

CHEMICAL PRODUCT PATENTS AND *BIOGEN* INSUFFICIENCY
BEFORE THE HOUSE OF LORDS

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Generics (UK) Ltd v Lundbeck A/S [2009] UKHL 12 is about the validity of patents for chemical products. It is also about the object of patent protection, and the balance struck by the patent system between the interests of the public and individual inventors. Finally, it is about the development of UK patent law in the era of the Convention on the Grant of European Patents (1973) 13 I.L.M. 268 (European Patent Convention).

The case involved a patent for a popular antidepressant drug comprising a (+) enantiomer. Before the priority date of the patent, the enantiomer (known as escitalopram) was only available in racemic form as part of the compound citalopram. After discovering a way to resolve that compound and thereby produce escitalopram, Lundbeck obtained a European patent, which, being a patent for the enantiomer as such covered every method of making the product.

Generics applied for revocation of the patent under s.72(1) of the Patents Act 1977. The grounds were that escitalopram was not “a patentable invention”, and that the patent claim in respect of the drug was not sufficiently supported by the specification. In particular, at the priority date of the Lundbeck patent, escitalopram formed part of the state of the art and was also lacking the inventive step required by s.1(1) of the Act. Further, even if escitalopram were a patentable product, it exceeded the technical contribution to the art disclosed in the patent specification, and was thus not sufficiently supported in law within the meaning of s.14(5)(c) and s.72(1)(c) of the Act.

At first instance, Kitchin J rejected the patentability point ([2007] EWHC 1040; [2007] R.P.C. 32). In his judgment, the claim was for the (+) enantiomer as such, which was novel on the principles of *Synthon BV v. SmithKline Beecham Plc* [2005] UKHL 59; [2006] R.P.C. 10, namely, that the prior art neither disclosed the product, nor enabled (with common general knowledge) an ordinary skilled person to produce the product. Further, while producing the enantiomer was an obviously desirable goal, Lundbeck’s method was not obvious to try, which made the enantiomer an inventive one. This left the issue of sufficient support, and the proportionality of the patent rights in the light of the technical contribution to the art.

The question of sufficiency is the focus of the case. Important was the principle of the Technical Board, interpreting the European Patent Convention, that “the extent of the monopoly, as defined by the claims, should correspond to the technical contribution to the art in order for it to be supported or justified” (T_409/91 (*EXXON/Fuel Oils*) [1994] O.J. E.P.O. 653 at [3.3]). That principle was accepted in *Biogen v Medeva* [1997] R.P.C. 1 (H.L.), and described by Lord Hoffmann in that case as requiring revocation of a patent for a class of recombinant antigens on the ground of insufficient support (at 50-52):

“[I]n concentrating upon the question of whether Professor Murray’s invention could, so to speak, deliver the goods across the full width of the patent or priority document, the courts and the EPO allowed their attention to be diverted from what seems to me in this particular case the critical issue. It is 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.

[*GENENTECH I/Polypeptide expression* (T_292/85) [1909] O.J. E.P.O. 275] shows that 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. The patent may claim results which it does not enable, such as making a wide class of products when it enables only one of those products and discloses no principle which would enable others to be made. 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. ...

I accept the judge’s findings that the method was shown to be capable of making both antigens and I am willing to accept that it would work in any otherwise suitable host cell. Does this contribution justify a claim to a monopoly of *any* recombinant method of making the antigens? In my view it does not. The claimed invention is too broad. Its excessive breadth is due, not to the inability of the teaching to produce all the promised results, but to the fact that the same results could be produced by different means.”

Considering the implications of this reasoning, Kitchin J noted the emphasis in *Biogen* on restricting the availability of patents to ensure that “research and healthy competition” are not stifled by allowing the first who achieves an obviously desirable goal to monopolise every

way of achieving that goal (at [262]). Kitchin J reasonably concluded from this *dictum*, read in the context of *Biogen* as a whole, that being first to isolate a chemical product, the properties of which were previously known, might entitle a person to a patent for the method but not for the isolated product itself. The reason was the inventive step, which was restricted to the method of isolating the product. That such step might make the product inventive did not, he suggested, detract from this, for a patent for a novel and inventive product might still be invalid for excessive breadth. The implication for the (+) enantiomer was clear: it was patentable under s.1(1) of the Act, but insufficiently supported in the *Biogen* sense.

On appeal this decision was overturned ([2008] EWCA Civ 311). According to Lord Hoffmann on the Court of Appeal, with whom Smith and Jacob LJ agreed, Kitchin J erred in tying the requirement for support to the inventive step disclosed in the patent rather than the actual invention itself (at [41]). In his Lordship's judgment (at [29]):

"In order to decide whether the specification is sufficient, it is ... first necessary to decide what the invention is. That must be found by reading and construing the claims, in which the inventor identifies what he claims to be his invention. As the Board of Appeal of the European Patent Office said in *Exxon/Fuel Oils* ... 'It is the definition of the invention in the claims that needs support'."

In *Biogen* the invention was a class of recombinant products, while in *Lundbeck* it was a chemical product as such independent of any method of making the same. As a result, the requirements of sufficiency differed between the cases (at [30]):

"Section 60(1) of the Act makes it clear that a claim may be either to a product or a process. In the case of a product claim, performing the invention for the purposes of section 72(1)(c) means making or otherwise obtaining the product. In the case of a process claim, it means working the process. A product claim is therefore sufficiently enabled if the specification discloses how to make it. There is nothing to say that it must disclose more than one way."

While "sympathetic to the feeling" of Kitchin J below that the distinction between the relevant patents owed little to their respective contributions to the art (at [42]), the statutory allowance of patents for products determined the validity of the *Lundbeck* grant, and made it (Lord Hoffmann said in his judgment) "too late to have regrets about the breadth" of the claim (at [46]).

The House of Lords affirmed this decision, seeming to support the Court of Appeal's view that in a case involving a chemical product the technical contribution made to the art is by definition the (patentable) product itself. The exception to this was Lord Walker, for whom it was not enough that the product contribute to the art; it needed to do so sufficiently to justify a patent. In *Lundbeck*, he implied, the contribution was sufficient, for escitalopram was a thing of "lasting importance" (see at [33]).

The question at the heart of the *Lundbeck* case is how does one determine the contribution to the art in the case of a method of first making a product, and how does one decide whether that contribution justifies a patent for the product as such? According to Kitchin J, the contribution to the art is the inventive step, which must therefore lie in the product itself in order for that product to support a patent. According to the higher Courts, however, the contribution to the art is the invention claimed, which must therefore be a product as such in order to support a patent for the same. While this seems to subvert the *EXXON* principle, it proceeds from the existence of a patentable "invention", which the UK courts have accepted to require a technical contribution to a relevant art (*Aerotel Ltd v Telco Holdings Ltd* [2006] EWCA Civ 1371 at [40]; *Symbian v Comptroller General of Patents* [2008] EWCA Civ 1066 at [7]). Hence, even on the view of the House of Lords, a product ought only to support a patent if, when conceived *qua* invention, it makes a contribution of a technical nature.

The central point to emerge from *Lundbeck* is the need to consider sufficient support with regard to the category of invention claimed. Consider for example this statement by Lord Walker (at [22]):

"Judges have often observed that the wide abstract terms in which patent law is expressed must always be related to the facts of the particular case. That is especially true in relation to the sufficiency of a product claim, since the term 'product' covers such an extremely wide variety. A product may be as simple as a baby's disposable diaper (see *Mölnlycke AB v Procter & Gamble Ltd* [1992] FSR 549) or a corkscrew (see *Hallen Co v Brabantia (UK) Ltd* [1991] RPC 195) or as complex as an 'heavier-than-air flying machine' referred to by Lord Hoffmann in *Biogen*, or a class of microscopic organisms, produced by recombinant DNA technology, such as was considered by this House in *Biogen* and *Kirin-Amgen*."

The same is true, it is submitted, beyond sufficient support, with respect to the s.1(1) requirements themselves. Further, it underlines the importance of proper conception of the

particular product (and invention) in question. These points have implications for the analysis in *Lundbeck*.

With respect to the nature of escitalopram, for example: as accepted by each of the *Lundbeck* Courts, escitalopram was not a chemical product but rather an *isolated* chemical product. Indeed, this distinction was central to their Lordships' finding that the invention was not anticipated by the racemate, notwithstanding the principle of *Merrell Dow Pharmaceuticals Inc v Norton & Co Ltd* [1995] R.P.C. 76 (H.L.) – consistent with the principle of *EXXON* above – that “the novelty of [an] invention must be co-extensive with the monopoly” (at 82), and its express implication for products as follows: “If there is any method of manufacture or form of the product which is part of the state of the art, then to that extent the invention is not new” (at 82-83). In *Lundbeck*, a racemic form of escitalopram was part of the state of the art, but this did not deprive escitalopram of novelty, for when conceived correctly *qua* invention, that product was confined to its isolated form (see [2007] EWHC 1040 at [62]-[64]; [2008] EWCA Civ 311 at [9]-[13]; [2009] UKHL 12 at [6]).

Given this judicial conception of escitalopram, it is arguable that *Biogen* ought not to have been distinguished. The reason is that a patent claim to an isolated product is analogous to a claim to a recombinant product in its importation of a process element. The result is that the principles of *Biogen* ought to have applied, and Kitchin J's decision of insufficiency upheld.

Reading *Lundbeck*, one is struck by the role played by Lord Hoffmann in developing contemporary patent law. It was his Lordship who authored the *Biogen* judgment, and entrenched the principle from *EXXON* above that in order for a patent claim to be valid it must correspond to the technical contribution to the art. It was also his Lordship who came down from the House of Lords in *Lundbeck* to clarify that principle in deference to the Act, and the inherent patentability of chemical products. And finally, it was his Lordship who, in *Biogen* again, described inherent patentability as an “academic” concept (at 41). This last is challenged by the *Lundbeck* decisions, which underline the centrality of inventions to the Act, and vindicate the view of Lord Mustill in *Biogen* that inherent patentability is not an “academic” issue, but one sometimes requiring “close conceptual analysis”, particularly in the context of new technologies “far distant from the mechanical and chemical inventions to which so much of traditional patent law relates” (at 31-32).

Among other things, *Lundbeck* is a reminder of the tensions that inhere in contemporary patent law as a result of its europeanisation. Since 1977, UK patent legislation has been part of an international legal system that permits decentralized decision-making but that requires the harmonized development of its substantive norms, at least on the part of national courts (see s.130(7); cf T154/04 (*DUNS LICENSING ASSOCIATES/Estimated sales activities*)). Even among EPC Contracting States, however, the UK has a unique position within that system on account of its constitutional and patent law traditions, which have arguably exacerbated the tensions above by encouraging an approach to patentability that differs from the approach of the European Boards – and sometimes the decisions of other national courts – in matters of method and occasionally of substance. One example of this difference reflected in *Lundbeck* is the greater deference by the UK courts to precedent and the terms of the (harmonized) Act. That deference is apparent from the reasoning of the courts, which is more detailed and careful than the reasoning of the Boards, producing a more coherent and connected line of decisions authored by a smaller number of judges around a smaller number of authoritative cases. *Lundbeck* takes its place in that line of decisions, more than two centuries after *Boulton v Bull* (1795) 2 H. B.L. 463; 126 E.R. 651 (CP), where the inherent patentability of chemical products, and the need to ensure fairly based claims, were each first recognized expressly by a court. That the House of Lords is still working to reconcile satisfactorily those two principles reflects the depth and complexity of the issues they involve.

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