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Regeneron Pharmaceuticals Inc v (1) Kymab Ltd (2) Novo Nordisk A/S

Brian Cordery (Bristows) · Monday, February 8th, 2016

Case reported and summarized by Gregory Bacon, Bristows LLP

Mr Justice Carr is only a few months into his judicial career, but having already provided welcome guidance on the role of plausibility in considering both the questions of inventive step and sufficiency (see earlier blog post on *Actavis v Eli Lilly*), he has now produced a lengthy judgment on subject matter of great technical complexity with particularly interesting conclusions on construction of product-by-process claims and applying the statutory test of insufficiency where it is alleged that an invention is not enabled across the breadth of the claim.

At a very simplified level, Regeneron's patents relate to transgenic mice used for the study of monoclonal antibodies, but those interested in the genetic engineering and immunology aspects of the case are invited to read the judgment. The Court construed all of the claims in dispute broadly. This analysis included the product-by-process claims, which were to a genetically modified eukaryotic cell, mouse embryonic cell, or mouse, in each case "obtainable by" methods described in a process claim on which the product-by-process claims were dependent. That process claim was to a particular type of genetic modification to a part of the immunoglobulin heavy chain variable gene locus such that human heavy chain variable region genes are introduced in the endogenous position of the mouse locus, so as ultimately to create a reverse chimeric antibody.

In this case the breadth of all the claims in dispute, properly construed, led to problems on sufficiency. The judge noted that for a claimed class if the invention does not work with substantially all of the products or methods falling within the scope of the claim then the claim will be insufficient. Whilst the judge recognised that the subject matter of the patents was highly complex and a significant amount of work would be expected to be required to develop it, the policy of encouraging innovation in highly technical fields needed to be balanced against the importance of guarding against patents which required invention on the part of the skilled person to implement and where the scope of claims exceeds the technical contribution. On the facts, the judge held that the specific process claim that characterised the "obtainable by" claims was insufficient as it did not enable the insertion of genomic fragments of the size required in order to achieve the replacement of the gene segments described

without undue burden and without invention. None of the methods disclosed in the patent would have worked. The judge accepted that the skilled person was entitled to apply their common general knowledge in the event of failure of the methods disclosed. If an obvious, standard approach would occur to the skilled person then this would be an answer to the objection of insufficiency. In this case, however, none of the proposed alternative approaches were held to have been ones that would have occurred to the unimaginative skilled person.

As to the product-by-process claims, the judge summarised the principles derivable from the judgment of Birss J in *Hospira v Genentech* in relation to "obtainable by" claims as follows:

(i) their purpose is to claim a product irrespective of how it was made but with a shared characteristic which results from using a given process;
(ii) the claim has to specify the characteristic being referred to;
(iii) "obtainable by" claims present clarity problems and should only be permitted if there is no alternative way of defining the product in question; and
(iv) for a product to be "obtainable by" a process it must have every characteristic which is the inevitable consequence of that process.

The scope of the product-by-process claims therefore extended to products (cells and mice) which contained the introduced genes in the endogenous position regardless of the method used (which was the position argued for by the patentee), even though the process by which the products were "obtainable by" described only one such method. On sufficiency, the judge had held that these "obtainable by" claims were therefore of a considerably wider scope than the method claim, and thus also insufficient. He also held that even if he had concluded that the process claim was not of excessive breadth, the wider product-by-process claims were still insufficient as they extended to cells and mice in which the entire mouse locus in question had been replaced by the entire human locus.

The other invalidity attacks of added subject matter, lack of novelty and lack of inventive step were all rejected, and the judge also ruled that, had the patent not been invalid, it would have been infringed by Kymab's mice strains. However, it is worth noting in passing that the patentee took an unusual approach in calling three witnesses of fact, in addition to the experts, to support its argument on inventive step. The first two witnesses, who were active in the field at the priority date although not employed by the patentee, gave evidence that the idea of modifying the particular locus (to create a reverse chimeric antibody) never occurred to them or their colleagues. The third witness was one of the inventors of the patent and explained how he arrived at the concept of a reverse chimeric locus. The written evidence of all three witnesses was not challenged at trial, and the judge held that their evidence provided a useful insight into the thought processes of leaders in the field at the priority date on inventive step. It is somewhat unusual to call the inventor as a witness in English patent litigation and it will be interesting to see if this marks the start of a new trend.

Readers may also be aware of the practice in the UK of circulating draft judgments to the parties on a confidential basis a few days before they are made public so that

typographical or other obvious errors may be highlighted to the judge before the final judgment is issued. In this case, Regeneron made further submissions following circulation of the draft judgment which alleged that there were certain material omissions from the draft judgment, and that the judge should consider these issues in order provide further findings of fact for the Court of Appeal. The judge recognised that it was important that parties should draw to the attention of the court any material omissions in a judgment, rather than attempt to save up such points for the Court of Appeal. Nevertheless, the judge held (after inviting the opposing parties to respond) that the effect of the patentee's post-judgment submissions was to seek to re-open the argument about whether the claimed inventions were enabled. He also discouraged the post-judgment submissions in future cases.

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