Kluwer Patent Blog

Regeneron Pharmaceuticals Inc. and Bayer Pharma AG v. Genentech Inc. [2013] EWCA Civ 93

Brian Cordery (Bristows) · Wednesday, April 3rd, 2013

In our post on 30 October 2012 we referred to forthcoming appeals dealing with how the question of obviousness should be tackled by the English courts. The Court of Appeal has now given its verdict in several judgments. The latest decision in **Regeneron v Genentech** dealt not only with the question of obviousness but also questions of novelty and sufficiency, construction and infringement. The Court of Appeal has upheld the decision of Mr Justice Floyd at first instance* in the English Patents Court that Genentech's patent was valid and infringed.

A brief summary of the facts: Regeneron and Bayer applied to revoke Genentech's EP (UK) 1 238 986 (the "986 patent") which discloses and claims the use of agents called human vascular endothelial growth factor (VEGF) antagonists for the treatment of non-cancerous diseases characterised by excessive blood vessel growth. Regeneron in one action and Bayer in another action sought revocation of the 986 patent on the grounds of lack of novelty, obviousness and insufficiency. They also sought to "clear the way" in respect of a product called VEGF-Trap which Bayer wished to sell in the UK for the treatment of a condition known as ARMD (a leading cause of premature blindness). Genentech counterclaimed for infringement. At first instance, Mr Justice Floyd rejected all the attacks on the 986 patent, further holding that the claims encompass the VEGF-Trap product.

Obviousness

Regarding obviousness, the appellants argued that Mr Justice Floyd erred in five respects:

1. The judge was wrong to approach the case on the basis that an assessment of the prospects of success is mandatory in every case;
2. In so far as the prospects of success are relevant, the judge applied the wrong test – i.e. whether the skilled person would have been optimistic that the antagonists had therapeutic utility;
3. The prospects of success were sufficient to warrant an actual trial and the judge should therefore have concluded that the invention was obvious;
4. If the judge was right in construing the claims as he did, then he failed to apply that construction when considering the issue of obviousness; and
5. The judge should have held that the claims cover ineffective antagonists and conditions for which VEGF-antagonist therapy is not effective and it is not inventive simply to claim a range of products which have no technical significance and solve no technical problem.

Giving the lead judgment in the Court of Appeal, Lord Justice Kitchin rejected all of the criticisms of Mr Justice Floyd's approach and held that he had applied the correct test when making his assessment. The claims of the 986 patent were inventive. It is interesting to note that the decision made reference to the following observations in **Medimmune v Novartis** [2012] EWCA Civ 1234 at 90-91:

"90. One of the matters which it may be appropriate to take into account is whether it was obvious to try a particular route to an improved product or process. There may be no certainty of success but the skilled person might nevertheless assess the prospects of success as being sufficient to warrant a trial. In some circumstances this may be sufficient to render an invention obvious. On the other hand, there are areas of technology such as pharmaceuticals and biotechnology which are heavily dependent on research, and where workers are faced with many possible avenues to explore but have little idea if any one of them will prove fruitful. Nevertheless they do pursue them in the hope that they will find new and useful products. They plainly would not carry out this work if the prospects of success were so low as not to make them worthwhile. But denial of patent protection in all such cases would act as a significant deterrent to research.
91. For these reasons, the judgments of the courts in England and Wales and of the Boards of Appeal of the EPO often reveal an enquiry by the tribunal into whether it was obvious to pursue a particular approach with a reasonable or fair expectation of success as opposed to a hope to succeed. Whether a route has a reasonable or fair prospect of success will depend upon all the circumstances including an ability rationally to predict a successful outcome, how long the project may take, the extent to which the field is unexplored, the complexity or otherwise of any necessary experiments, whether such experiments can be performed by routine means and whether the skilled person will have to make a series of correct decisions along the way …"

Construction and infringement

Regeneron and Bayer submitted that Mr Justice Floyd had misconstrued the claims of the 986 patent as not requiring any therapeutic effect in the disease or disorder in question, and that he was inconsistent in considering the various attacks on the 986 patent. The appellants also claimed that the judge wrongly held that the claims encompass any variant of a naturally occurring receptor which retains the ability to bind VEGF and inhibits its activity.

The Court rejected the arguments on construction, holding that the 986 specification clearly showed that Genentech intended variants to be included within the scope of the monopoly and Bayer's VEGF-Trap fell within the scope of the 986 patent.

Novelty

Regarding novelty, the appellants argued that an article published by Kim disclosed VEGF antagonists in the form of antibodies and discussed their potential use for treating relevant diseases. However, the Court held that the relevant article did not provide the same teaching as the 986 patent and did not give clear and unmistakeable directions to perform the claimed invention. Further, Lord Justice Kitchin held that it was clear that Mr Justice Floyd construed the claims entirely correctly as requiring the achievement of a therapeutic effect and he duly applied this construction when considering novelty.

Sufficiency

As for sufficiency, Regeneron and Bayer submitted that Mr Justice Floyd should have found the

986 patent to be insufficient because the monopoly claimed was too broad, arguing that the claims were entirely speculative and covered a huge range of diseases and disorders without the experimental work needed to support them and that the 986 patent imposed on the skilled person an undue burden to establish which antagonists are effective for which disease states.

As with the other arguments, the Court of Appeal rejected this submission, noting that it was plausible that VEGF antagonism could be used to treat any non-cancerous neovascular disease and that it was not necessary to establish efficacy by carrying out clinical trials. In addition, the Court commented that a claim for an invention of broad application may properly encompass embodiments which may be provided or invented in the future and which have particularly advantageous properties, provided such embodiments embody the technical contribution made by the patent.

Comment

The *Regeneron* case demonstrates that it is always tough to overturn a first instance finding of inventive step. Even though the gap between Kim and the disclosure of therapeutic utility was not huge, the Court of Appeal rejected the attacks on the trial judge's decision as he had applied the principles correctly and then taken all the evidence in the round. The decision also shows that the English Courts will permit quite broad claims if they consider that a principle of general application was disclosed.

* [2012] EWHC 657

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