Kluwer Patent Blog Article – Takeda v Roche [2019] EWHC 1911 (Pat)

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Among the flurry of pre-summer vacation judgments coming from the Patents Court is one from Mr Justice Birss (17 July 2019), concerning the validity of Hoffman-La Roche's patent EP (UK) 2 007 809. EP'809 is a formulation patent for the monoclonal antibody vedolizumab, marketed as Entyvio® and used to treat ulcerative colitis and Crohn's disease. The judgment tackles some complex areas of law. In short, Birss J found the Takeda's product would infringe EP'809, but for the damning validity assessment that found it lacking novelty, obvious by virtue of a lack of technical contribution and insufficient.

Infringement
The evidence in the case put forward five different ways in which to calculate percentage of fucose within the sugar chain of the antibody, which was required to be 99% to fall within claim 1. Each calculation gave different results. The method chosen was critical to infringement; and that chosen by the Judge found that the amount of fucosylation was 99.8%, therefore falling within the claim. Infringement then depended on the way in which "antibody" was defined in the patent. The antibody must have "at least a functionally active (FcR binding) Fc part of lgG1 or lgG3 type comprising glycosylated Asn297". Takeda argued that the degree of binding in the vedolizmuab molecule was so small that it would have no functional effect. The Judge acknowledged it was a "close call", but found it was more likely than not that some binding occurred. Therefore, Takeda infringed all relevant claims of Roche's patent.

Novelty
The issue of anticipation revolved around enablement, and whether the prior art enabled the skilled person to produce something within the claim. The judgment contains a detailed analysis of this complex area of case law, disagreeing with how some EPO rulings have evaluated enablement (Borealis T1833/14; Solvay T2045/99). The crux of the Judge's conclusion is this: if the skilled person attempted to put into effect a disclosure from the prior art, would they make something that fell within the claims of the patent? If yes, enablement would be satisfied. It does not matter that the skilled person's creation would not reproduce *exactly* the product or process described in the prior art. In the context of antibodies in particular, the Judge reasoned this must be the correct approach: otherwise any slight variation in the antibody population of the prior art and the new product, at a certain degree of detail, would render it distinguishable and therefore novel. Applying this to the prior art in the case, the Judge found that each was an anticipating disclosure, and that they were enabled: the skilled team would not be able to make exactly the same antibody as disclosed, but they would make their own version that fell within the claims of the patent.

Obviousness
The Judge rejected Takeda's classical obviousness attack on the basis of skilled person's motivation to actually make the product (something that is not relevant when considering novelty and the state of the art). There was no motivation to product an antibody with the high levels of fucose claimed in the patent; the skilled person "would not bother to do so".
However, in balancing the principles that a patent monopoly should correspond to the technical contribution in the art, it was held that EP'809 was not an advance over the existing body of scientific knowledge. It was therefore held obvious in accordance with the principles laid down by the TBA of the EPO in the AgrEvo case (T939/92).

Insufficiency
The key ground of insufficiency was ambiguity: whether the skilled person can establish whether a product falls within the claims. Here, the relevant evaluation related to the percentage of individual glycans within an antibody sample, and there existed two different machines that the skilled person could use for the analysis. Depending on the machine used, the results either fell inside or outside claim 1. The Judge therefore held claim 1 to be truly ambiguous, and insufficient.
As well as the legal points addressed above, the decision is interesting because of Birss J's findings about the common general knowledge relating to what would happen when a skilled team would set about making an antibody in 2006. The Judge held, among other things, that at the time the skilled team using only their common general knowledge would have no undue difficulty at all making an antibody to a given target antigen. This included chimeric, humanized or human antibodies and each could be made into a pharmaceutical composition comprising such antibodies. Whilst such steps would require an enormous amount of work, significant funding and a large team of people, it was nevertheless all common general knowledge and did not involve an undue burden.