

## CASE COMMENTS

# MEDIIMMUNE JUDGMENT GIVES PATENT LAWYERS PAUSE FOR THOUGHT

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In a mammoth judgment (71,000 words over 161 pages), Arnold J has dismissed MedImmune's claim that Novartis' Lucentis product (generic name ranibizumab), for treatment of wet age-related macular degeneration, infringed two of MedImmune's patents.<sup>1</sup> The patents were also held to be invalid. The judgment is of such length and complexity that we shall not attempt to summarise it, nor to consider all the issues raised (many of which are highly fact-specific). Instead, we shall discuss only those issues raised which are of general importance and significance in patent law.

### Background

The case concerns two patents owned jointly by MedImmune and the Medical Research Council. The patents concern methods for producing antibodies. As this is a highly technical area of scientific research, the judgment commences with a very detailed account of the relevant science, including amino acids, proteins, nucleic acids, genes, antibodies and phages (viruses that infect bacterial cells).

### Instruction of Expert Witnesses

The judgment provides some very useful comments and guidance on the instruction of expert witnesses and preparation of expert reports in patent actions, which are worth considering in detail. After setting out the relevant

provisions of the CPR and the Protocol for the Instruction of Experts to give Evidence in Civil Claims, the judge said that:

*For these reasons expert witnesses in patent actions require a high level of instruction by the lawyers. Furthermore, even if they are experienced authors, they need considerable assistance from the lawyers in drafting their report. In practice, most expert reports in patent cases are drafted by the lawyers on the basis of what the expert has told them and the draft is then amended by the expert.*

The authors agree that this is normal practice in patent actions. However, the judge recognised that '... this process entails a risk of loss of objectivity on the part of the expert even if the expert is striving to remain independent and impartial. It is therefore crucial that the lawyers involved should keep the expert's need to remain objective at the forefront of their minds at all times.'

The judge provides two examples of 'common traps for the unwary'. The first concerns the frequent scenario where an expert is asked to provide his opinion on whether taking a particular step would have been obvious over a particular prior art document. Arnold J stresses that even where an expert is of the view that the step was obvious, care must be taken in the expert report to consider the entirety of the prior art document, and to set out in the report those parts of the prior art document that point the other way or are equivocal. Whereas, ultimately, the duty to do this lies with the expert, given that the report will generally be drafted by lawyers (as stated above), it is necessary for the lawyers to 'bring home to the expert the need to give a balanced account of the document in his report'.

The second example is where the expert may have had some involvement with the invention in issue, or a similar invention. It is incumbent on the lawyers to ensure that the expert discloses such contributions and, if necessary, explains them in his report.

The above is, of course, best practice, but as Arnold J pointed out:

*The law reports are littered with cases, including some patent cases, in which judges have criticised expert witnesses for failing to be objective or in other ways. It is regrettably true that from time to time an expert witness does succumb to the temptation of giving*

<sup>1</sup> *MedImmune Limited v Novartis Pharmaceuticals UK Limited and Medical Research Council* [2011] EWHC 1669 (Pat).

*partisan evidence, and that is clearly unacceptable. But I wish to emphasise that the lawyers who instruct expert witnesses bear a heavy responsibility for ensuring that an expert witness is not put in a position where he can be made to appear to have failed in his duty to the court even though he conscientiously believes that he has complied with that duty. It is also important that courts should be cautious about criticising an expert witness purely on the basis of omissions from his report unless it is clear that the fault lies with the expert rather than those instructing him, bearing in mind that the court will not usually be privy to the expert's full instructions (whatever may be the effect of CPR r. 35.10(4), which it is not necessary to go into for present purposes).*

No doubt the judge drew upon his own considerable experience at the bar in order to inform what must be welcomed as an honest admission of reality and pragmatism.

In respect of the four specific experts instructed in the case, the judge held that all had complied with their duties to the court. Nonetheless, the guidance provided by Arnold J is useful, and should be considered and adopted by all patent litigation practitioners.

## Insufficiency

The validity of the patents was challenged on the grounds of insufficiency. The statutory test, as set out in section 72(1)(c) of the 1977 Act, is that a patent is invalid 'if the specification does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art'. There are a number of English cases, however, in which a patent claim has been held to be invalid on the grounds that the claim is overly broad, even though the patent specification does disclose sufficient information to enable the skilled person to carry out the invention in at least one way. This was formulated by the House of Lords in *Biogen v Medeva*<sup>2</sup> in what became known as 'Biogen insufficiency'. The Court of Appeal stressed in *Kirin-Amgen*<sup>3</sup> that this is not a free-standing reason for revocation of a patent, but is a sub-category of the wider class of insufficiency as defined in section 72(1)(c) of the 1977 Act.

The scope of 'Biogen insufficiency' was restricted by the House of Lords in *Generics (UK) Ltd v H. Lundbeck A/S*.<sup>4</sup>

In that case, the House of Lords held that 'Biogen insufficiency' is not applicable to straightforward product claims. Specifically, it was held that a claim to a single enantiomer of a known compound was valid, even though the patent disclosed only a single method of preparation of the enantiomer.<sup>5</sup>

Nonetheless, 'Biogen insufficiency' was not abolished by the decision in *Lundbeck*, and the judges in that case made it clear that claims of a more complex nature than straightforward product claims, such as that in *Biogen* itself (which was a claim to a product identified partly by the way it had been made and partly by what it did), could still be invalid if they cover ways of achieving the desired result which owe nothing to the teachings of the patent. The judges in *Lundbeck* drew a distinction between the patent's technical contribution to the art, and the inventive concept underlying the patent. The two are not necessarily co-terminous, and it is only if the claim is broader than the patent's technical contribution that it will be invalid for insufficiency. In *Lundbeck* itself, whereas the inventive concept was the particular method of making the single enantiomer, the technical contribution was the single enantiomer itself. The claim was to the single enantiomer however made, and was therefore fully enabled in light of the technical contribution. In such a case, the patentee gets the benefit of rather more than just what he has invented, and 'Biogen insufficiency' is of no assistance to a party seeking to revoke the patent.

In this case, Arnold J considered that the relevant claims were 'method claims of fairly broad scope, and not claims to a single product', and that the case was 'much closer to *Biogen v Medeva* and *Kirin-Amgen v Hoechst* than it is to *Generics v Lundbeck*'. However, after considering the respective parties' proposed constructions of the claims, he concluded that MedImmune was

*... correct to characterise the invention disclosed in the Patents as a principle of general application. At its core, it is a technique for selecting a binding molecule of interest from amongst a potentially large population of other binding molecules. The technique does not depend on the precise identity of the binding molecule. On the contrary, part of the usefulness of [the] technique is that it can be applied to a diverse range of binding molecules, fragments and derivatives. Nor does the technique depend on the*

2) [1997] RPC 1.

3) [2003] RPC 3.

4) [2009] UKHL 12.

5) The *Lundbeck* case is discussed in an earlier article by the authors, published in *Bio-Science Law Review* 10(3), November 2009.

*precise application which the user has in mind. Nor does implementation of the technique for the purpose of a new application involve undue burden on the part of the skilled team ...*

Presumably, Arnold J considered that the technical contribution to the art was broader than the inventive concept underlying the patent, and that the claims did not go beyond that technical contribution (although he did not use that actual wording). Accordingly, the relevant claims were not invalid on grounds of insufficiency.

## Infringement

As stated above, both patents were process patents. By section 60(1) of the Patents Act 1977, process patents are infringed where the defendant:

(b) uses the process or he offers it for use in the United Kingdom when he knows, or it is obvious to a reasonable person in the circumstances, that its use there without the consent of the proprietor would be an infringement of the patent; or

(c) where the invention is a process, he disposes of, offers to dispose of, uses or imports any product obtained directly by means of that process or keeps any such product whether for disposal or otherwise.

Novartis' process for manufacturing ranibizumab was carried out in the United States, so section 60(1)(b) was not applicable, meaning that MedImmune needed to establish that Novartis' ranibizumab was a product obtained directly by means of the patented process in order to prevail. Arnold J held that the process used to manufacture ranibizumab did not fall within the claims of the patents. However, he then went on to consider whether, if the process used did fall within the scope of the claims, ranibizumab could be said to be a 'product obtained directly' by means of that process.

After reviewing the case law on section 60(1)(c), including *Pioneer Electronics Capital Inc v Warner Music Manufacturing Europe GmbH*,<sup>6</sup> *Halliburton Energy Services Inc v Smith International (North Sea) Limited*<sup>7</sup> and *Monsanto Technology LLC v Cargill International SA*,<sup>8</sup> Arnold J concluded that 'a product could be obtained directly from a claimed process

despite further processing provided that there was no loss of identity, there being no such loss where it retained its essential characteristics'.

Applying this, the judge concluded that if Novartis' ranibizumab had been produced by a process falling within the claims of the patents, it would have been a product obtained directly by means of that process, and therefore would have infringed under section 60(1)(c).

The judge also considered whether this (obiter) conclusion was affected by the Biotech Directive. Article 8(2) states:

*The protection conferred by a patent on a process that enables a biological material to be produced possessing specific characteristics as a result of the invention shall extend to biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through the propagation or multiplication in an identical or divergent form and possessing those same characteristics.*

In *Monsanto Technology LLC v Cefetra BV*,<sup>9</sup> the ECJ held that Article 9<sup>10</sup> of the Biotech Directive effected an exhaustive harmonisation of the protection conferred by patents falling within it, with the result that it precluded national patent legislation from offering wider protection. Novartis contended that, by analogy, Article 8(2) also effected an exhaustive harmonisation. This was apparently conceded by MedImmune. Novartis then argued that, as the patent falls within the scope of the Biotech Directive, the protection afforded is restricted to 'biological material directly obtained through that process and to any other biological material derived from the directly obtained biological material through the propagation or multiplication in an identical or divergent form and possessing those same characteristics'. As ranibizumab is not a 'biological material' within the definition of Article 2(1)(a) of the Biotech Directive ('any material containing genetic information and capable of reproducing itself or being reproduced in a biological system'), Novartis argued that it fell outside the scope of the protection conferred by the patents.

The judge appeared to agree that if Article 8(2) applied to the claims in question, their scope would be circumscribed as contended by Novartis. However, in the judge's view, the

6) [1997] RPC 757.

7) [2006] RPC 2.

8) [2008] FSR 7.

9) [2010] ECR I-000.

10) 'The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.'

claims were *not* in respect of processes that enable a biological molecule to be produced, and Article 8(2) did not apply. In the authors' view, this must be correct – if the *direct* result of a process is not a biological material, the process cannot be said to be one that enables a biological material to be produced. Article 8(2) may serve to circumscribe the protection where a biological material produced by a process that enables a biological material to be produced is subject to further processing which converts it into a non-biological

material. However, it is inappropriate to try to apply Article 8(2) to claims that are not to a process for producing a biological material. Furthermore, the authors consider that protection of a biological material that is subject to further processing into a non-biological material would almost certainly be precluded by the decision in *Pioneer Electronics* in any event, as it could not be said to have retained its essential characteristics. As a result, the effect of Article 8(2) on patent claims may be smaller than appears at first glance.