect of failure" and, if they succeed, claims the fruits of their research. It is therefore insufficient*".

With regards to infringement, it was held that Lilly's product solanezumab would infringe the patent if it were valid.

The decision is interesting in several respects. Of particular note is that the judge held that the parties ought to have prepared and agreed a primer in "a technically challenging case such as this." Primers are documents designed to guide the Court as to the relevant technology. They should be prepared in an uncontroversial form without spin in favour of one side's case or another. Unfortunately in many cases it has been the case that the parties' advisors have ended up having lengthy and therefore costly squabbles about the content of primers – so much so that often the substantive issues themselves can be in danger of being eclipsed. It remains to be seen if Arnold J's observations will cause primers to come back into use. Further, it will often be a balancing act for patentees (especially for biotech companies) who wish to file a patent application as early as possible and waiting for data to support the invention. Development difficulties are indeed relevant to the issue of insufficiency but one might argue that Arnold J's approach to sufficiency in this case was rather strict.

This entry was posted on Friday, July 19th, 2013 at 3:48 pm and is filed under (Indirect) infringement, antibodies, Biologics, Inventive step, Sufficiency of disclosure, United Kingdom, Validity
You can follow any responses to this entry through the Comments (RSS) feed. Both comments and pings are currently closed.