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UK House of Lords clarifies enablement law

On 25 February 2009 the UK House of Lords, the highest court in the UK, delivered its judgement in the case of Generics (UK) Ltd. v. Lundbeck A/S[1]. This case was an appeal from the Court of Appeal brought by the appellants, generic drug manufacturers, against the decision of the Court of Appeal upholding the validity of respondent Lundbeck's European patent (UK) 0 347 066. The Appellate decision itself reversed a decision of the High Court, which found the patent invalid for lack of sufficient disclosure (lack of enablement).

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Lord Hoffmann's long shadow

There are a number of intriguing aspects to this case, most of which revolve around the UK's most respected patents Judge, Lord Hoffmann.

The High Court's first instance decision on insufficiency was based on the House of Lords' former decision in *Biogen v. Medeva*[2], in which the lead judgement was delivered by Lord Hoffmann. The approach to insufficiency adopted by Lord Hoffmann in that case has become known, since then, as "Biogen" insufficiency.

In a departure from normal practice, Lord Hoffmann, coming down from the House of Lords to the Court of Appeal, heard the Appeal in the present case. He reversed the decision of the High Court judge, holding that his own *Biogen* rationale was inapplicable to the facts of the case.

Finally, the House of Lords, this time without Hoffmann, has upheld the decision of the Court of Appeal – that is, the decision of Lord Hoffmann.

Biogen

Any analysis of this decision must therefore start with *Biogen*. That case concerned a vaccine for Hepatitis B Virus (HBV), and pioneering work done before the sequencing of the HBV genome. The inventor, Prof. Murray, expressed genetic material from the so-called Dane particle of HBV in *E. coli* using the plasmid pBR322. He relied on an approach in which nucleic acid fragments were chosen for expression because they were large, and therefore more likely to contain the genes encoding the relevant HBV antigens, HBsAg and HBcAg. Since the Dane particle was not sequenced, it was not possible to be sure what genetic material was being inserted into the vector.

The claim at issue was functionally defined, in that it required that a nucleic acid incorporated into a vector should be able to express the HBs and HBc antigens. After the fling date of *Biogen*, the Dane particle was sequenced, enabling the genes encoding these antigens to be isolated precisely. This allowed production of an HBV vaccine using methods which owed nothing to that of Prof. Murray; however, the *Biogen* claim encompassed such later methods.

Lord Hoffmann, in *Biogen*, took the view that the contribution to the art made by Prof. Murray consisted in expressing the Dane particle without sequencing. He considered that this was the inventive step which embodied in the invention. Lord Hoffman equated the inventive contribution made by Prof. Murray with the technical contribution to the art made by the invention.

Applying the maxim that the extent of protection conferred by the claims should be commensurate with the contribution made to the art, the court concluded that the claims were too broad, since they covered approaches to expressing the HBV antigens which owed nothing to the developments made by Prof. Murray. In this respect the Court in *Biogen* (and in the present case)

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made much of the fact that it was following the lead of the EPO Technical Board of appeal in the Exxon decision (T409/91). This kind of insufficiency attack became known as "Biogen insufficiency" in the UK.

The Citalopram case; a simple compound claim

It is immediately apparent that this approach does not apply in all cases. For example, according to normal practice, an invention of a new chemical compound can be claimed using the structural elements of the compound itself. It is not expected, nor is it necessary, for the claim to be limited either to the method by which the compound is actually produced or to how it is used. This is required only in the description of the patent specification; the compound claim is to the compound *per se*. How, then can the insufficiency principle outlined in *Biogen* be applied?

This is the problem that the Courts found them selves faced with in the present case. The patent in suit claimed the (+) enantiomer of the known anti-depressant, citalopram. Citalopram had previously been marketed as a racemate, and the patentee Lundbeck discovered that the (+) enantiomer was responsible for the therapeutic effect; the (-) enantiomer if anything inhibited this effect. It was not contested by the parties before the House of Lords that the claim to the enantiomer was novel and inventive. Only sufficiency remained in question.

It is accepted that enantiomers are very difficult to isolate from racemates. The appellants took the position that isolating an enantiomer of any drug was a desirable goal; the difficulty lay in actually doing so. Lundbeck's claims, it was argued, should be limited to the method which they had invented, because that was the inventive concept.

The Court of Appeal rejected this argument. Lord Hoffmann distinguished the *Biogen* case on the grounds that it related to a "product by process" claim, and moreover a claim which covered a very large number of products. In contrast, the Lundbeck claim was a "simple product" claim, directed to a single chemical entity.

What Lord Hoffmann may have meant by "product by process" is itself not immediately clear; such a label is usually applied to a claim of the structure "product x, made by process y". Claim 1 in *Biogen*, in contrast, was structured as "a product, characterised in that it is capable of function y". However, the product was itself stated to be a "recombinant DNA" product, and in *Biogen* the position was taken that this referred to the way in which it had been made, that is by recombining DNA molecules[3].

The House of Lords took a slightly different approach. Whilst taking great care to sidestep the "product by process" issue, Lord Walker took the opportunity to emphasise that there is a difference between the "inventive concept" on the one hand and the "technical contribution to the art" on the other. The former, he stated, is directed to the kernel of the invention, whilst the latter more to the extent to which the inventive concept has progressed the development of the art. This means that, in the present case, the technical contribution to the art is the provision of the (+) enantiomer. This justifies a claim directed to this enantiomer. The inventive concept or kernel of the invention may have been a method for isolating the enantiomer, but this did not require that the claim be limited to the method disclosed.

Lord Neuberger attempted to take on the product by process issue more directly, although even he was forced to characterise the *Biogen* claim as "almost a process-by-product-by-process claim". What this means, in the view of this author, is even more obscure. However, Lord Neuberger agreed with Lord Walker that a difference must be acknowledged between the "inventive concept" and the "technical contribution to the art". In considering simple product claims, Lord Neuberger asserted, considering the inventive concept instead of the actual contribution to the art can lead to errors.

Is *Biogen* still good law?

The answer here has to be "yes", because the House of Lords has gone to great lengths to distinguish the present decision on the facts of the case. However, the clarification of the distinction between the inventive concept and the technical contribution to the art is very important. In *Biogen*, the decision was made on the basis of the inventive concept, and it is now clear that this approach is not universally applicable.

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compound and claims covering a plurality of compounds – especially functionally defined claims. However, it seems to me that there is little logic in this approach. It is not clear why a more complex claim should be assessed according to one standard (inventive concept) and a simple claim according to another (technical contribution to the art). It is telling that the EPO Technical Board of Appeal found Biogen's claim to be sufficient, following its own decision in T409/91. It is likely that, in future, UK courts will follow the EPO approach more closely, and not put so much emphasis on the "inventive concept" as to the actual technical contribution to the art. The standard of assessing the technical contribution to the art is that adopted by the EPO, and I expect that the UK courts will tend to this approach in future.

Practice considerations

This case continues last year's pro-patent approach of the UK courts, reversing a previous anti-patent stance that had been prevailing in the UK for some years. It clarifies the UK approach to sufficiency, which had been saddled with a dual concept of "normal" and "Biogen" insufficiency, ostensibly by ruling that the *Biogen* decision is not helpful in deciding cases relating to simpler inventions. Perhaps more accurately, in my view, the decision clarifies the application of the concept of "technical contribution to the art", in relation to sufficiency questions. This means that the same concept of sufficiency should apply to all inventions, and it will no longer be necessary to take the two-tier approach. It should therefore be more straightforward for practitioners to arrive at a view on sufficiency.

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[1] [2009] UKHL 12
[2] [1997] RPC 1
[3] The problem with this approach is that "recombinant DNA" refers to a molecule in which DNA from different sources has been recombined, that is arranged in a different manner from that occurring in nature, and as such points to a structural difference in the DNA molecule which differentiates it from natural DNA. It is not, strictly speaking, a product-by-process because it does not matter how the DNA is recombined.

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