The Lundbeck case

Lindsay Lane
8 New Square, Lincoln's Inn,
London

Background facts

- Lundbeck had discovered and patented the SSRI anti-depressant citalopram
- By the priority date (1988) citalopram was in advanced development and its beneficial properties were well known
- It was known that citalopram was a racemate – a 50:50 mixture of two enantiomers

Motive to resolve

- Awareness of potential differences in activity / toxicity of enantiomers provided "a clear motive to isolate and test the enantiomers".
- "Investigation of the enantiomers of citalopram was an obvious goal for the ordinary skilled medicinal chemist in 1988."

Lundbeck's patent

- Lundbeck identified two routes to making the enantiomers, both involving resolution of the diol precursor into its enantiomers followed by stereoselective conversion to the enantiomers of citalopram
- It discovered that the activity lay almost entirely in the (+) enantiomer

Claims

- Claim 1: (+) citalopram
- Claim 3: a pharmaceutical composition comprising (+) citalopram as an active ingredient
- Claim 6: a method for making (+) citalopram which comprises converting the (-) diol in a stereoselective way to (+) citalopram

Novelty and inventive step

At first instance and on appeal:

- Claims 1 and 3 were novel because they were to be interpreted as excluding the prior art racemate
- All claims involved an inventive step; it was not obvious that the necessary reaction of the resolved diol intermediate could be performed without loss of stereochemistry; it was not obvious to resolve citalopram by chiral HPLC

Biogen v. Medeva (1)

- S.14(3) = Art 83; s.14(5)(c) = Art 84; s.71(1)(c) = Art 100(b) / Art 138(1)(b)
- "The substantive effect of s.14(5)(c), namely that the description should…constitute an enabling disclosure, is given effect by s.72(1)(c)."

Biogen v. Medeva (2)

"S.72(1)(c) is…intended to give the court a jurisdiction in revocation proceedings…to hold a patent invalid on the substantive ground that…the extent of the monopoly claimed exceeds the technical contribution to the art made by the invention as described in the specification. …The disappearance of "lack of fair basis" as an express ground for revocation does not in my view mean that general principle which it expressed has been abandoned. The jurisprudence of the EPO shows that it is still in full vigour and embodied in Arts 83 and 84…"

Biogen v. Medeva (3)

"Furthermore, Art 84 EPC also requires that the claims must be supported by the description, in other words, it is the definition of the invention in the claims that needs support. In the Board's judgment, this requirement reflects the general legal principle that the extent of the patent monopoly, as defined by the claims, should correspond to the *technical contribution* in order for it to be supported, or justified."

- T 409/91 *Exxon / Fuel Oils*

Biogen v. Medeva (4)

The critical issue was not "whether the claimed invention could deliver the goods across the full width of the patent" 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."

Biogen v. Medeva (5)

"there is more than one way in which the breadth of a claim may exceed the technical contribution to the art embodied in the invention. ... Or it may claim every way of achieving a result when it enables only one way and it is possible to envisage other ways of achieving that result which make no use of the invention."

Biogen v. Medeva (6)

"care is needed not to stifle further research and healthy competition by allowing the first person who has found a way of achieving an obviously desirable goal to monopolise every other way of doing so."

Lundbeck (High Court)
[2007] EWHC 1040, [2007] RPC 32

"The inventive step taken by the inventors of the Patent was not deciding to separate the enantiomers of citalopram but finding a way it could be done. The technical contribution they made was the discovery that the diol intermediate could be resolved and then the enantiomers of the diol converted into the enantiomers of citalopram whilst preserving their stereochemistry."

"Claims 1 and 3 of the Patent cover all ways of making the (+) enantiomer of citalopram. For example, they cover resolving citalopram on a preparative chiral HPLC column. Does this method of resolution owe anything to the teaching of the Patent or any principle it discloses? In my judgment it does not. By June 1988 the preparation of the individual enantiomers of citalopram was an obviously desirable goal and their testing was trivial. There is no teaching in the Patent as to how that goal is to be achieved other than by use of the diol intermediate. … 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 are too broad. They extend beyond any technical contribution made by Lundbeck."

Lundbeck (Court of Appeal) [2008] EWCA Civ 311, [2008] RPC 19

- Lord Hoffmann: "In the case of a product claim, performing the invention for the purposes of s.72(1)(c) means making or otherwise obtaining the product. … A product claim is sufficiently enabled if the specification discloses how to make it. There is nothing to say that it must disclose more than one way."
- Jacob LJ: The claim was to the (+) enantiomer, and the patent enabled the skilled person to make it, so Art. 83 was satisfied.

- Lord Hoffmann: The claim in *Biogen* was to a class of products made by recombinant technology. The decision was limited to that form of claim and "cannot be extended to an ordinary product claim in which the product is not defined by a class of processes of manufacture."
- Jacob LJ: None of the passages in *Biogen* relied on were concerned with a novel, non-obvious and enabled product claim.

- Lord Hoffmann: "Where a product claim satisfies the [patentability] requirements, the technical contribution is the *product* and not the process by which it was made, even if that process was the only inventive step" – see T 595/90 *Kawasaki Steel*. There is no connection between the requirement of sufficiency of the claimed invention and the inventive step.
- Jacob LJ: "In the context of substance claims the technical contribution includes provision of the substance itself – one that could not be provided before. Merely because it was wanted before does not diminish the technical contribution."

Lundbeck (House of Lords) [2009] UKHL 12

Lord Walker:

The fundamental distinction from *Biogen* was that Lundbeck's claim was to a single chemical compound whereas the claimed invention in *Biogen* was one with a large number of possible embodiments. The appeal could only succeed if there was a general principle that required single compound claims to be restricted to the technical contribution to the art, and that was the inventive concept (here, the diol process).

"'Inventive concept' is concerned with the *identification* of the core (or kernel, or essence) of the invention – the idea or principle…which entitles the inventor's achievement to be called inventive. The invention's technical contribution is concerned with the *evaluation* of its inventive concept – how far forward has it carried the state of the art? The inventive concept and the technical contribution may command equal respect but that will not always be the case."

- Biogen's invention's technical contribution to the art "was not of lasting strategic importance" and "was not…something of lasting importance"; *Biogen* was "an example of a brilliant inventive concept which did not however make a significant permanent contribution to the art."
- Had Lundbeck found that both enantiomers were equally useful its invention "would, at least in commercial terms, have made no significant technical contribution to the art. … But the inventive concept would have been no different."

- Here, the technical contribution was the isolated (+) enantiomer
- Claim 1 was to that single chemical compound
- *Exxon* required the claim to be justified by the actual technical contribution to the art, but said that a claim was sufficient if one could make all the claimed products by methods disclosed or being part of the CGK.

Lord Mance:

While there were passages in *Biogen* which can be read as supporting tying the scope of any patent to the inventive step or technical contribution involved in its creation and justifying this on utilitarian grounds, nowhere in *Biogen* was the claim treated as a simple claim in respect of a novel product or address the issue that would on that basis arise, as to whether such a claim can or should be restricted in scope by reference to the inventive step involved in its creation.

- "
- What the description discloses must under s.14(5)(c), read together with s.14(3), enable a skilled person to make the patented product across its full width or to its full extent. This does not mean that it must also enable the skilled person to make it by all possible methods."
- There was no support for the Appellants' submissions in the EPC or the Act, or the UK case law.

- The *Kawasaki Steel* line of cases was conclusive – the EPO "could not sensibly have given such unequivocal endorsement to the patentability of a product in such circumstances, had it envisaged that the patent would be liable to revocation in so far as it purported to cover other methods owing nothing to the inventive method..."
- The passage from *Exxon* quoted in *Biogen* has never been applied to a simple product claim and the case was dealing with a situation where the description did not support all the embodiments covered by the claim.

Lord Neuberger:

Absent *Biogen* there was no support for the Appellants' case:

- There was nothing in the EPC or the Act to support the proposition that if a patent claims a novel and non-obvious product and sufficiently explains how to make it, the claim can be rejected because there may be other ways of making it which owe nothing to the teaching of the patent.
- The *Kawasaki Steel* line of cases showed the EPO consistently reasoning along the same lines as the Court of Appeal.

As to *Biogen*:

- The claim was not a simple product claim, but "at least as much a process claim as a product claim".
- While *Biogen* (and *Exxon*) showed that the monopoly to be granted is to be assessed by reference to the technical contribution, the technical contribution was to make available for the first time the isolated (+) enantiomer – the technical contribution is what is new to the art and non-obvious.

- "There is a difference between the 'inventive step' or 'inventive concept' on the one hand and the 'technical contribution to the art' on the other" (agreeing with Lord Walker). "'Inventive step' suggests how something has been done and, in the case of a product claim at any rate, one is primarily concerned with what has been allegedly invented, not how it has been done. On the other hand, where the claim is for a process or (as in *Biogen*) includes a process, the issue of how the alleged invention has been achieved seems to be more in point."