



INTELLECTUAL PROPERTY UPDATE | 25 February 2009

‘SIMPLE PRODUCT CLAIMS’ ESCAPE BIOGEN (BUT WHAT ELSE DOES ...?)

The House of Lords today gave its judgment in *Lundbeck v Generics* [2009 UKHL 12], dismissing Generics’ appeal and upholding Lundbeck’s patent. This concludes the final installment in the story of Lundbeck’s patent for escitalopram – a single enantiomer drug for the treatment of depression – and provides the final word on the applicability of so-called “Biogen insufficiency” to simple product claims.

In upholding the Court of Appeal Judgment, the House of Lords confirmed that:

- the principles arising in *Biogen* do not apply to a simple product claim;
- if a product is novel and non-obvious, the product itself is the ‘technical contribution’ to the art;
- a product which is an ‘obviously desirable goal’ (such as an enantiomer) should not be treated any differently to other product claims. To the contrary, Lord Neuberger went as far as saying:

“... where (as here) the product is a known *desideratum*, it can be said (as Lord Walker pointed out) that the invention is all the more creditable, as it is likely that there has been more competition than where the product has not been thought of. The role of fortuity in patent law cannot be doubted: it is inevitable, as in almost any area of life”

HISTORY OF THIS ACTION

At first instance ([2007] EWHC 1040 (Pat)), Kitchin J. found that the enantiomer was both novel and non-obvious, but that by 1989 (the priority date) enantiomers of known racemates were “obviously desirable goals”. He therefore followed the principle apparently laid down by Lord Hoffman in the House of Lords in *Biogen v Medeva*, namely that “the first person to find a way of achieving an obviously desirable goal in not permitted to monopolise every other way of doing so”. To do so would exceed the ‘technical contribution’ to the art. On that basis, he therefore found the claims to the enantiomer invalid for Biogen-insufficiency.

On appeal ([2008] EWCA Civ 311), Lord Hoffman (unusually sitting in the Court of Appeal) held that Kitchin J. had misinterpreted his judgment in *Biogen* which he said applied only to “product-by-process” type claims. It did not apply to simple product claims – such as Lundbeck’s claim to its enantiomer. With Jacob LJ in agreement, the Court of Appeal overturned the finding, and we thought we had our final word on Biogen insufficiency.

However, in October last year, the Lords gave permission to *Generics* to appeal once more. The Lords heard the appeal in January (a very speedy timetable) and have today given their judgment.

TODAY’S JUDGMENT

Today’s decision was unanimous, Lord Neuberger giving the leading judgment, Lords Walker and Mance giving their own substantive consenting judgments, and (although not in issue) Lord Scott giving a brief speech about the conundrum concerning novelty specifically of enantiomers.

However, despite the panoply of judgments, there was more of a feel of stalwart support for each of Lord Hoffman’s earlier judgments (Lords Walker and Neuberger going as far as characterising his

judgment in *Biogen* as a 'Tour de Force') than there was guidance as to how or whether (if, indeed, at all) the principles in *Biogen* should apply to any particular case in the future.

The Lords agreed (following the recent trend of the UK Patents Courts) that clear principles arising from the EPO and its boards of appeal should be adhered to in the UK, and the starting point for the analysis was the principle laid down in the EPO's decision T409/91 *EXXON/Fuel Oils* [1994] (OJEPO 653) that "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 the Court of Appeal, Lord Hoffman had said that Kitchin J. was mistaken in equating the "inventive concept" of Lundbeck's patent (i.e. the process), with the "technical contribution". What he should have found was that the novel and non-obvious enantiomer was *itself* the technical contribution.

The Lords agreed, although their analysis of this section of Lord Hoffman's judgment led to some fairly technical discussion, particularly on the part of Lord Walker (with which Lord Neuberger agreed), as to how the two concepts, 'inventive step' and 'technical contribution', should be defined and distinguished. However, this may remain largely academic, not least as Lord Mance seemed less clear as to whether the two should (or needed to) be distinguished.

The Lords agreed that when seeking to revoke a patent for "sufficiency", in addition to considering the clarity and completeness of the specification (under section 14(3), consideration must also be given to the "support" given by that description for the claims (under s.14(5)(c)). As Lord Walker pointed out:

"Section 14(3) and (5)(c) operate together, as EPC Articles 83 and 84 operate together, to spell out the need for an "enabling disclosure", which is central to the law of patents."

With those principles in mind, Lord Neuberger considered whether (leaving aside the *Biogen* judgment for the time being) there was anything in the legislation (either UK or EPC) which meant that Lundbeck's claim to its enantiomer should be held invalid for insufficiency. On this he found that:

"... the product claim in the present case is valid. I appreciate 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."

He then turned to Lord Hoffman's *Biogen* Judgment and addressed whether that should make any difference. This latter exercise was what Lords Walker and Mance also primarily dealt with.

Both Lords Neuberger and Mance acknowledged that there were sections of the *Biogen* judgment which, if read out of context, could be construed to support Kitchin J.'s first instance finding. However, all three judges agreed that the *Biogen* Judgment was concerned with a very complicated claim that was certainly not comparable with Lundbeck's simple product claim.

Lord Walker said:

"Statements of general principle relating to inventions with many embodiments may be irrelevant to an invention which consists of a single chemical compound. ... That is in my opinion the fundamental reason why *Biogen* does not provide a direct answer to this appeal."

Lord Mance's view was:

"... perhaps even more relevant in my view is the fact that nowhere in *Biogen Inc. v. Medeva plc* do the speeches treat or discuss the claim as a simple claim in respect of a novel product ... It seems to me therefore that the Court of Appeal was not in the present case bound by the reasoning or result in *Biogen Inc. v. Medeva plc* to arrive at a conclusion that the present claims 1 and 3 were invalid"

And Lord Neuberger said:

“the opinion of Lord Hoffmann in *Biogen* [1997] RPC 1, though a *tour de force* as Lord Walker says, is of no assistance to the appellants in this case. It applied in the light of the very unusual nature of the claim in that case”

Each of the Lords, on those respective bases, dismissed the appeal and found Lundbeck’s patent claims to its simple enantiomer product sufficient, and therefore valid.

DISCUSSION:

This Judgment is good for Lundbeck, and for the research pharmaceutical industry generally – whose business is often reliant on patent claims to simple pharmaceutical products. Further, harmonization of UK patent law with Europe, by removing the threat of a ‘Biogen insufficiency’ attack against such patents (as this judgment has done) also benefits patentees by providing some cross-border certainty.

However, as stated above, it does not provide comprehensive guidance as to the status of the *Biogen* decision, which remains House of Lords authority, and the spectre of “Biogen insufficiency” still hangs over patentees. In the Court of Appeal, Lord Hoffman indicated that the principles in *Biogen* only apply to “product-by-process” type claims. Lord Neuberger, on the other hand, said the following:

“Far from being a straightforward product claim (as in this case) or even a product-by-process claim (as discussed in *Kirin-Amgen* [2005] RPC 9, paras 86–91 and 101), the claim [in *Biogen*] was to a product identified in part by how it was made and in part by what it did – almost a process-by-product-by-process claim.”

Biogen still applies to cases like *Biogen*, and might now be said to be limited to those claims of a “very unusual nature” namely ‘process-by-product-by-process’ claims (whatever they may be). On the other hand, we now know it does not apply to ‘simple product claims’, whether to ‘obviously desirable goals’ or not. However, there is a gulf in between which remains (*dare-we-say*) insufficiently defined.

Howrey LLP acted for the Respondent, H. Lundbeck A.S, in this appeal

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