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Eli Lilly v HGS – Declaration Denied

Brian Cordery (Bristows) · Thursday, July 24th, 2014

It is perhaps a poor reflection on the CJEU that it regularly issues rulings that, when the case is restored before the referring court, lead both parties to an action to claim victory. However this happened yet again when Warren J was given the unenviable task of implementing one of the trio of references decided by the CJEU last December in the world of SPCs.

Most readers will already be familiar with the facts of the **Eli Lilly v HGS** case. HGS has a patent directed to Neutrokin- α which includes a claim to antibodies which bind to this protein. This claim is drawn at a fairly broad level – anything that binds specifically to the full length Neutrokin- α polypeptide or the extracellular domain of this polypeptide falls within the claim. This patent has survived numerous challenges in the UK and at the EPO. Lilly has developed an antibody, tabalumab, which was accepted for the purposes of the present proceedings to fall within the claims of the HGS patent. Lilly were concerned that HGS would seek an SPC for tabalumab based on HGS' patent and Lilly's MA, if the MA was granted before HGS' patent expired. They therefore sought a declaration from the English Patents Court that any such SPC would be invalid. Originally, there were two grounds of objection – (i) that tabalumab was not “protected” by a basic patent for the purpose of Article 3(a) of the SPC Regulation as interpreted in **Medeva** [1] and subsequent cases (the “Specified Issue”) and (ii) that HGS should not be able to file for an SPC based on a competitor's MA (the “Third Party Issue”) Eventually, the Specified Issue but not the Third Party Issue was referred to the CJEU by the English Patents Court.

As noted above, the CJEU issued its ruling in December 2013 [2] on the same day as its decisions in **Actavis v Sanofi** [3] and **Georgetown II** [4]. The case was then restored before the English Patents Court and a hearing took place over two days in May and June 2014. In a judgment dated 18 July 2014 [5], Warren J has refused to grant Eli Lilly's declaration that any SPC filed by HGS for tabalumab would be invalid.

Warren J considered that the CJEU ruling was unclear and unsatisfactory in many respects. However, in his view, the most important parts of the decision were: (i) paragraph [32] where the CJEU had held that the protection conferred by a basic patent was to be assessed with reference to the extent of the invention covered by the patent as provided for by Section 125 UK Patents Act and Article 69 EPC; and (ii) paragraph [33] where the CJEU had confirmed that the infringement test was not the correct approach.

The Judge also considered that an assessment following the extent of protection test should be subject to one proviso – namely that where the claims contain some general word or words

extending their scope beyond the principal wording of the claims, a product would not be considered to be specified unless it fell within the claim absent the general words. In other words, if a patent is directed to “A” but contains a claim “A *pharmaceutical composition comprising A*”, A+B would not be protected by this patent even though “comprises” means “*contains but is not limited to*” under EPC drafting conventions. Thus, Arnold J’s decision in **Astellas** [6] would still be correct although Kitchin J’s decision in **Gilead** [7] may not be depending on whether “...and optionally other therapeutic ingredients” came within the definition of “general words”. In a very English turn of phrase, Warren J set out that the task of the Court is to consider “*what a patent is and is not ‘really about’*” and noted that, although this is not the (rejected) infringement test, it will give the same result as the infringement test “*in many cases*”.

Drawing support from the Explanatory Memorandum and the Opinion of AG Fennelly in the **Biogen** [8] case, Warren J also noted that the purpose of the SPC Regulation is to encourage all kinds of pharmaceutical research. On this basis, the Judge thought it was not right in principle that the satisfaction of Article 3(a) depended on who carried out the research leading to the MA for the product for which the SPC had been sought. He noted the comment from the CJEU at paragraph [43] that “*the refusal of an SPC for an active ingredient which is not specifically referred to by a patent... may be justified – in circumstances such as those in the main proceedings and as observed by Eli Lilly – where the holder of the patent in question has failed to take any steps to carry out more in-depth research and identify his invention specifically...*”. However the Judge considered that: (i) this was more apposite to the Third Party Issue which had been formally abandoned and (ii) the CJEU had exceeded its jurisdiction insofar as it had found as a fact that HGS had failed to carry out the research to identify its invention specifically.

For the author, a curious aspect of the judgment of Warren J is contained in paragraph 60 where the Judge found that the CJEU used the same words “specified/identified” to mean different things in paragraphs [36] and [38] of its ruling. In essence, the Judge’s finding was that, following *Medeva*, in order to satisfy Article 3(a) a product must be specified/identified in the claims of the basic patent and that when the CJEU used the word “identified” in paragraph [38], it meant “identified” in this sense of the word – i.e. “fell within the scope of protection of”. However, when the CJEU opined that tabalumab could not be “identified” in the HGS patent in paragraph [36], it meant “described as such” in a more restrictive sense. Thus, although the CJEU had expressly held: (i) it was necessary for a product to be identified in the claims of a patent for Article 3(a) to be satisfied; and (ii) tabalumab was not identified by the claims of HGS’ patent, this did not mean that tabalumab was not protected by the basic patent relied on for the purposes of Article 3(a). Readers might be forgiven for assuming that the same word was intended to have the same meaning when used in virtually consecutive paragraphs of the CJEU’s ruling.

It seems inevitable Warren J’s judgment will be appealed and it will be interesting to see what the Court of Appeal make of the CJEU’s latest pronouncement. In the meantime, the Third Party Issue remains ripe for a further reference.

[1] Case C-322/10

[2] Case C-493/12

[3] Case C-443/12

[4] Case C-484/12

[5] [2014] EWHC 2404 (Pat)

[6] *Astellas Pharma Inc v Comptroller-General of Patents* [2009] EWHC 1916 (Pat)

[7] *Gilead Sciences Inc’s SPC Applications* [2008] EWHC 1902 (Pat)

[8] C-181/95

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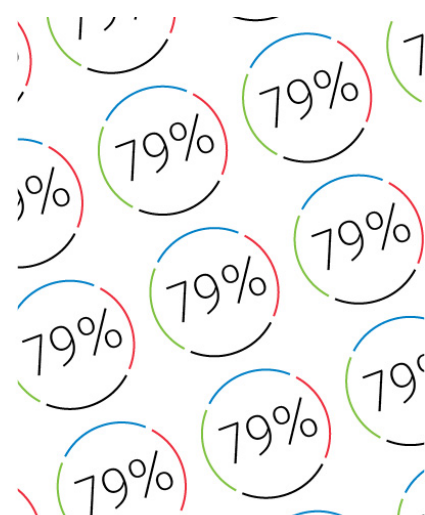
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