HOUSE OF LORDS SESSION 2008–09

[2009] UKHL 12

on appeal from:[2008]EWCA Civ 311

OPINIONS

OF THE LORDS OF APPEAL

FOR JUDGMENT IN THE CAUSE

Generics (UK) Limited and others (Appellants) *v* H Lundbeck A/S (Respondents)

Appellate Committee
Lord Phillips of Worth Matravers
Lord Scott of Foscote
Lord Walker of Gestingthorpe
Lord Mance
Lord Neuberger of Abbotsbury

Counsel

Appellants:
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Mark Chacksfield
Tom Mitcheson
(Generics (UK) Limited: Instructed by Taylor Wessing LLP)
(Arrow Generics Limited: Instructed by Forsyth Simpson)
(Teva (UK) Limited: Instructed by Roiter Zucker)
(Teva Pharmaceutical Industries Limited: Instructed by Roiter Zucker)

Respondents:
Andrew Waugh QC
Justin Turner
(Instructed by Simmons and Simmons; Howrey LLP)

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LORD PHILLIPS OF WORTH MATRAVERS

My Lords,

1. I have had the benefit of reading in draft the speeches of each of your Lordships. They reach the same conclusion for the same reasons. I share both the conclusion and the reasoning and would, accordingly, dismiss this appeal.

LORD SCOTT OF FOSCOTE

My Lords,

2. Section 1(1) of the Patents Act 1977 lays down four conditions that must be satisfied if a patent for an invention is to be granted. The first of these is that "the invention is new". This condition is easy enough to understand if the invention is a process whereby something or other can be made or done. But I find it less easy to understand if the claimed invention is of a chemical product where, as here, the existence of the product is known, its chemical and molecular structure is known and, up to a point, its characteristics are known. The present case concerns a claim to a product patent. The product is the (+) enantiomer of citalopram. Citalopram is an organic compound, patented by the respondent many years ago and the patent for which has expired. Trade rivals can, and do, now make and market citalopram as an anti-depressant.

3. As my noble and learned friend Lord Neuberger of Abbotsbury has explained citalopram is a racemate, that is to say, a combination of two types of molecules, each a mirror image of the other, and each having the same chemical formula and, subject to the mirror image characteristic, the same stereochemical structure. What was not known prior to the teaching of the patent in issue in the present case was how to separate the (+) and (-) enantiomers of citalopram and, therefore, what their respective contributions were to the anti-depressant quality of citalopram. Having devised a novel means of separating the (+) and (-) enantiomers and subjected each to tests, the respondents have discovered that it is the (+) enantiomer that has the desired anti-depressant effect, and that the (-) enantiomer has, if anything, an inhibiting effect. A much more effective anti-depressant is, therefore, achieved by isolating and marketing the (+) enantiomer of citalopram. This is what the respondents have done and claim to be entitled to a patent monopoly to protect.

4. There can be no doubt that the respondent is entitled to patent protection for its process of separating the (+) and (-) enantiomers of citalopram. That is not in dispute. What is in dispute is their claim to a product patent for the (+) enantiomer. The appellants' objection, however, pressed before your Lordships by Mr Thorley QC, has not been that the (+) enantiomer lacked novelty but has been one of insufficiency. Lack of novelty was a point taken before Kitchin J and before the Court of Appeal but failed in both courts and has not been pursued on this appeal to the House.

5. My Lords, having had the great advantage of reading in draft the opinion of Lord Neuberger I find myself in full agreement with his reasons for concluding that the appeal on the insufficiency point must be dismissed and there is nothing I can usefully add on that issue. I want, however, to add a few words on the novelty point not because it has been in issue on this appeal but because I have found the proposition that the (+) enantiomer is, for the purposes of section 1(1) of the 1977 Act, a new product to be sufficiently puzzling as to require some examination.

6. Section 2 of the Act explains the concept of novelty :

> "(1) An invention shall be taken to be new if it does not form part of the state of the art.

> (2) The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in the United Kingdom or elsewhere) by written or oral description, by use or in any other way …"

It is common ground that prior to the priority date claimed by the respondent for its "product" invention the (+) enantiomer of citalopram had not been made available to the public otherwise than as an unseparated part of the racemate that constituted the citalopram molecule. In its *separated* form the (+) enantiomer had not at any time before the priority date been made available to the public. It follows, therefore, that the (+) enantiomer was "new" for the purposes of section 1(1)(a) of the Act.

7. It is pertinent to note that European Patent Office jurisprudence upholds claims to product patents for separated enantiomers that had not previously been separated. In a decision given on 30 August 1988 in Case T 0296/87 the EPO asked itself the question (para.6)

> "…whether a known chemical formula evidently containing a (single) asymmetrical carbon atom destroys the novelty not only of the compound in the form of its racemate, but also of its enantiomers …."

and held (para.6.2) that

> "The novelty of the … enantiomers is … not destroyed by the description of the racemates"

and (in para.6.3) that

> "The situation is different if the state of the art includes enantiomers … which are specifically named *and can be produced*" (emphasis added)

8. This EPO jurisprudence is, it appears, now well established and fully meets the doubts that I had had about novelty. I would, in agreement with the reasons given by Lord Neuberger, dismiss this appeal.

LORD WALKER OF GESTINGTHORPE

My Lords,

Introduction

9. The scientific background to this appeal and the essential features of the patent in suit are set out fully in the first-instance judgment of Kitchin J [2007] RPC 729, paras 8-25 and 26-35 respectively. The same material is covered more briefly at the beginning of the judgment of my noble and learned friend Lord Hoffmann when sitting in the Court of Appeal [2008] RPC 437, paras 1-5. I gratefully adopt Lord Hoffmann's summary:

> "1. Citalopram is one of a class of anti-depressant drugs known as selective serotonin reuptake inhibitors ('SSRIs') which inhibit reuptake of the neurotransmitter serotonin by nerve cells and thereby promote neural transmission. This is claimed to alleviate the symptoms of depression, although the mechanism is far from clear and the claim remains controversial: see Kirsch et al, Initial Severity and Antidepressant Benefits (2008) 5 P LoS Medicine 260-268. Nevertheless, the SSRIs have had huge commercial success. Citalopram is sold in the United Kingdom under the brand name Cipramil and other SSRIs are fluoxetine (sold as Prozac) and paroxetine (Seroxat). The patent for Citalopram was held by the Danish company H Lundbeck A/S ('Lundbeck') but expired several years ago. Since

then it has been sold in its generic form by a number of manufacturers.

2. Citalopram is a racemate, consisting of equal numbers of two molecules called enantiomers, which are made up of the same atoms and have much the same physical properties, but differ in the three-dimensional shape in which the atoms are bonded together. Such molecules are called chiral (from χειρ, a hand) because, like a pair of hands, they are mirror images which cannot be completely supraimposed on each other. They are conventionally designated (+) and (-). It has been well known for many years that, despite their similarities, the two enantiomers may bind to different proteins and produce different biological effects. The most notorious example was thalidomide, which consisted of a (+) enantiomer which was effective to prevent morning sickness in pregnant women and, unknown to the consumers, a (-) enantiomer which was teratogenic and caused severe birth defects.

3. The resolution of a racemate by separation into its enantiomers is not a straightforward matter. Because they have the same boiling point, they cannot be separated by conventional fractional distillation. For similar reasons, fractional crystallisation may not work. There are indirect methods of coming at the problem and Lundbeck began to try to find one of them from about 1980. It seems to have involved a good deal of trial and error and they were not successful until 1987.

4. When they had resolved the racemate, Lundbeck found that the reuptake inhibitory effect was caused entirely by the (+) enantiomer, which is called escitalopram. In 1989 they applied for the patent in suit, EP (UK) 0, 347, 066, with a priority date of 14 June 1988. The drug has been marketed with success under the brand name Cipralex. More recent research has shown that the (-) enantiomer actually slows down the inhibitory effect, so that the (+) enantiomer works better without it.

5. The patent is entitled 'New enantiomers and their isolation.' Three claims are in issue:

(a) Claim 1, to the enantiomer itself: "(+) -1-(3-dimenthylaminopropyl)-1-(4'-fluorophenyl)-

1,3-dihydroisobenzofuran-5-carbonitrile . . . and non-toxic addition salts thereof."

(b) Claim 3, to a 'pharmaceutical composition in unit dosage form comprising, [as] an active ingredient, a compound as defined in claim 1.'

(c) Claim 6, to 'a method', (which I shall describe later) 'for the preparation of a compound as defined in claim 1.'"

10. It will be apparent that claims 1 and 3 in the patent are to products (a chemical compound and a pharmaceutical preparation with that compound as its active ingredient); claim 6 is to a process. The distinction between product claims and process claims, especially in relation to the appropriate test for sufficiency, is at the heart of this appeal. The sufficiency of the claims is now the only issue in the appeal. Initially the appellants (all companies which make or market generic forms of citalopram) attacked claims 1 and 3 as lacking novelty (because of the disclosure of the racemate in the patent which the respondent, Lundbeck, holds for citalopram); they attacked claims 1, 3 and 6 as invalidated by obviousness; and they attacked claims 1 and 3 as invalidated by insufficiency, in that they claimed the (+) enantiomer in general terms (that is, however it was produced) but disclosed only two methods of producing it.

11. The attacks based on lack of novelty and obviousness failed in both courts below, and are not renewed before your Lordships. But on sufficiency the lower courts reached different conclusions. Kitchin J (paras 250 to 265) held claims 1 and 3 to be invalid for insufficiency. He based this conclusion very largely on the decision of your Lordships' House in *Biogen Inc v Medeva Plc* [1997] RPC 1 ("*Biogen*"), in which the leading speech was given by Lord Hoffmann. The Court of Appeal (Lord Hoffmann and Smith and Jacob LJJ) reached a different conclusion. Lord Hoffmann (with whom the Lords Justices agreed, Jacob LJ adding some brief reasons of his own) sympathised with what he called "the judge's instinctive reaction to the inherent breadth of a product claim." But the judge had, in Lord Hoffmann's opinion, extracted too broad a principle from *Biogen*, which was not a simple product claim but a "product-by-process" claim, and moreover a claim to a wide class of such products.

12. The distinction between product claims and process claims is assumed, rather than spelled out, in the Patents Act 1977 (which

notoriously does not define "invention", but in section 1 lays down various inclusionary or exclusionary conditions for patentable inventions). The distinction is implicit in section 60 (1) (meaning of infringement), which defines infringement primarily by reference to these terms:

> "(a) where the invention is a product, he makes [etc] the product . . .
>
> (b) where the invention is a process, he uses the process [etc] . . .
>
> (c) where the invention is a process, he disposes of [etc] any product obtained directly by means of that process . . ."

13. The distinction is however not always straightforward. Although there is a requirement that an application for a patent should be limited so as to "relate to one invention only or to a group of inventions so linked as to form a general inventive concept" (EPC Art 82; compare Patents Act 1977 section 14(5)(d) which has "single inventive concept"), it is commonplace (as in the patent in suit) for the claims to be a mixture of product claims and process claims.

14. The appellants' case, reduced to its simplest form, is that the Court of Appeal's decision is an unwarranted departure from *Biogen*, and infringes the general legal principle (stated by the Technical Board of Appeal in para 3.3 of its decision in *Fuel Oils/EXXON* (T 409/91) [1994] OJEPO 653,—"*Exxon*"—by way of explanation of "support" in Art 84 of the EPC),

> "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 Hoffmann cited this passage in *Biogen*, at p.49, and again in his judgment in the Court of Appeal in this case, para 35. The respondent's case, again in its simplest form, is that the relevant claims are claims to a product, not a process, and that (as Lord Hoffmann put it in para 36 of his judgment in the Court of Appeal):

> "When a product claim satisfies the requirements of section 1 of the 1977 Act, 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."

Sufficiency

15. I shall have more to say about product claims, but I must now address sufficiency. The three commonest grounds for attacking the validity of a patent are (a) lack of novelty (that is, the invention does not go beyond the state of the art); (b) obviousness (that is, that there is an advance in the state of the art, but it is an obvious advance lacking any inventive step); and (c) insufficiency. Insufficiency is less easily summarised because it is generally used (though the terminology is not always uniform) to link two concepts, drawn from EPC Articles 83 and 84:

> "83. Disclosure of the Invention
>
> The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
>
> 84. The Claims
>
> The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description."

16. The word "sufficiently" in Article 83 echoes the primary requirement of sufficiency which is expressed in almost identical words in section 14(3) of the Patents Act 1977:

> "The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art."

Article 84 is reproduced in section 14(5)(c):

> "The claim or claims shall—
>
> . . .
>
> (c) be supported by the description."

The significance of the reference to the "person skilled in the art", and this notional technician's approach to the task of performing an invention, have often been described by the court. There are helpful passages in the judgment of Aldous J in *Mentor Corp v Hollister Inc* [1991] FSR 557, 562 and in the judgment of Lloyd LJ in the same case [1993] RPC 7, 10-13.

17. Some judges have in the past been puzzled that section 72 of the Patents Act 1977 (power to revoke patents on application) reproduces (in subsection (1)(c)) the substance and wording of the requirement in section 14(3), but does not appear to reproduce section 14(5)(c). That puzzle was near the surface of the discussion, but was not in terms resolved, by this House in *Asahi Kasei Kogyo KK's Application* [1991] RPC 485 ("*Asahi*"). That appeal raised an issue on section 5(2)(a) of the Patents Act 1977 (which also refers to an invention being "supported"). Lord Oliver of Aylmerton, with the agreement of the rest of the House (and with Lord Jauncey of Tullichettle delivering a concurring opinion), seems to have treated the requirements of section 14(3) as necessarily including those of section 14(5)(c). Lord Oliver said at pp 535-6:

> "The Act does not contain any definition of the word 'supported' but some assistance can be obtained from the provisions of section 14(5) which require the claim in an application to be 'supported' by the description. That must, I think, involve the conclusion that if that which is contained in the description of the specification does not enable the claim to be established, it cannot be said to 'support' it, for the Act can hardly have contemplated a complete application for a patent lacking some of the material necessary to sustain the claims made. Since, therefore, subsection (3) of section 14 requires in terms that the specification disclose the invention in a way which will enable it to be performed by a person skilled in the art (i.e. it must contain an 'enabling disclosure') it follows that a description in an earlier application which contains no enabling disclosure will not 'support' the invention so

> as to enable it, as an invention, to claim priority from the date of that application under section 5(2)(a)."

18. That is how Lord Hoffmann (with the concurrence of the rest of the House) understood *Asahi* in *Biogen*. He stated (at p 47):

> "The explanation of section 14(5)(c) in *Asahi* seems to me to provide an answer to a point which puzzled the Court of Appeal in *Genentech Inc's Patent* [1989] RPC 147. The Court noted that although section 14(5)(c) is a statutory requirement for a valid patent application, non-compliance is not a ground for revocation of a patent which has been granted. Section 72(1) states exhaustively the grounds upon which a patent may be revoked. These grounds do not, as such, include non-compliance with section 14(5). But the substantive effect of section 14(5)(c), namely that the description should, together with the rest of the specification, constitute an enabling disclosure, is given effect by section 72(1)(c). There is accordingly no gap or illogicality in the scheme of the Act."

Lord Mustill (at p 31) expressly concurred in this. In dividing his opinion into sections Lord Hoffmann distinguished between "support for the claims" (section 12) and "sufficiency" (section 14) but he applied the same reasoning to both.

19. There is therefore high authority that the requirements of section 14(3) and section 14(5)(c) are closely connected. The main difference between them is that section 14(3) relates to the specification as a whole, whereas section 14(5)(c) relates to the claims which define the monopoly sought by the inventor. I repeat in a fuller form the citation from *EXXON* set out in para 14 above:

> "Furthermore, Article 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* to the art in order for it to be supported, or justified..."

20. 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: see Lord Oliver in *Asahi* at pp531-532, and Lord Hoffmann in *Biogen* at pp46-51 and in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 169 ("*Kirin-Amgen*") at paras 102-116. The disclosure must be such as to enable the invention to be performed (that is, to be carried out if it is a process, or to be made if it is a product) to the full extent of the claims. The question whether there is sufficient enabling disclosure often interacts with a question of construction as to the extent of the claims. For instance in *American Home Products Corp v Novartis Pharmaceuticals UK Ltd* [2001] RPC 159 ("*American Home Products*") the disclosure would have been insufficient if the claims had extended, not merely to rapamycin (a known antifungal antibiotic which proved effective as an immunosuppressant) but also to derivatives of rapamycin. The Court of Appeal held that the claims should be narrowly construed, and on that basis there was sufficient enabling disclosure.

21. The main thrust of the appellants' case is that Lundbeck made only a limited technical contribution to the resolution of citalopram, because it fully disclosed only one method of producing the (+) enantiomer, that is by the route of resolution of the diol intermediate. Therefore, it is said, the *Exxon* principle invalidates claims 1 and 3 because (although expressed as ordinary product claims) they are really in the nature of product-by-process claims, and should have been limited to escitalopram as produced by the diol intermediate method. In considering this argument I find it necessary to return to some fairly basic points of patent law—commonplace to the specialist in this field, but not necessarily obvious to the non-specialist.

Product claims

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—"*Mölnlycke*") 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*. Where the product is manufactured the specification is likely to include drawings as well as a verbal description, but the drawings are almost always described as an example (or embodiment). Otherwise (in the absence from United Kingdom patent law of a doctrine of equivalents—see *Kirin-Amgen* [2005] RPC 169, paras 36 ff) competitors would probably be able, by some small variation in design, to exploit the inventive concept without infringement. For similar reasons (especially in the field of chemical compounds) patent applications are likely to seek to obtain protection, not for a single compound, but for a class of compounds, and sometimes an almost unimaginably large class (see for instance *Pharmacia Corp v Merck & Co Inc* [2002] RPC 41, where claim 1 is set out, in an accessible form, in para 11; Arden LJ recorded, in para 150, that it comprised "literally trillions" of formulae).

23. In other cases the scope for different embodiments may be quite limited. *Mölnlycke* provides a simple and homely example. It might have been thought that by the 1980's there was little room for further improvements in the design and manufacture of one-piece disposable diapers. But there was a technical problem. For reasons of economy the diapers must be made with very thin plastic, usually polyethylene, which tears easily. The problem was to find a means of fastening and unfastening adhesive tapes or tabs (and refastening them if the baby was dry) without tearing the thin fabric. The inventive concept was a dedicated fastening surface consisting of a transverse plastic strip which was relatively strong, and inelastic and had "suitable surface properties". Simple though this was, the patent was attacked (unsuccessfully) on grounds of insufficiency as well as obviousness, because (it was said) the skilled man trying to carry out the invention could not answer the questions: How strong? How inelastic? Which of various forms of adhesion would be "suitable"? That was the context—as far removed as it could be from the mysteries of genetic engineering—of Morritt J's misinterpretation (as Lord Hoffmann called it in *Biogen* at p 48) of the principle in *Genentech I/Polypeptide Expression* (T 292/85) [1989] OJ EPO 275.

24. A "product-by-process" claim is a claim to a product, but described in such a way as to define it by the process by which it is produced. Such claims are discouraged by the European Patent Office ("EPO"). They are permitted by the EPO only where there is a claim to a new substance whose difference from a known substance cannot be

described in chemical or physical terms (see *Kirin-Amgen* [2005] RPC 169 at paras 88-91, and also at para 109; note that erythropoietin itself could not have been patented because it was a known substance occurring in nature). The expression "product-by-process" was used in argument in *Biogen* (at p 27) and this submission was accepted, if not in those precise terms, by Lord Hoffmann in his opinion in the paragraph (at p 40) which is quoted in paragraph 26 below. Lord Hoffmann also used it, in relation to *Biogen,* in his judgment in the Court of Appeal (in para 33).

25. A single chemical compound is a product for the purposes of UK patent law (the restrictive provisions of section 38A of the Patents Act 1907, as amended in 1919, having disappeared from the Patents Act 1949). It is moreover a product of a special character, since it is a product which, simply as a chemical compound (as in claim 1 of the patent in suit), can have only one embodiment (though if it is used in a pharmaceutical preparation it can of course have numerous embodiments in terms of dosages and non-active ingredients, as in claims 3 and 5 of the patent in suit). Statements of general principle relating to inventions with many embodiments may be irrelevant to an invention which consists of a single chemical compound.

The claims in Biogen and in the patent in suit

26. That is in my opinion the fundamental reason why *Biogen* does not provide a direct answer to this appeal (although it is certainly material to the issue of "technical contribution"). The invention set out in claim 1 of the patent in suit in *Biogen* was one with a very large number of possible embodiments. As Lord Hoffmann put it in his opinion in *Biogen* (p 40, emphasis supplied):

> "The claim is to a product, a molecule identified partly by the way in which it has been made ('recombinant DNA') and partly by what it does (the words following 'characterised by'). It generalises what Professor Murray had done in two ways. First, as to the results he had achieved. He had made a particular form of recombinant plasmid (pBR322 with fragments of Dane particle DNA) which had transformed *E coli* and, he said, caused it to express the genes of HBcAg and HBsAg. The claim was for **any** recombinant DNA molecule which expressed the genes of **any** HBV antigen in **any** host cell. Secondly,

> there was generalisation of the method which he had used. He had made his DNA molecule from a standard pBR322 plasmid and large fragments from Dane particle DNA, chosen simply on the basis that they should be large. This was a technique imposed upon him by lack of information about the coding sequences. Thereafter, he employed conventional means to express the DNA in a conventional bacterial host. The claim was for **any** method of making a DNA molecule which would achieve the necessary expression."

27. Where classes of compounds are claimed, difficult interlocking problems as to construction and sufficiency may arise (as in *American Home Products).* They do not arise in this case. The fact that claim 1 is to a single chemical compound is what makes the present appeal unusual (and, I venture to say, relatively straightforward, once the issues of lack of novelty and obviousness are out of the way, as they are in your Lordships' House).

28. In describing the issues before the House as relatively straightforward I do not in any way disparage the lengthy written and oral submissions which have been addressed to your Lordships. Those submissions have been of great assistance. But as the argument in the appeal has progressed I have formed the view that the appellants can succeed only if they persuade your Lordships that there is a general principle in EPC Article 84 and section 14(5)(c) of the Patents Act 1977 that requires a product claim to a single chemical compound to be restricted to the invention's technical contribution to the art, and that that means the inventive concept (in this case the diol intermediate process).

Technical contribution

29. During the oral argument before your Lordships there was some discussion of whether "inventive concept" means the same as "technical contribution to the art." Neither expression is a statutory term of art. Lord Hoffmann used both expressions several times in his opinion in *Biogen*, the former mostly in section 10 (headed "Inventive Step") and the latter mostly in section 12 ("Support for the Claims"). Mr Thorley QC submitted in his reply that the two expressions (as used in Lord Hoffmann's opinion) are synonymous.

30. I do not think that this is quite right. The expressions are certainly connected, but I do not think it is helpful (either in considering Lord Hoffmann's opinion, or generally) to treat them as having precisely the same meaning. "Inventive concept" is concerned with the *identification* of the core (or kernel, or essence) of the invention—the idea or principle, of more or less general application (see *Kirin-Amgen* [2005] RPC 169 paras 112-113) which entitles the inventor's achievement to be called inventive. The invention's technical contribution to the art 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.

31. *Biogen* itself is, I think, a good illustration of this. Before your Lordships Lord Hoffmann's opinion in *Biogen* has been subjected to closer and more searching scrutiny by the House than any that I can recall, with the possible exception of the House's scrutiny in *Deutsche Morgan Grenfell v Inland Revenue Commissioners* [2007] 1 AC 558 of the speech of Lord Goff of Chieveley in *Kleinwort Benson Ltd v Lincoln City Council* [1999] 2 AC 349. If I may respectfully say so, Lord Hoffmann's opinion in *Biogen* is a *tour de force*. I have frequently commended it to bar students as an example of how a great judge can suffuse even the most technical subject with intellectual excitement. But its vivid and powerful language must be read in the context of the facts and issues in that case.

32. *Biogen* was a difficult and complicated case—much more complicated than the present appeal before the House. The first-instance hearing occupied two working weeks and the hearing in the Court of Appeal took even longer. It is noteworthy that despite the much-quoted passage in Lord Hoffmann's opinion (at p 45) counselling caution in an appellate court's review of a trial judge's evaluation of the facts, Lord Hoffmann did differ from Aldous J in his identification of the inventive concept, and (at pp 45-46) he differed from the Court of Appeal (and agreed with Aldous J) on the issue of obviousness for the very reason that the Court of Appeal had unquestioningly accepted the judge's view of the inventive concept. The better view was that the inventive concept was (p 45, emphasis supplied):

> "The idea of trying to express **unsequenced** eukaryotic DNA in a **prokaryotic** [non-mammalian] host."

33. This was a striking achievement by Professor Murray (Lord Hoffmann, at p 52, called it "a brilliant Napoleonic victory") which stole a march on researchers who were taking the more systematic route of sequencing the genome. But in terms of its technical contribution to the art it was not of lasting strategic importance because within a few months of Professor Murray's achievement the genome had been sequenced. As Lord Hoffmann put it (p 52):

> "Professor Murray invented a way of working with the genome in the dark. But he did not switch on the light and once the light was on his method was no longer needed. Nor, once they could use vectors for mammalian cells, would they be concerned with the same problem of introns which had so exercised those skilled in the art in 1978. Of course there might be other problems, but Biogen 1 did not teach how to solve them. The respondents Medeva who use restriction enzymes based on knowledge of the HBV genome and mammalian host cells, owe nothing to Professor Murray's invention."

In short, the invention's technical contribution to the art was not (except as a matter of history) something of lasting importance; and the patent was insufficient (p 53) to sustain a claim to every method of using recombinant DNA technology to produce HBV antigens.

34. *Biogen* is therefore an example of a brilliant inventive concept which did not however make a significant permanent contribution to the art, because of the pace at which the state of the art was advancing. Pharmaceutical research is a highly competitive activity, backed by huge resources, and there will always be winners and losers. Jacob LJ (at para 57) was rightly not moved by the thought that Professor Bøgesø might be getting "more than he deserved". Had he spent seven years isolating the enantiomers and found that both were equally effective and non-toxic his invention would, at least in commercial terms, have made no significant technical contribution to the art. Neither Lundbeck nor any of its competitors would have wanted to manufacture escitalopram. But the inventive concept would have been no different. The technical contribution was, as the Court of Appeal recognised (paras 36 and 59) the isolated enantiomer now called escitalopram, but it would on this hypothesis have proved no more useful than the unresolved racemate citalopram.

Exxon

35. My noble and learned friends Lord Mance and Lord Neuberger of Abbotsbury (whose opinions I have had the advantage of reading in draft) both draw attention to the importance of UK patent law aligning itself, so far as possible, with the jurisprudence of the EPO (and especially decisions of its Enlarged Boards of Appeal). National courts may reach different conclusions as to the evaluation of the evidence in the light of the relevant principles, but the principles themselves should be the same, stemming as they do from the EPC. There is no decision of an Enlarged Board of Appeal directly in point on the subject of technical contribution. The most relevant decision of a Technical Board of Appeal is *Exxon,* decided in 1993.

36. The claimed invention was in the field of additives for fuel oils to prevent the oil filter in a diesel engine being clogged at low temperatures by the formation of very small ice crystals. It was an area in which much research had already been undertaken. The appellant made a main request and an auxiliary request, both of which failed on grounds related to EPC Articles 83 and 84. After the passage quoted at para 19 the Technical Board of Appeal continued (para 3.3):

> "This means that the definitions in the claims should essentially correspond to the scope of the invention as disclosed in the description. In other words, as was stated in decision T 26/81 (OJ EPO 1982, 211, point 4 of the reasons), the claims should not extend to subject-matter which, after reading the description, would still not be at the disposal of the person skilled in the art."

37. The Board also stated (para 3.5):

> "Although the requirements of Article 83 and Article 84 are directed to different parts of the patent application, since Article 83 relates to the disclosure of the invention, whilst Article 84 deals with the definition of the invention by the claims, the underlying purpose of the requirement of support by the description, insofar as its substantive aspect is concerned, and of the requirement of sufficient disclosure is the same, namely to ensure that the patent

> monopoly should be justified by the actual technical contribution to the art. Thus a claim may well be supported by the description in the sense that it corresponds to it, but still encompass subject-matter which is not sufficiently disclosed within the meaning of Article 83 EPC as it cannot be performed without undue burden, or vice versa."

38. These statements of principle appear to me to support the views that I have expressed. But for present purposes the most significant part of the decision in *Exxon* is in the later part of para 3.5:

> "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, ie 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 (see eg T 206/83, OJ EPO 1987, 5). In the latter case, it was not held sufficient for the purpose of Article 83 EPC to disclose a method of obtaining **only some** members of the claimed class of chemical compositions."

That statement could hardly be clearer. Claim 1 in the patent in suit is to a single chemical composition.

39. Your Lordships were referred to other decisions of Technical Boards of Appeal of the EPO that are in line with the decision in *Exxon*. But it is not necessary to multiply statements of essentially the same point.

40. For these reasons, which I understand to be essentially the same as those of Lord Mance and Lord Neuberger, I would dismiss this appeal.

LORD MANCE

My Lords,

41. The issue on this appeal is short though fundamental. Where a patent claim relates to a product, rather than a method, is the patent liable to revocation on the ground of insufficiency under s.72(1)(c) of the Patent Act 1977 if the only inventive step involved in the product consists in the method by which it is made available and if its description and specification disclose only that inventive method and superior methods are found by others which owe nothing to that method? Can such a claim be said to have been supported in its full width by the description given, in the sense identified as necessary by Lord Hoffmann giving the main speech in this House in *Biogen Inc. v. Medeva plc* [1997] RPC 1, 47?

42. The claim is to the (+) enantiomer, one of two mirror image enantiomers making up the racemate citalopram. Citalopram is an anti-depressant drug for which H Lundbeck A/S ("Lundbeck") had held a patent which had expired. The preparation or separation of its individual enantiomers, in order to identify to which the beneficial effects of citalopram might be due, was an obviously desirable goal, and their testing was trivial. The inventive step taken by Lundbeck lay in finding a way in which to prepare or separate the individual enantiomers. See per Kitchin J [2007] RPC 32, para. 264. Once done, this proved that the beneficial effects of citalopram were attributable to the (+) enantiomer. Lundbeck claimed accordingly to patent by claims 1 and 3 the (+) enantiomer (under the description escitalopram) and its pharmaceutical composition. These are the claims in issue, which Kitchin J held invalid and the Court of Appeal upheld. Claim 6 related to the particular method which Lundbeck used to prepare escitalopram and is now accepted as valid.

43. The courts below held and it is not now in issue that claims 1 and 3 were not open to objection on the grounds of either lack of novelty or obviousness, and that the preparation or separation of escitalopram involved an inventive step satisfying s. 1(1)(a) and (b) of the 1977 Act. The conclusion that escitalopram was novel derived from an application of the House's previous decision in *Synthon BV v. SmithKline Beecham Plc* [2005] UKHL 59; [2006] RPC 10. The prior art did not disclose any subject matter which, if performed, would necessarily result in an infringement of claims 1 and 3, and there was no disclosure enabling an

ordinary skilled person to make (or "perform") escitalopram by using common general knowledge. The prior disclosure of the racemate citalopram did not disclose either of its individual enantiomers. No-one previously had been able to prepare, separate or make available the individual enantiomers. The challenge made under s.72(1)(c) read against the background of s.14(3) and (5) is to the sufficiency of the enabling disclosure, having regard to the later development of superior methods of preparing escitalopram.

44. The essential difference in the courts below was that Kitchin J confined the legitimate scope of the patent claim by reference to the inventive step, while the Court of Appeal 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. The question now is which answer should be adopted.

45. As a matter of principle or philosophy or from a utilitarian viewpoint, arguments could be advanced in favour of either: see for example the early discussion paper prepared by a Committee of Experts of the Council of Europe dated Paris, 30th November 1951 (CM/WP IV (51) 27). Considerations such as equity, incentivisation to research and development and administrative and legal simplicity can all be deployed. The approach taken by Kitchin J ties the scope of any patent for an invention, whether relating to a product or to a process, to the inventive step or technical contribution involved in the invention. (The concepts of inventive step or technical contribution appear to have been treated by Lord Hoffmann in *Biogen Inc. v. Medeva plc* as effectively synonymous: compare e.g. p.43 lines 45-48, p.45 lines 3–10, p.49 lines19-22, p.51 line 43 – p.52 line 7 and p.52 line 34; but, if technical contribution is given some other meaning, then in that event the scope of the patent could simply be tied to the inventive step.) The alternative approach says that, once a novel product has been created by some inventive step or technical contribution, a patent may be sustained in respect of the product, however it might in future prove possible to make it. That is the approach taken in the Court of Appeal, and (although the present point was not there in issue) it gains some support (not surprisingly) from a passage in Lord Hoffmann's speech (with which other members of the House agreed) some three months later in *Conor Medsystems Inc. v. Angiotech Pharmaceuticals Inc.* [2008] UKHL 49, [2008] 4 All ER 621, para. 17.

46. The question to be decided on this appeal is which of these two approaches applies under domestic legislation, the Patents Act 1977. But the provisions of that Act are to be read as having, as nearly as possible, the same effects in the United Kingdom as the corresponding provisions of the European Patent Convention with which the Act was intended to bring United Kingdom law into conformity (see s.130(7)). Both the statute and the Convention leave much room for judicial interpretation, and I do not myself think that the answer to the problem that the House has to address is axiomatic in the light of the language of either. My noble and learned friend, Lord Walker of Gestingthorpe said in the case of *Synthon* that "In the interpretation and application of patent statutes judge-made doctrine has over the years done much to clarify the abstract generalities of the statutes and to secure uniformity in their application" (para. 57), while adding that: "Nevertheless it is salutary to be reminded, from time to time, that the general concepts which are the common currency of patent lawyers are founded on a statutory text, and cannot have any other firm foundation" (para. 58). Account must not only be taken of domestic judge-made doctrine; the jurisprudence of the European Patent Office under the Convention will always carry much persuasive weight in United Kingdom courts: see *Merrell Dow Pharmaceuticals Inc. v. H N Norton & Co. Ltd.* [1996] RPC 76, 82; *Conor Medsystems Inc. v. Angtiotech Pharmaceuticals Inc.* (above),para 3, per Lord Hoffmann.

47. There are passages in Lord Hoffmann's speech in *Biogen Inc. v. Medeva plc* which can be read as supporting an approach tying the scope of any patent, whether to a product or to a process, to the inventive step or technical contribution involved in its creation, and as justifying this on utilitarian grounds. Thus Lord Hoffmann referred at p.49 to the Technical Board of Appeal in *Exxon/Fuel Oils* (T 409/91) [1994] OJ EPO 653, para. 3.3 as reasserting "well-established principles for what amounts to sufficiency of disclosure", when it said that the requirement for the claims to be supported by the description (article 84 of the European Patent Convention, mirrored in s.14(5)(c) of the Patents Act 1977) "reflects the 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 Hoffmann also said at p.52 in *Biogen Inc. v. Medeva plc* that Professor Murray "showed by his invention" (the word being here used I think to mean inventive step) that "it could be done", i.e. that "known recombinant techniques could …. be used to make the antigens in a prokaryotic host cell" (see p.51 lines 46-47). He continued:

> "Those who followed, even by different routes, could have greater confidence by reason of his success. I do not think this is enough to justify a monopoly of the whole field. I suppose it could be said that Samuel Morse had shown that electric telegraphy could be done. The Wright Brothers showed that heavier-than-air flight was possible, but that did not entitle them to a monopoly of heavier-than-air flying machines. …. The technical contribution made in such cases deserves to be recognised. But 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. (See Merges and Nelson, *On the Complex Economics of Patent Scope* (1990) 90 Columbia Law Review 839.)"

48. It is a theme of Robert P Merges and Richard R Nelson's article in the Columbia Law Review that the scope of patent protection should or might in one way or another be tied more closely to the relevant inventive step. But in the present connection their main concern related to a different issue to the present, namely the recognition under American law of the possibility of a valid patent in respect of a synthetically created version of a substance available in a natural form. Thus, at p.903 when discussing the "special problem that crops up in the chemical patent field" when there is invented "a synthetic version of a substance found in humans or animals", Merges and Nelson suggest that "the argument is not convincing that what the original inventor invented was the product, in addition to her particular process for making it". (They are throughout refreshingly ready to acknowledge the value of the female contribution.) In returning to the point at p.914, they acknowledge that "the tradition [under American law] of granting a product rather than a process patent goes back as far as *Parke-Davis & Co. v. H K Mulford & Co* 189 F 95 (CCSDNY 1911) when Learned Hand upheld a product patent on purified human adrenalin", continuing:

> "In such cases protection consistent with the actual achievement of the inventor would have been provided if the initial patent had been for a *process*, or at most a "product-by-process", rather than for a product. And inventive efforts to come up with a significantly better process to make the product would not be blocked. These concerns seems to have animated a recent British case denying broad claims for Genentech's t-PA drug [*Genentech Inc's Patent* [1989] RPC 147].

> One perhaps controversial way to achieve this would be to recognise a reverse equivalents defence [*that is, an American law defence available to an alleged infringer who has made so far changed in principle a product described in a patent claim that it performs in a substantially different way*] when a recombinant product is accused of infringing a prior purification patent."

In the present case, there is no question of escitalopram having been either naturally or synthetically available before Lundbeck found a method of making it, and it is also not possible under United Kingdom law to patent a synthetic version of a product which is already available naturally, so that the problem under American law which concerned Merges and Nelson could not anyway arise.

49. Mr Simon Thorley QC in his conspicuously clear submissions for Generics (UK) Ltd. and the other appellants in this appeal submitted that the passages from Lord Hoffmann's speech to which I have referred in paragraph 47 above represent the ratio of *Biogen Inc. v. Medeva plc*. He reinforces this with a further submission that that case was, like the present, concerned with a simple claim to a novel product. In his submissions for Medeva plc in *Biogen Inc. v. Medeva plc*, Mr Thorley did indeed refer to claim 1 as a product claim, but both the opposing submissions for Biogen Inc. and the speeches in this House appear to me to have preferred to describe the position in more complex terms. At p.40 in particular, Lord Hoffmann said that "The claim is to a product, a molecule identified partly by the way in which it has been made ("recombinant DNA") and partly by what it does (the words following "characterised by"). It generalises what Professor Murray had done in two ways. First, as to the results he had achieved. ….. Secondly, there was generalisation of the method which he had used. ……. The claim was for any method of making a DNA molecule which would achieve the necessary expression".

50. As to Mr Thorley's submission that the claim in *Biogen Inc. v. Medeva plc* was as a matter of factual analysis related to a novel product, the recombinant DNA molecule, which could be patented as such, Mr Waugh QC for Lundbeck challenged this, and submitted with reference to an article by Summers summarised by Aldous J at first instance - [1995] RPC 25, 57 lines 39-47 – that Professor Murray had invented nothing new when he made such a molecule, and that his only invention consisted in the development of the notion that such a molecule could be used to create the HBV antigens, which would in turn cause a patient's immune system to produce the desired antibodies. I see

considerable force in Mr Waugh's submission on this point, but 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 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.

51. This is most apparent when one looks at the passages in Lord Hoffmann's speech at pp.48-49, where he corrects an error which had crept into the first instance decisions of *Mölnlycke AB v. Procter & Gamble Ltd.* [1992] FSR 549, *Chiron Corp. v. Organon Teknika Ltd.* [1994] FSR 202 and *Biogen Inc. v. Medeva plc* itself. The error was to treat an invention consisting of a product as sufficiently disclosed for the purposes of s.14(3) if the description and specification enabled a skilled person to make a single embodiment, rather than to perform it across its full width or to its full extent as was, Lord Hoffmann held, the correct approach. It is particularly noticeable that, while in the *Mölnlycke* case issue was joined as to whether the disclosure must enable "all possible embodiments" or whether (as Morritt J there held) only one would suffice (pp.595 and 600), it was "not in dispute that under the Patents Act 1977 it is not a ground of revocation if the specification fails to disclose the best method of performing the invention" (p.600). Admittedly, Morritt J had (at pp.594-5) held non-compliance with s.14(5)(c) to be no basis for revocation under s.72 (a conclusion not accepted in this House in *Biogen Inc. v. Medeva plc*), but that is a separate point. What the description discloses must under s.14(5)(c), read 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.

52. 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 in so far as they extended in scope to any method of making escitalopram other than that devised by Lundbeck. The question whether this was the correct approach in principle was open to the Court to consider and determine for itself. Lord Hoffmann in paras. 26 and 42 of his judgment in the present case expressed understanding for and sympathy with the judge's instinctive reaction to the inherent breadth of a product claim. Kitchin J's reaction was, as he himself made very clear, based on the fact that there was nothing inventive about the idea that escitalopram might have valuable properties by itself or therefore about the aim of separating, preparing or testing it. This is not a case where someone found or made a substance which no-one had previously

thought of or thought would have any value. The only inventive step was the means by which Lundbeck managed to separate or prepare escitalopram; and this involved no general or common principle of which the appellants made any use when they claimed to produce and market the (+) enantioner in competition with escitalopram. One reaction to these circumstances might be that it is surprising that the product escitalopram should be regarded as in any relevant sense novel (or in the language of s.1(1)(a) new) at all. But that reaction is precluded by the definition of novelty accepted in *Synthon*. Hence, the stark issue identified at the outset of this speech. Is patent protection in respect of a new product qualified where the only inventive step involved in making the product available consists in the method by which it is made available, and its description and specification disclose only that inventive method and superior methods are found by others which owe nothing to that method?

53. As Lord Hoffmann and Jacob LJ observed in their judgments, both the Convention and the Patents Act 1977 distinguish between an invention consisting in a product and an invention consisting in a process (see e.g. articles 52-57, 167 and s.60). As I have said, the significance of the distinction does not appear to me to be spelled out in a manner which resolves the present issue unequivocally. But it can at least be said to be surprising if so significant a qualification exists with regard to the protection available to a product as opposed to a process that there is no positive trace of it in the Convention or statutory language. S.60 of the Act, providing that there is infringement if, where the invention is a product, a person "makes, disposes of, offers to dispose of, uses or imports the product or keeps it whether for disposal or otherwise" would also fit uneasily with an approach according to which the patent would be invalid if the product was made by a method owing nothing to the inventive step. The appellants rely on article 83 and s.72(1)(c) as involving a requirement that not merely the invention in all its embodiments, but also all the methods of making it sought to be protected, should be sufficiently disclosed by its description and specification. Under s.125 the words "patented invention" mean an invention for which a patent is granted, unless the context otherwise requires, and in *Pharmacia Corp. v. Merck & Co. Inc.* [2001] EWCA Civ 1610; [2002] RPC 41, para. 55, Aldous LJ held that the context otherwise required in respect of s.72(1)(c) and that "There the use of the word "invention" must include the technical contribution which supports the monopoly claimed, with the result that those sections require an enabling disclosure of that technical contribution". However, in illustrating this, with reference to the House's decision in *Biogen*, he took only as examples a claimed invention consisting of "a class of compounds", or "a selection of certain compounds", making it clear that

he was speaking of claims covering different products or different embodiments of a single invention, rather than expressing any different view, about the sufficiency of a single method of achieving a patented product, to that which had been common ground before Morritt J in *Mölnlycke* (para. 51 above).

54. Apart from the submission (which I have rejected) that the appeal must succeed on the basis of *Biogen*, the appellants' approach does not therefore in my opinion find direct support in either the statutory language or any United Kingdom authority, whatever may be the principled arguments that can be advanced in its favour. I would find this alone surprising, if the appellants' approach is a good one. Further, I can foresee that the appellants' approach, however principled, could well add in practice to the issues which may arise as to the validity or proper scope of patent claims to what under *Synthon* are novel products prepared by inventive methods. Finally, and in my view conclusively, this is, as Lord Hoffmann underlined in the Court of Appeal, an area where there is clear jurisprudence of the European Patent Office and of its Boards of Appeal: *Kawasaki Steel Corp.* [1994] OJEPO 695; T 0233/93 *E I Du Pont* (28 October 1996); T 1195/00 *Alcan International Ltd.* (24 May 2004); and T 0803/01 *Novartis AG* (9 September 2003). It is true that in each of these cases the issue was one of obviousness, and in none was an objection of insufficiency raised. But that, as Lord Hoffmann said, is itself very significant.

55. The Board of Appeal in the *Kawasaki Steel* case 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 entity, may become nevertheless non-obvious and claimable as such if there is no known way or applicable (analogy) method in the art to make it and the claimed methods for its preparation are therefore the first to achieve this in an inventive manner". It 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(s) described in the claim. The passage quoted by Lord Hoffmann at p.49 in *Biogen* from the Board of Appeal's decision in *Exxon/Fuel Oils* has never been applied to a simple product claim such as the present, and a reading of the full text from which it is taken shows that it too was dealing 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.

56. I would add that Mr Waugh sought to gain further support from the fact that in American and Australian litigation about escitalopram no suggestion of insufficiency has been raised. I do not myself find it profitable to try to assess why parties have not raised arguments of law in jurisdictions which have evidently different patent legislation and case-law to our own. The Australian High Court does not even accept the correctness of the conclusion in *Biogen* that the description and specification must amount to an enabling disclosure across the full width (and not merely in relation to one among other embodiments) of the invention: the amusing comments on *Biogen* made in para. 67 of the judgment of Gleeson CJ, McHugh, Gummow, Hayne and Heydon JJ in *Lockwood Security Products Pty. Ltd. v. Doric Products Pty. Ltd.* [2004] HCA 58 stress the independence of Australian from United Kingdom patent law and show that there is very little scope to argue any point at all on insufficiency in Australia.

57. For the reasons I have given in paragraphs 41 to 55, I would however dismiss this appeal.

LORD NEUBERGER OF ABBOTSBURY

My Lords,

58. This appeal raises a point of principle relating to product claims in patents, and it also requires consideration of the ambit of the reasoning of this House in *Biogen Inc v Medeva plc* [1997] RPC 1.

The factual and technical background

59. 1-(3-dimethylaminopropyl)-1-(4'-fluorophenyl)-1,3-dihydroisobenzofuran-5-carbonitrile is an organic compound which was first synthesised by the respondent, H. Lundbeck A/S, in 1972. The compound, whose generic name is citalopram, was patented by the respondent, but that patent expired many years ago. Citalopram was found to have a significant antidepressant effect, by virtue of its action as a selective serotonin reuptake inhibitor ("SSRI") in the brain. It was launched on the market in 1989, under various brand names, and has proved very successful. At least in terms of volume, it is currently the world's highest selling branded antidepressant.

60. As manufactured in accordance with the teaching of this patent, citalopram was known to be a racemate. In other words, it existed as a mixture of two types of molecule, known as enantiomers, in equal proportions. Enantiomers have precisely the same chemical formula, and precisely the same three-dimensional, stereochemical, structure, save that one is the mirror-image of the other. Many organic compounds which have therapeutic or other effects have enantiomers and exist as a racemate, either because it is how they are formed in nature, or (as in the case of citalopram) because it is the form in which they are manufactured. Each of the two enantiomers can be conventionally distinguished from the other in one of three different ways, namely (i) by a prefix of (+) and (-), which is based on the direction in which it rotates polarised light, (ii) by a prefix of D or L which is based on the chemical glyceraldehyde, which itself exists in two enantiomeric forms, and (iii) by a prefix of R or S, which depends on priority rules, the detail of which is not necessary to explain.

61. It has long been known that two enantiomers can have different properties from each other. Thus, where a particular racemate has a therapeutic effect, it may transpire that the effect is attributable more to one enantiomer than to the other, or that one of the enantiomers has a toxic, or other, side-effect which is not shared by the other. The only way in which it is possible to tell whether the effects of the two enantiomers of a particular racemate differ, and if so how, is by obtaining relatively pure forms of each enantiomer and comparing them experimentally. At any rate as yet, it is impossible to predict such differences in advance.

62. Accordingly, the notion of obtaining pure forms of each enantiomer of a racemate, which has a therapeutic, or other beneficial, effect, is obvious. However, the ease with which one can obtain relatively pure forms of each (or either) enantiomer varies from one racemate to another. In the case of citalopram, it proved particularly difficult. The respondent appears to have taken seven years of hard work, between 1980 and 1987, to manufacture a relatively pure form of each of the two enantiomers of citalopram. This was achieved by finding a way of separating, or resolving, the two enantiomers of a diol (which was one of the intermediate substances in the manufacture of citalopram) and then proceeding separately with the manufacture of each of the enantiomers of citalopram.

63. Having obtained separate samples of the two enantiomers, the respondent then carried out experiments to compare them. These

experiments established that virtually the whole of the therapeutic effect of citalopram as an SSRI lay in the (+)-enantiomer, which has the generic name escitalopram. Subsequent research has now established that the (-)-enantiomer actually inhibits the therapeutic effect of the (+)-enantiomer.

64. Having isolated the (+)-enantiomer and established that it was a substantially more effective SSRI than the racemate, the respondent applied for, and obtained, the patent the subject of the present appeal, EP (UK) 0,347,066. This patent (which I shall call "the Patent") has a priority date of 14 June 1988, and primarily claims escitalopram, i.e. (+)-1-(3-dimethylaminopropyl)-1-(4'-fluorophenyl)-1,3-dihydro-isobenzofuran-5-carbonitrile. As my noble and learned friend Lord Walker of Gestingthorpe explains, the Patent also makes other claims, including the process by which escitalopram had been manufactured. Esciptalopram has been successfully marketed under the brand name Cipralex since 2002.

These proceedings

65. The three appellants, Generics (UK) Ltd, Arrow Generics Ltd, and Teva UK Ltd and Teva Pharmaceutical Industries Ltd, all wish to market generic citalopram (i.e. the racemate), and they started these proceedings in 2005, claiming revocation of the Patent. The claims came before Kitchin J, who, in a clear and full judgment, decided that, although the attacks based on lack of novelty and on obviousness failed, the attack on the Patent's claim to the (+)-enantiomer succeeded on the ground of insufficiency: see [2007] EWHC 1040 (Pat), [2007] RPC 32. The Court of Appeal upheld the Judge's conclusions on lack of novelty and obviousness, but reversed his decision on insufficiency: see [2008] EWCA Civ 311, [2008] RPC 19. Accordingly, they concluded that the main claim of the Patent, namely the claim to the (+)-enantiomer, was valid.

66. The only point in issue on this appeal is that on which the Court of Appeal disagreed with Kitchin J, namely whether the claim to the (+)-enantiomer was insufficient. Accordingly, we are proceeding on the basis that the enantiomer is a new product, in particular as against the racemate, and on the basis that the obtaining of the enantiomer was not obvious. The question is whether the claim fails on the ground of insufficiency.

The statutory framework

67. As Lord Walker observed in *Synthon BV v SmithKline Beecham plc* [2005] UKHL 59, [2006] RPC 10, para 57, "[t]he law of patents is wholly statutory", although "the courts have shown an inclination to enrich the bare simplicity of the stautory text with their own explanatory commentary", which "has over the years done much to clarify the abstract generalities of the statutes and to secure uniformity in their application". Nonetheless, as he went on to say in the following paragraph, "it is salutary to be reminded, from time to time, that the general concepts which are the common currency of patent lawyers are founded on a statutory text, and cannot have any other firm foundation."

68. The current statute governing the validity of patents is, of course, the Patents Act 1977, which must be read together with the European Patent Convention ("the EPC"). Indeed, all the provisions of the 1977 Act of central relevance for present purposes have been specifically framed "as nearly as practicable" to have "the same effects in the United Kingdom as the corresponding provisions of the [EPC] have in the territories to which [it applies]": see section 130(7) of the 1977 Act.

69. The distinction between product claims and process claims, which is, as Lord Walker says, at the heart of this appeal, is effectively taken for granted in the 1977 Act, but it is implicit in section 60 which is concerned with infringement. It specifically refers to cases "where the invention is a product" and to cases "where the invention is a process". As one would expect the same concepts are referred to in the EPC - see arts 52 to 57 and 167.

70. Section 1(1) of the 1977 Act (reflecting art 52 of the EPC) provides that a "patent may be granted only" if the invention it claims satisfies four requirements. Those requirements are that it "(a) … is new", (b)… involves an inventive step", "(c) … is capable of industrial application", and (d) … is not excluded by subsections (2) and (3)…". There has never been any suggestion by the appellants that paras (c) or (d) apply in this case; and they no longer seek to rely on paras (a) and (b), now that Kitchin J has concluded that, as at June 1988, escitalopram was both new and inventive (the antithesis of obvious), and the Court of Appeal has upheld those conclusions.

71. Furthermore, it is not, and could not be, suggested by the appellants that a patent cannot be granted for a specified molecule or specified molecules, or a substance comprising specified molecules. Such a suggestion would be completely inconsistent with what has been universally assumed by patent law experts, the U.K. and European Patent Offices and the courts; it would also undermine an enormous number of patents (many of which have been unsuccessfully challenged) granted under the 1977 Act. Indeed, such a suggestion would be inconsistent with the reasoning in the very case on which the appellant primarily relies, namely *Biogen* [1997] RPC 1. Any such suggestion would also be inconsistent with the statutory history set out at [2008] RPC 19, paras 43 to 46 by Lord Hoffmann in the Court of Appeal in this case.

72. That is not, of course, the end of the issue in this case, as section 1(1) is effectively negative in nature, and the fact that product claims can extend to specific molecules does not mean that the product claim to escitalopram in this case is valid. However, it demonstrates that the appellants have to look elsewhere to find grounds for establishing the invalidity of the Patent's principal claim. Now that their arguments on lack of novelty and obviousness have been disposed of, the appellants' case is, as mentioned, based on an allegation of insufficiency.

73. However, at any rate on the face of it, that allegation is not assisted by the statutory provision concerned with that topic, namely section 14 of the 1977 Act. Section 14(3) (reflecting art 83 of the EPC) requires the specification of a patent to "disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art". And section 14(5)(c) (reflecting art 84 of the EPC) requires any claim to "be supported by the description". There is no suggestion that the description in the Patent does not enable a person equipped with the appropriate degree of skill and knowledge to manufacture escitalopram. Nor is there any suggestion that the description does not make good the contention that escitalopram has substantially enhanced therapeutic effectiveness as an SSRI over the prior art, namely citalopram.

74. Of course, sections 1 and 14 are concerned with the grant of patents, whereas it is section 72 (reflecting art 100 of the EPC) which is concerned with the revocation of patents, and which is therefore the section directly in point on this appeal. Section 72(1) provides that a patent can "only" be revoked on certain specified grounds. These grounds include "(a) the invention is not a patentable invention", and

"(c) the specification … does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art". Section 72(1)(a) reflects section 1(1) though it may also go further. Section 72(1)(c) appears only to reflect section 14(3), but, as explained by Lord Hoffmann in *Biogen* [1997] RPC 1, 47, it also extends to what is covered by section 14(5)(c).

The reasoning of the courts below

75. In a sense, it was at this point that the reasoning of the Court of Appeal in this case ended. At [2008] RPC 19, para 36, Lord Hoffmann said that "[w]hen a product claim satisfies the requirements of section 1 of the 1977 Act, 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". Accordingly, as sections 1 and 14 appeared to be satisfied by the patent, he concluded that the claim to escitalopram was valid.

76. To the same effect, Jacob LJ said at [2008] RPC 19, para 52, that, as at June 1988, the pure (+)-enantiomer, as a product, was "novel and non-obvious", and if "one asks the straightforward question 'Does the patent enable the skilled man to make it?' the answer is an equally straightforward 'Yes'. So, in the language of art 83, the patent 'discloses the invention in a manner sufficiently clear and complete for it to be carried out.'"

77. The different view formed by Kitchin J was not based on any disagreement with this approach as far as it goes, but on reasoning which is helpfully summarised in his judgment at [2007] RPC 32, paras 264 and 265. He described the obtaining of the purified enantiomers as "an obviously desirable goal", and said that, accordingly, the "inventive step" was "not deciding to separate the enantiomers …, but finding a way it could be done". He went on to say that the technical contribution made by the Patent was not to find a new product, but to find a way of making a product, namely a single enantiomer of citalopram, through the medium of isolating the diol intermediate.

78. Accordingly, the Judge concluded that, as the specification disclosed that the respondent had found only one way to make the (+)-enantiomer, it would be a monopoly disproportionate to the technical contribution if the Patent effectively covered all ways of making the

enantiomer, which would be the effect of the product claim. The principle he relied on was succinctly encapsulated in a short sentence virtually at the end of his judgment, namely "The first person to find a way of achieving an obviously desirable goal is not permitted to monopolise every other way of doing so".

79. The sole authority upon which Kitchin J relied in support of this analysis was the speech of Lord Hoffmann in *Biogen* [1997] RPC 1. I propose first to consider whether his conclusion is justified on the basis of any principle or authority other than what was said in this House in *Biogen* [1997] RPC 1, and then to address the reasoning in *Biogen* [1997] RPC 1.

The insufficiency argument apart from Biogen [1997] RPC 1

80. The starting point must, of course, be the 1977 Act and the EPC. I have already identified and discussed the centrally relevant provisions of the 1977 Act, namely section 72(1)(a) and (c), which reflect art 100 of the EPC and refer back to sections 1(1), 14(3), and 14(5), which in turn reflect arts. 52, 83, and 84 of the EPC. It is hard to discern any statutory provision (or, by the same token, any provision in the EPC) to support the proposition that, once it has been established that a product claimed in a patent is novel and non-obvious, and the specification sufficiently explains to the person skilled in the art how to make it, the claim can nonetheless be rejected because there may be other ways of making the product which owe nothing to the teaching of the patent.

81. Mr Simon Thorley QC, for the appellants, relied on section 14(5)(c): he said that where, as in this case, a product was a known *desideratum*, the first person to make it could rely on his way of making it as "support" for a claim for that process, but not for a claim for the product, as the single process did not support a claim for the product. I think that that argument ascribes an effect to section 14(5)(c) which it does not have. In *Asahi Kasei Kogyo KK's Application* [1991] RPC 485, 536, Lord Oliver of Aylmerton explained that "a description would not 'support' the claims for the purpose of subsection (5)(c) unless it contained sufficient material to enable the specification to constitute the enabling disclosure which subsection (3) required" (to quote Lord Hoffmann's summary in *Biogen* [1997] RPC 1, 47). That brings one straight back to section 14(3), and, as already mentioned, the specification of the Patent clearly sets out the diol method of

manufacturing escitalopram, and therefore it plainly satisfies section 14(3).

82. As Mr Andrew Waugh QC, for the respondent, contended, and as the opinion of my noble and learned friend Lord Scott of Foscote (which I have had the privilege of seeing in draft) implies, given that there is now an unchallenged finding that the (+)-enantiomer was novel as at the priority date, the appellants' argument really involves suggesting that, at least when it comes to product claims, the 1977 Act envisages two types of novelty, one expressly mentioned in section 1(1)(a) and the other implied into section 14(5)(c). That seems an unlikely proposition: either a product is novel or it is not.

83. It was also contended on behalf of the appellants that, if the Patent extended to escitalopram as a product, the respondents would be accorded a monopoly which exceeded their technical contribution to the art. Although it is an extra-statutory concept, I accept 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. That is an approach regularly adopted by the Technical Board of Appeal of the European Patent Office ("the Board"): see, for example, T409/91 *EXXON/Fuel Oils* [1994] OJEPO 653, para 3.3. However, to put it at its lowest, it can be said that the respondent's technical contribution in this case was to make available, for the first time, a product which had previously been unavailable, namely the isolated (+)-enantiomer of citalopram. On that basis, it would appear to follow that the respondent was entitled to claim the enantiomer.

84. Subject, at any rate, to *Biogen* [1997] RPC 1 (and some cases purportedly following it), your Lordships have not been referred to any decided case in this jurisdiction which calls into question the approach of Lord Hoffmann and Jacob LJ in this case, as summarised in paras 74 and 75 above. It is true that in *British United Shoe Machinery Co Ltd v Simon Collier Ltd* (1908) 26 RPC 21 (aff'd (1909) 26 RPC 534, (1910) 27 RPC 567), Parker J said:

> "[I]f the principle is new, and you show one mode of carrying it into effect, you may protect yourself against all other modes…. . If, however, the principle is not new, you can only protect yourself against those modes … which are substantially the same as the mode you have yourself invented" (see at p 49).

85. It seems to me, however, that the application of that observation to this case could, to put it at its lowest, fairly be said to assist the respondent: given that the (+)-enantiomer claimed has been judged to be new, it should be patentable. However, that observation was concerned with the permissible breadth of a process claim, not with the circumstances in which it is permissible to make a product claim. Indeed, it is interesting to note that Kitchin J's formulation of the principle he was applying at the end of [2007] RPC 32, para 265, and quoted at the end of para 78 above, seems also to be concerned with process claims, not product claims.

86. While, as my noble and learned friend Lord Mance says, no real help in this case can be obtained from judicial decisions in countries which are not signatories to the EPC, quite different considerations apply to decisions of the Board. Your Lordships' House has frequently emphasised that the principles of patent law adopted by courts in this jurisdiction should, if at all possible, be the same as those adopted by the Board – see for instance *Merell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76, 82, *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2004] UKHL 46, [2005] RPC 9, para 101, and *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* [2008] UKHL 49, [2008] 4 All ER 621, para 3.

87. In that connection, the approach of the Board has been consistently along the same lines as that of the Court of Appeal in this case. Thus, in T595/90 *Grain-orientated silicon sheet/Kawasaki* [1994] OJEPO 695, 703, the Board said:

> "[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 entity, may become nevertheless non-obvious and claimable as such if there is no known way or applicable (analogy) method in the art to make it and the claimed methods for its preparation are therefore the first to achieve this in an inventive manner".

(See also the decisions cited by Lord Hoffmann at [2008] RPC 19, paras 38 and 39.)

88. Indeed, specifically in relation to the type of question arising in this case, the Board has held on more than one occasion that the fact that "the two enantiomers … actually exist unseparated in the racemate…. [and generally] can also be separated …" are "considerations [which] are immaterial to the question of novelty … and will be more usefully applied to the examination as to inventive step" (quoted from T0296/87, *Hoechst,* 30 August 1988, para 6.5, and see also, for example, T1046/97, *Enantiomer/Zeneca*, 2 December 1999, para 2.1.1.4). That would suggest that Kitchin J's conclusion on novelty was correct and that he rightly addressed the issue of obviousness, but that, having decided those issues in favour of the respondent, he should have upheld the claim to escitalopram.

89. It is true that in none of these decisions of the Board was any consideration given to whether the product claim failed on the ground of insufficiency for the reason given by Kitchin J in this case at [2007] RPC 32, paras 264 to 265. However, the argument based on obviousness considered by the Board is very similar to the insufficiency reason given by Kitchin J. It also seems to me that, in the light of the expertise and experience of the members of the Board, and the number of decisions where the insufficiency reason could have been raised, it is fanciful to suggest that, if the reason had been arguable, it would not have been raised before or by the Board by now. As mentioned below, much of the reasoning in *Biogen* [1997] RPC 1 was based on decisions of the Board, and members of the Board appear to be well aware of their previous decisions, and, at least in general, anxious to have a consistent approach. Further, the decision in *Biogen* [1997] RPC 1 was well known in the world of patents, and it did not cause the Board to change its view on the issue of product claims, as is demonstrated by the reasoning in *Enantiomer/Zeneca* in relation to enantiomers, and, more generally, in T1195/00 *Alcan International Ltd,* 24 May 2004.

90. In the light of this discussion, it appears clear to me that, unless precluded by the reasoning in *Biogen* [1997] RPC 1, on which Kitchin J primarily relied in his decision and on which Mr Thorley primarily relies in his argument, 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. Further, 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. Luck as well as skill often determines, for

instance, who is first to file, whether a better product or process is soon discovered, or whether an invention turns out to be valuable. Further, while the law must be principled, it must also be clear and consistent.

The insufficiency argument based on Biogen [1997] RPC 1

91. As I have mentioned, the principal plank in the appellants' argument is the opinion of Lord Hoffmann in *Biogen* [1997] RPC 1, no doubt for the reasons just discussed. Mr Thorley was able to point to a number of observations in that opinion which, at least if read on their own, might at first sight be said to support his contention that, given that the (+)-enantiomer was known to be a desirable goal, the only technical contribution of the Patent was the diol method of making the enantiomer, and accordingly it is that process, and not the enantiomer, which should have been claimed.

92. Of the seven passages in the speech of Lord Hoffmann Mr Thorley particularly relied on, I shall limit myself to three, although the observations which follow apply equally to the other passages. At [1997] RPC 1, 48, Lord Hoffmann said that "if the claims include a number of discrete methods or products, the patentee must enable the invention to be performed in respect of each of them". But in this case the claim is to a single product, and it is clear that the product is enabled by the disclosure in the Patent.

93. At [1997] RPC 1, 50, there is this: "[The issue] 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". This is perhaps the most important of the three passages for present purposes. The vital point is that Lord Hoffmann was not dealing with a simple product claim, as is involved in this Patent. As he explained at [1997] RPC 1, 40, the claim in that case was "to a product, a molecule identified partly by the way in which it has been made …. and partly by what it does". In that case, the patentee could claim neither the product (a DNA fragment of the so-called Dane particle), as it had already been made (see per Aldous J at first instance at [1995] RPC 25, 57), nor the process (recombinant DNA technology enabling expression in a cell), as it had already been invented (see at [1995] RPC 25, 58 and 65). Nor could he identify the product in any other way, as it had not been mapped or sequenced (see e.g. at [1995] RPC 25, 65).

94. Accordingly, the invention claimed in *Biogen* [1997] RPC 1 was, as it were, the notion of subjecting the product (the unsequenced DNA fragment from the Dane particle) to the process (recombinant DNA technology) in order for it to be expressed to produce HBV antigens. It was therefore at least as much as a process claim as a product claim. In those circumstances, one can well see why the claim was held to be insufficient. The patent disclosed one way in which the DNA fragments could produce HBV antigens, but the claim "cover[ed] other ways in which they might be delivered, ways which owed nothing to the teaching of the patent or any principle which it disclosed" – [1997] RPC 1, 50. Accordingly, the claim was very different from a simple product claim as in the present case. This analysis of the facts in *Biogen* [1997] RPC 1 also explains why Lord Hoffmann said at pp. 51-52 that "the excessive breadth" of the patent in that case was due "to the fact that the same results could be produced by different means" from that disclosed by the patent.

95. Finally, at [1997] RPC 1, 54, Lord Hoffmann emphasised that "the extent of the monopoly claimed [should not] exceed … the technical contribution to the art made by the invention as described in the specification". As already explained, in the context of a simple product claim such as the present (especially where the claim is to a single chemical product), the technical contribution is (at least in the absence of special factors) the product itself. As I have suggested, the technical contribution can often be equated with non-obvious novelty – what is new to the art and not obvious is really another way of identifying the technical contribution.

96. The notion that Lord Hoffmann was not seeking to depart from the established approach of the Board is supported by the weight he placed on the reasoning in its decisions, especially *Genentech/Polypeptide expression* [1989] OJEPO 275 and T409/91 *EXXON/Fuel Oils* to which I have referred – see at [1997] RPC 1, 48-53. The fact that he took a different view from the Board on the patent in suit does not detract from this point: he was considering an argument which had not been raised in the opposition proceedings – see section 12 of his judgment at [1997] RPC 1, 52-53. Indeed, at the end of that section Lord Hoffmann was at pains to point out that there was no "divergence between the jurisprudence of this court and that of the EPO".

97. It is perhaps worth referring to one passage in the Board's decision in T409/91 *EXXON/Fuel Oils*, which was relied on by Mr

Thorley, and was quoted in *Biogen* [1997] RPC 1, 49. The quotation, taken from para 3.3 of the decision, concludes with the statement that there is 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". However, the passage continues:

> "This means that the definitions in the claims should essentially correspond to the scope of the invention as disclosed in the description. In other words,… the claims should not extend to subject-matter which, after reading the description, would still not be at the disposal of the person skilled in the art."

98. Thus, it is clear that, in that paragraph the Board was discussing insufficiency and support in the normal sense, and there is nothing to suggest that, in the case of a product claim, once it is decided that the product is novel, the technical contribution may not be the product itself, if it is a known *desideratum*.

99. In my opinion, therefore, in agreement with the Court of Appeal, 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. 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 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.

100. Kitchin J is by no means alone in having taken the mistaken view that the reasoning in *Biogen* [1997] RPC 1 is of much wider application, and in particular that it applies to any product claims (at least where they are claims to chemical compounds). I made exactly the same mistake at first instance in the *Kirin-Amgen* case – see at [2002] RPC 1, paras 300-312. A number of articles to which reference was made in the written cases also appear to have proceeded upon the same view.

101. It may be that this is in part attributable to the focussing by Lord Hoffmann in *Biogen* [1997] RPC 1, 42-46 on the "inventive step" involved in the alleged invention in that case. 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 hand. I respectfully agree with the explanation of the difference between the two concepts given in paras 29 to 31 of Lord Walker's opinion. When considering the validity of a simple product claim (such as is under scrutiny on this appeal), it may be that concentrating on the identification of the inventive step rather than the technical contribution can lead to error. "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* [1997] RPC 1) includes a process, the issue of how the alleged invention has been achieved seems to be more in point.

Conclusion

102. For these reasons (which are, I believe, effectively the same as those expressed by Lord Walker and Lord Mance) I would dismiss this appeal. As I understand all your Lordships are of the same opinion, I would also propose that the parties are given 14 days to make submissions as to costs.