

## Biogen “insufficient” to catch simple product claims

### 1. Introduction

1.1 The House of Lords Decision in Generics (UK) Limited and ors v H Lundbeck A/S<sup>1</sup> has provided clarification regarding the sufficiency requirements of the (UK) Patents Act 1977 in relation to product claims.

### 2. History

2.1 This case concerned citalopram, a member of a class of anti-depressant drugs which inhibit reuptake of the neurotransmitter serotonin by nerve cells. Citalopram exists as a racemate, i.e. a mixture (in equal proportions) of two enantiomers<sup>2</sup>. Enantiomers have the same chemical formula and three-dimensional stereochemical structure, except that one is the mirror-image of the other. It has long been known that enantiomers can have different properties and that the ease with which relatively pure forms of each (or either) enantiomer can be obtained varies according to the racemate in question.

2.2 In the case of citalopram, this had proved particularly difficult and was achieved by finding a way of separating the two enantiomers of an intermediate compound and then proceeding separately with the manufacture of each enantiomer. It was then established that the therapeutic effect of citalopram was virtually all due to the (+) enantiomer.

2.3 The consequent patent application by H Lundbeck A/S in 1989 resulted eventually in EP (UK) 0347066 (“the Patent” in suit).

### 3. The issues at first instance and at the Court of Appeal

3.1 Three claims of the Patent had been in issue at the first instance and at the Court of Appeal:

<sup>1</sup> [2009] UKHL 12

<sup>2</sup> One enantiomer can be distinguished from the other using the (+) and (-) convention, which is based on the direction in the enantiomer rotates polarised light.

- Claim 1, to the (+) enantiomer itself
- Claim 3, to a 'pharmaceutical composition... comprising...a compound as defined in claim 1.
- Claim 6, to a method for the preparation of a compound as defined in claim 1.

3.2 Attacks based on lack of novelty and obviousness failed in both the High Court<sup>3</sup> and the Court of Appeal<sup>4</sup>, and did not form part of the appeal to the House of Lords. However, where Kitchin J had held claims 1 and 3 to be invalid for insufficiency, the Court of Appeal (Lord Hoffmann and Smith and Jacob LJJ) reached the opposite conclusion.

3.3 In the High Court, Kitchin J had been satisfied that, at the priority date, the person skilled in the art considered it “*obviously desirable to separate out and test the enantiomers...*” and had stated that, as a result, the “*inventive step taken by the inventors...was not deciding to separate the enantiomers of citalopram but finding a way it could be done*”<sup>5</sup>. He went on to characterise the technical contribution made by the inventors as the discovery that intermediate compound’s enantiomers could be resolved and converted into the enantiomers of citalopram whilst preserving their stereochemistry (i.e. effectively a new way of making the claimed product). As the Patent only disclosed one way to make the (+) enantiomer, he concluded that “*the first person to find a way of achieving an obviously desirable goal is not permitted to monopolise every other way of doing so*”. Claims 1 and 3 were found to be invalid as a result of insufficiency as they extended “*beyond any technical contribution made [by the Patentee]*”<sup>6</sup>.

3.4 The only authority relied upon by Kitchin J in this analysis was the judgment of the House of Lords in *Biogen v Medeva*<sup>7</sup>, where the contested patent had described one recombinant method for preparing known antigens of the hepatitis B virus.

<sup>3</sup> [2007] EWHC 1040 (Pat)

<sup>4</sup> [2008] EWCA Civ 311

<sup>5</sup> [2007] EWHC 1040 (Pat), paragraph 266

<sup>6</sup> [2007] EWHC 1040 (Pat), paragraph 267

<sup>7</sup> [1997] RPC 1

A claim extending to the antigens when prepared by any recombinant method were held insufficient, as in Lord Hoffmann's opinion, the question was "*not whether the claimed invention could deliver the goods, but whether the claims cover other ways in which they might be delivered; ways which owe nothing to the teaching of the patent or any principle which it disclosed.*"<sup>8</sup> Such a situation, where the extent of sufficiency is related to the technical contribution made by the claimed invention and is found wanting, has since come to be known as "*Biogen* insufficiency".

3.5 As mentioned above, the Court of Appeal took a different view to Kitchin J, with Lord Hoffmann stating that "[w]hen a product claim satisfies the requirements of section 1 of the 1977 Act<sup>9</sup>, the technical contribution to the art is the product and not the process by which it was made, even if that process was the only inventive step"<sup>10</sup>. Accordingly, he concluded that the claim to the (+) enantiomer was valid.

#### 4. The insufficiency arguments as seen by the House of Lords

4.1 Lord Mance summarised the key issue before the House of Lords by commenting that Kitchin J had confined the legitimate scope of the patent claim by reference to the inventive step, while the Court of Appeal had held that a patent claim to a single novel product embraces all methods of producing that product, even if the description and specification cover only one such method and others emerge owing nothing to it.

4.2 Both Lords Neuberger and Mance both commented to the effect that, apart from the submission that the appeal must succeed on the basis of *Biogen v Medeva*, the appellants' approach did not find direct support in either the Patents Act or any UK authority.

<sup>8</sup> [1997] RPC 1, paragraph 70

<sup>9</sup> Section 1(1) Patents Act 1977 specifies that a patent may be granted for an invention only in respect of which the following conditions are satisfied: (a) the invention is new; (b) it involves an inventive step; (c) it is capable of industrial application; and (d) the grant of a patent for it is not excluded.

<sup>10</sup> [2008] EWCA Civ 311, paragraph 36

4.3 In considering the approach regularly taken by EPO Technical Boards of Appeal<sup>11</sup>, Lord Neuberger stated that, at least as a general rule, the monopoly to be granted to the patentee is to be assessed by reference to the "technical contribution" made by the teaching of the patent. In his opinion, the Patentee's technical contribution was, "*at the lowest*", to make available a previously unavailable product (the isolated (+) enantiomer of citalopram) and that it would appear to follow that they were entitled to claim that enantiomer *per se*.

4.4 Paragraph 3.3 of the Board of Appeal decision in T409/91 *EXXON/Fuel Oils* contains the statement that it a general legal principle that:

*"...the extent of the patent monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported, or justified."*

Lord Neuberger concluded that there was nothing in the above paragraph (which is also discussed by Lord Hoffmann in *Biogen v Medeva*<sup>12</sup>) to suggest, in the case of a claim to a novel product, that the technical contribution may not be the product itself, if it is a known *desideratum*.

4.5 The most significant part of the decision in T409/91 was considered by Lord Walker to be paragraph 3.5, which states:

*"In the Board's judgment, this case differs from those where a class of chemical compounds is claimed and only one method of preparing them is necessary to enable a skilled person to carry out the invention, i.e. to prepare all compounds of the claimed class. Rather, the present case is comparable to cases where a group of chemical compounds is claimed, and not all of the claimed compounds can be prepared by the methods disclosed in the description or being part of the common general knowledge."*

<sup>11</sup> see, for example, T409/91 *EXXON/Fuel Oils* [1994] OJEPO 653

<sup>12</sup> see [1997] RPC 1, paragraph 65

4.6 Lord Mance made the similar conclusion that the Board of Appeal's decision in *Exxon/Fuel Oils* has never been applied to a simple product claim such as that in issue in the Patent, and that the decision in *Exxon* had dealt with a situation where the description did not support all the inventions or all the embodiments of the invention in respect of which the patent claim was made. He went on to consider that this was, in fact, an area where the EPO Technical Boards of Appeal had developed clear jurisprudence, albeit in cases where the issue was one of obviousness. Taking as an example the Board of Appeal decision in T595/90<sup>13</sup>, which had concluded that "a product which can be envisaged as such with all characteristics determining its identity together with its properties in use, i.e. an otherwise obvious [product], may become nevertheless non-obvious and claimable as such if there is no known way...to make it...", Lord Mance considered that the Board could not sensibly have given such unequivocal endorsement to the patentability of a product in such circumstances, if it had envisaged that the patent would be liable to revocation because it covered other methods owing nothing to the inventive method(s) described in the claim.

4.7 To summarise, according to Lord Neuberger it appeared clear that unless precluded by the reasoning in *Biogen v Medeva*, claim 1 of the Patent was valid. He made the point of stating that he appreciated "that this means that, by finding one method of making a product, a person can obtain a monopoly for that product. However, that applies to any product claim."

## 5. The insufficiency arguments based on *Biogen v Medeva*

5.1 Upon consideration of certain passages relied on by the appellant, it was held that the opinion of Lord Hoffmann in *Biogen* was of no assistance in this case, as the claim in the present case was to a single product that was clearly enabled by the disclosure in the Patent. *Biogen* was instead said to apply in light of the very unusual nature of the claim in that case,

<sup>13</sup> Grain-orientated silicon sheet/Kawasaki [1994] OJ EPO 695

which was far from being a straightforward product claim<sup>14</sup>. Similarly, Lord Walker considered that the claim in *Biogen v Medeva* had not been considered a simple claim concerning a novel product; the issue of whether such a claim should be restricted in scope by reference to its inventive step had not been addressed in that case.

## 6. Conclusions

6.1 This unanimous decision of the House of Lords makes it clear that a simple product claim that is both novel and inventive meets the UK requirements regarding sufficiency where the specification discloses a single method of making the product. The Patentee will, in such circumstances, therefore be entitled to a monopoly for that product. This will be the case even if the inventive step lies solely within the method of making a simple product, as the product is a known *desideratum* in light of the prior art.

6.2 The reasoning of the House of Lords in *Biogen v Medeva* remains valid. "Biogen-insufficiency" remains a consideration where the claims cover subject matter which owes nothing to the teaching of the patent or any principle which it disclosed, but the circumstances in which it applies remain ill-defined. However, the present case makes clear that it is not applicable to claims for a single product.

<sup>14</sup> In *Biogen*, the technical contribution made to the art was considered to be a way of producing a genus of generically defined products, rather than those products themselves.

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