

**Court of Appeal, London, 10 April 2008, Lundbeck v Generics**



**PATENT LAW**

**Novelty:**

- disclosure of the racemate did not disclose the isolated enantiomer; no enabling anticipation

8. A patentable invention must be new (Patents Act 1977, section 1(1)(a)) and an invention is not new if it forms part of the state of the art (section 2(1)). The state of the art comprises all matter made available to the public before the priority date: section 2(2). The claimants rely as prior art upon Lundbeck's US patent for citalopram, US 4,136,193, published 23 January 1979 which disclosed the chemical structure of citalopram and that it was a racemate.

9. In order to anticipate a patent, the prior art must disclose the claimed invention and (together with common general knowledge) enable the ordinary skilled person to perform it: *Synthon BV v Smithkline Beecham Plc* [2006] RPC 10. It is agreed that the prior art did not anticipate the isolated enantiomer. It is settled jurisprudence in the European Patent Office that disclosure of a racemate does not in itself amount to disclosure of each of its enantiomers: see decisions T 296/87 (OJ 1990, 19, point 6.2) T 1048/92 and T 1046/97 *Optically active triazole derivatives and compositions*, point 2.1.2.2.

**Obviousness:**

- Not obvious to try:

24. I do not think that the judge can possibly be said to have been unaware that the whole of the claimant's case on obviousness could be summed up by saying that it was obvious to try the diol route. (...)

- The judge then summed up (at paragraph 72) the current state of the law:

*"The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."*

25. No criticism has been made of this statement of principle and in my opinion the judge proceeded to apply it correctly to the facts of the case.

- In particular, he took into account, first, that there were "a number of avenues of research" open to the skilled man seeking a solution to the problem and that therefore he would not have taken the diol

route unless satisfied there was a "real prospect" that the necessary reaction would work. The claimants' case that the diol route was obvious to try was based upon Dr Newton's opinion that there was a "high expectation that the experiment would be a very facile ring closure and that it would work." But the judge rejected this assessment. Once he had done so, his conclusion that the diol route was not obvious seems to me unassailable.

**Sufficiency:**

- In an ordinary product claim, the product is the invention. It is sufficiently enabled if the specification and common general knowledge enables the skilled person to make it. One method is enough.

But the specification in Biogen described only one method of making the molecule by recombinant technology and disclosed no general principle. It was easy to contemplate other methods about which the specification said nothing and which would owe nothing to the matter disclosed.

In my opinion, therefore, the decision in Biogen is limited to the form of claim which the House of Lords was there considering and cannot be extended to an ordinary product claim in which the product is not defined by a class of processes of manufacture

- 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.

Source: [bailii.org](http://bailii.org)

**Court of Appeal, London, 10 April 2008**

(Lord Hoffmann, LJ Smith, LJ Jacob)

Neutral Citation Number: [2008] EWCA Civ 311

Case No: A3/2007/1326

Case No: A3/2007/1387

IN THE SUPREME COURT OF JUDICATURE

COURT OF APPEAL (CIVIL DIVISION)

ON APPEAL FROM THE HIGH COURT OF

JUSTICE CHANCERY DIVISION, PATENTS

COURT

Mr Justice Kitchin

05CO3689 / 06CO0457 / 06CO2767

Royal Courts of Justice

Strand, London, WC2A 2LL

Date: 10/04/2008

Before :

LORD HOFFMANN

LADY JUSTICE SMITH

and

LORD JUSTICE JACOB

-----

Between :

H. Lundbeck A/S Appellant

- and -

(1) Generics (UK) Limited & Ors

(2) Arrow Generics Limited

(3) Teva UK Limited and Teva Pharmaceuticals Limited Respondents

(...) -----

Mr Andrew Waugh QC and Dr Justin Turner (instructed by Simmons & Simmons) for the Appellant  
Mr Simon Thorley QC and Mr Michael Tappin (instructed by Taylor Wessing) for the Respondent (1)  
Mr Simon Thorley QC and Mr Mark Chacksfield (instructed by Forsyth Simpson) for the Respondent (2)  
Mr Simon Thorley QC and Mr Thomas Hinchliffe (instructed by Roiter Zucker) for the Respondent (3)

-----  
**Judgment Lord Hoffmann :**

1. Citalopram is one of a class of antidepressant 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 PLoS 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 χεῖρ, a hand) because, like a pair of hands, they are mirror images which cannot be completely superimposed 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-dimethylaminopropyl)-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, 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”.

6. These proceedings were commenced by companies which market generic citalopram in competition with escitalopram: Generics (UK) Ltd, Arrow Generics Ltd, and Teva UK Ltd and Teva Pharmaceuticals Industries Ltd. They say that Lundbeck is simply repatenting its invention of citalopram, or the active ingredient in that product, to extend its monopoly for another decade. They claim revocation of the patent on three grounds:

(a) Claims 1 and 3 lack novelty by reason of the disclosure of the racemate in Lundbeck’s patent for citalopram;

(b) Claims 1, 3 and 6 are invalid for obviousness;

(c) Claims 1 and 3 are invalid for insufficiency because they claim the enantiomer made by any method, but the specification discloses only two ways of making it.

7. Kitchin J rejected the first two grounds of attack but accepted the third. He therefore revoked claims 1 and 3 but upheld claim 6. The parties appeal and cross-appeal against these orders.

**Novelty**

8. A patentable invention must be new (Patents Act 1977, section 1(1)(a)) and an invention is not new if it forms part of the state of the art (section 2(1)). The state of the art comprises all matter made available to the public before the priority date: section 2(2). The claimants rely as prior art upon Lundbeck’s US patent for citalopram, US 4,136,193, published 23 January 1979 which disclosed the chemical structure of citalopram and that it was a racemate.

9. In order to anticipate a patent, the prior art must disclose the claimed invention and (together with common general knowledge) enable the ordinary skilled person to perform it: *Synthon BV v Smithkline Beecham Plc* [2006] RPC 10. It is agreed that the prior art did not anticipate the isolated enantiomer. It is settled jurisprudence in the European Patent Office that disclosure of a racemate does not in itself amount to disclosure of each of its enantiomers: see decisions T 296/87 (OJ 1990, 19, point 6.2) T 1048/92 and T 1046/97 *Optically active triazole derivatives and compositions*, point 2.1.2.2.

10. The claimants say, however, that claim 1 is not only for the isolated enantiomer. It is also for the enantiomer as an unresolved moiety of the racemate. To that extent, it is anticipated by the prior art which discloses the racemate and enables it to be made: compare Merrell Dow Pharmaceuticals Inc H N Norton & Co Ltd [1996] RPC 76.

11. This raises a question of construction. One could read the claim as including the enantiomer when part of the racemate. But is this what the skilled person would have understood the patentee to mean? True, it does not expressly disclaim the unresolved enantiomer. But the judge said the context would have made it obvious to the skilled person that the patentee was not laying claim to an unresolved moiety of the racemate. The title of the patent was “new enantiomers and their isolation” and the specification makes it clear that the racemate is not new. The European Patent Office would certainly not construe the claim as extending to the racemate. Thus in T 1046/97 Optically active triazole derivatives and compositions, the Board of Appeal said:

*“Claim 1 is a product claim directed to the specific enantiomer of the formula (+)- I, which the Board interprets as the pure (+) – enantiomer.”*

12. Mr Thorley QC, who appeared for the claimants, did not dispute that it would not occur to the skilled person that the patentee was intending to claim an unresolved part of the racemate. But in that case, what was he intending to claim? Merely to say what he did not claim would leave the scope of the claim too vague. When the Board of Appeal spoke of the “pure enantiomer”, what did it mean? It was not enough to say that it obviously meant something to the Board of Appeal. Professor Davies, the Waynflete Professor of Chemistry in the University of Oxford, who was called by Lundbeck as an expert witness, said that “pure” was conventionally understood to mean at least 95% pure. The judge did not accept that there was such a convention but said that he did not need to decide the point, particularly since the claim itself did not use the word “pure”. The question might become relevant when Lundbeck brought infringement proceedings. But for the purpose of deciding the question of anticipation, it was enough to say that the claim would not be construed as including an unresolved part of the racemate.

13. Mr Waugh QC, who appeared for Lundbeck, said that the judge did not do justice to the evidence of Professor Davies, whose assertion of a conventional usage of “pure” to mean 95% was uncontradicted. Reading the cross-examination upon which the judge relied as casting doubt upon this convention (Day 5, pp. 622-666), I think there is force in Mr Waugh’s submission. But I do not think that it matters because I have no doubt that the judge was right in saying that whatever the claim meant, it did not include an unresolved part of the racemate. It was therefore not anticipated.

#### **Obviousness**

14. The claimants’ case at the trial was that there were two methods or “routes” for resolving the racemate which would have been obvious to a skilled person at the priority date. One was by chiral high performance liquid chromatography (chiral “HPLC”). This was not a method mentioned in the specification. The other was by making diastereomeric salts of the amino diol (the last intermediate in the synthesis of citalopram) resolving it into its enantiomers, and then converting them into the enantiomers of citalopram by a reaction which preserved their distinctive three-dimensional structures. This is the method specified in claim 6, which I earlier promised to describe. The specification also disclosed another method which has not been said to be obvious and therefore need not be considered. The judge found that neither the chiral HPLC nor the amino diol routes was obvious. The claimants appealed against both findings but later abandoned the appeal on the chiral HPLC route. In this court, only the alleged obviousness of the amino diol route was in issue.

15. The judge heard a good deal of evidence on how the skilled person might set about trying to resolve citalopram. The parties were agreed that he would initially try to resolve the molecules of the final product. Professor Davies found 13 different possible techniques described in the literature and although the judge found (at paragraph 112) that the skilled person would not have known about all of them, that left several which he could and might try. In no case was the outcome predictable.

16. If a frontal attack failed, the skilled person could try an indirect approach by resolving an intermediate chiral product to produce its enantiomers, from which the pure enantiomers of citalopram could be made. That was the method of claim 6. The chiral intermediate there proposed, namely an amino diol (a diol is a molecule with two hydroxyl (-OH) groups.), would have lain readily to hand because Lundbeck itself disclosed it in a US patent (4,650,884 or “the ‘884 patent”) which it obtained in 1987. That patent was entitled “novel intermediate and method for its preparation” and put forward the amino diol as an intermediate stage in a better way of making citalopram than that which had been disclosed in the original patent 4,136,193.

17. It was accepted that the ‘884 patent disclosed the diol. There was no teaching of how to separate the enantiomers of the diol or how one might convert those enantiomers into the pure enantiomers of citalopram. On the contrary, the ‘884 patent was for a better method of making the racemate.

18. In order to convert the diol, with its two hydroxyl groups, into citalopram, it is necessary to promote a nucleophilic substitution reaction which will “close the ring”. As the skilled person would have known, there are two possible kinds of such ring-closing reactions. One is an SN1 reaction, in which the bond to the leaving group is broken before the bond with the incoming group is created. The other is an SN2 reaction, in which there is a transition stage in

which the leaving and incoming groups are half-bonded. The effect of an SN1 reaction is to destroy the original stereochemistry of the molecule and create a racemate. That was the reaction described in the '884 patent. An SN2 reaction, on the other hand, is "stereoselective" and preserves the three-dimensional form of the molecule, converting the diol enantiomer into the pure enantiomer of citalopram. The '884 patent gave no guidance on whether such a reaction was possible.

19. The claimants' expert witness was Dr Newton, who has had a long and distinguished career as a medicinal chemist at Glaxo. He said that the skilled man would have known from the contents of two papers by Sir Jack Baldwin (known to chemists as "Baldwin's Rules") that such an SN2 reaction was favoured. This was contested in a witness statement by Professor Davies. Dr Newton replied in a 3rd witness statement, defending his position, but added (at para 7):

*"In practice, the skilled team in 1988 would in my view have been unlikely to have spent a lot of time considering these types of issues. The reaction looked promising, and as the experiments concerned are simple and quick to perform, the skilled team would have gone ahead and tried them."*

20. In cross-examination (Day 2, pp. 180-81), Dr Newton made it clear that the reason why he thought the reaction looked promising was his interpretation of Baldwin's rules:

*"Mr Waugh: ...[Y]ou say [3rd witness statement, paragraph 7] 'In practice, the skilled team in 1988 would in my view have been unlikely to have spent a lot of time considering these types of issues.'*

*A. Absolutely right.*

*Q. I think this was set running inasmuch as you introduced Baldwin's rules into your report.*

*A. Yes...the skilled person would look at the system and say that looks fine as far as Baldwin's rules are concerned and try the experiment. In the high expectation that the experiment would be a very facile ring closure and that it would work."*

21. The judge did not agree. He pointed out that Dr Newton, when he offered his opinion, had the advantage of knowing that in fact the reaction had worked. In his opinion, (at paragraph 171):

*"The skilled person would not have proceeded down the diol route unless he was satisfied that there was a real prospect of an SN2 reaction working. This was by no means a one way street. There were a number of avenues of research open to him..."*

*In the light of all the evidence I do not believe the skilled person would have been so satisfied from a consideration of [Baldwin's Rules]."*

22. After noting one or two other points which the skilled man would have regarded as making an SN2 reaction unlikely, the judge concluded by agreeing with Professor Davies that it was "only with hindsight that it was possible to explain the outcome of a reaction which would otherwise have been unexpected."

23. Mr Thorley, who presented the appeal for the claimants with his usual elegant skill, acknowledged that an appellate court will not ordinarily reverse a trial

judge's finding on obviousness unless he has made some error of principle: see *Biogen v Medeva* [1997] RPC 1, 45. The error of principle which he identified was that the judge "failed to consider whether it was obvious for the skilled man to try the reaction to see if it worked." He said the judge had come to his conclusion solely on the basis of theoretical considerations such as whether the reaction was indicated as favoured by Baldwin's Rules. I cannot forbear to remark that it is not a little ironic that the judge should be criticised for having regard to such matters when it was the claimants who put them forward in support of their case.

24. I do not think that the judge can possibly be said to have been unaware that the whole of the claimant's case on obviousness could be summed up by saying that it was obvious to try the diol route. He made this understanding clear at an early stage in his judgment (paragraph 71) when he said: "This is a case in which it is said that the method of claim 6 was one which was obvious to try." He then cited from *Angiotech Pharmaceuticals Inc v Conor Medsystems* [2007] RPC 20, which represents this Court's last word on the extent to which the notion of some step being obvious to try is helpful in deciding whether an invention is obvious. The judge then summed up (at paragraph 72) the current state of the law:

*"The question of obviousness must be considered on the facts of each case. The court must consider the weight to be attached to any particular factor in the light of all the relevant circumstances. These may include such matters as the motive to find a solution to the problem the patent addresses, the number and extent of the possible avenues of research, the effort involved in pursuing them and the expectation of success."*

25. No criticism has been made of this statement of principle and in my opinion the judge proceeded to apply it correctly to the facts of the case. In particular, he took into account, first, that there were "a number of avenues of research" open to the skilled man seeking a solution to the problem and that therefore he would not have taken the diol route unless satisfied there was a "real prospect" that the necessary reaction would work. The claimants' case that the diol route was obvious to try was based upon Dr Newton's opinion that there was a "high expectation that the experiment would be a very facile ring closure and that it would work." But the judge rejected this assessment. Once he had done so, his conclusion that the diol route was not obvious seems to me unassailable.

#### **Sufficiency**

26. The judge held that claim 1 and claim 3 (which is dependent on claim 1) were insufficient. His reasoning was that claim 1, being a claim to the (+) enantiomer as a product, was a claim to a monopoly of that product however made: see section 60(1)(a) of the 1977 Act. But Lundbeck's inventive idea was not to discover that the enantiomer existed and had a medicinal effect. Everyone knew that the two enantiomers existed and that one or other or both had a

medicinal effect. What Lundbeck discovered was one way of making it. But that did not entitle them to a monopoly of every way of making it.

27. I can understand and sympathise with the judge's instinctive reaction to the inherent breadth of a product claim. Indeed, as I shall in due course show, he is not the first to have registered such a protest. But in my opinion his reasoning is not justified either by the statute or the authorities. **In an ordinary product claim, the product is the invention. It is sufficiently enabled if the specification and common general knowledge enables the skilled person to make it. One method is enough.**

28. The statutory basis for a claim for revocation on the grounds of insufficiency is section 72(1)(c):

*"[T]he court...may... revoke a patent [on the ground that] the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art"*

29. In order to decide whether the specification is sufficient, it is therefore first necessary to decide what the invention is. That must be found by reading and construing the claims, in which the inventor identifies what he claims to be his invention. As the Board of Appeal of the European Patent Office said in Exxon/Fuel Oils (T 409/91) [1994] OJ EPO 653, paragraph 3.3, *"It is the definition of the invention in the claims that needs support"*.

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

31. The judge founded his decision entirely upon **the decision of the House of Lords in Biogen v Medeva [1997] RPC 1**, which he subjected to a careful and detailed analysis. I shall try, with suitable diffidence (see Deutsche Morgan Grenfell Group plc v Inland Revenue Commissioners [2007] 1 AC 558, 567 at paragraph 14) to explain why I do not think that case yields so broad a principle.

32. **In Biogen** the inventor, Professor Murray, was the first to succeed in producing by recombinant genetic technology a DNA molecule which could express the antigens of the hepatitis B virus in a host cell. He wanted to patent his invention. But what had he invented? He could not claim to have invented the relevant DNA molecule, because it existed naturally in people suffering from hepatitis B. Nor could he claim to have invented the molecule isolated and outside the human body, because that had been done by purification of samples of the infective agent: see p. 35 of the judgment. What he had invented was a process for making it. But he obviously thought that simply to patent his process would not give him much of a monopoly, because the science was rapidly advancing and scientists would find other methods of making the

antigens, outside the scope of any process claim he could justify. That was in fact what happened.

33. What Professor Murray tried to do, with a view to claiming the widest possible monopoly, was to make a product claim to a DNA molecule which defined the product partly by the way it had been made and partly by what it did, namely to express the antigens. It was a hybrid or "product-by-process" claim, of a kind which has become relatively rare since **the decision of the House of Lords in Kirin-Amgen Inc v Hoechst Marion Roussel [2005] RPC 169**. It was not a simple product claim because, as I have said, that would have failed for lack of novelty. The principal claim (see p.40) was for:

*"A recombinant DNA molecule characterised by a DNA sequence coding for a polypeptide or a fragment thereof displaying HBV antigen specificity, said DNA sequence being operatively linked to an expression control sequence in the recombinant DNA molecule and being expressed to produce a polypeptide displaying HBV antigen specificity when a suitable host cell transformed with said recombinant DNA molecule is cultured, the transformed host cell not producing any human serum proteins and any primate serum proteins other than the polypeptide displaying HBV antigen specificity."*

I summarised this claim (at p. 40) as being for 'a molecule identified partly by the way it has been made ('recombinant DNA') and partly by what it does (the words following 'characterised by').

34. Thus, as a matter of construction, the House of Lords interpreted the claim as being to a class of products which satisfied the specified conditions, one of which was that the molecule had been made by recombinant technology. That expression obviously includes a wide variety of possible processes. But the law of sufficiency, both in the United Kingdom and in the EPO, is that a class of products is enabled only if the skilled man can work the invention in respect of all members of the class. The specification might show that this has been empirically demonstrated or it might disclose a principle which can reasonably be expected to apply across the class: see T 292/85 Polypeptide expression/GENENTECH [1989] OJ EPO 275; T409/91 Fuel Oils/EXXON [1994] OJ EPO 653; **Kirin-Amgen Inc v Hoechst Marion Roussel [2005] RPC 169, 202**. **But the specification in Biogen** described only one method of making the molecule by recombinant technology and disclosed no general principle. It was easy to contemplate other methods about which the specification said nothing and which would owe nothing to the matter disclosed.

35. In my opinion, therefore, **the decision in Biogen** is limited to the form of claim which the House of Lords was there considering and cannot be extended to an ordinary product claim in which the product is not defined by a class of processes of manufacture. It is true that **the House in Biogen** indorsed the general principle stated by the **Board of Appeal in T409/91 Fuel Oils/EXXON [1994] OJ EPO**, 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.”*

36. The judge said that in holding claim 1 insufficient, he was applying this principle. But then he treated the relevant “technical contribution to the art” as being the inventive step, namely a way of making the enantiomer. That, I respectfully consider, was a mistake. 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.

37. That proposition is in my opinion established by a number of decisions in the European Patent Office. In [T595/90 Kawasaki Steel Corporation \[1994\] OJ EPO 695](#) claim 1 was to a product, namely a certain description of high grade steel sheeting. In opposition proceedings, the Board of Appeal found that the claimed product “only has properties which were fully predicted and envisaged. i.e. the matter is obvious as such”. However, the Board went on, “this desideratum was not yet actually achieved” and was “hardly realisable on a commercial scale”. If the patentee had found a non-obvious way of making the product, he was entitled to a product claim, with the full monopoly of the product which that conferred:

*“It is the view of the Board that a product which can be envisaged as such with all its 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. (My emphasis).”*

38. This passage has been cited and applied in a number of subsequent cases: see, for example, the decision of the Technical Board of Appeal from opposition proceedings in T 0233/93 E I Du Pont (28 October 1996):

*“The patent in suit does not deny...that the combination of properties defining the claimed products had been a desideratum which the skilled community had striven to achieve. These properties, however, had been considered to be irreconcilable. According to the [jurisprudence] of the Boards of Appeal [citation of Kawasaki Steel] such a desired product, which may appear obvious per se, may be considered non-obvious and claimable as such, if there is no known method in the art to make it and the claimed methods for its preparation are the first to produce it and so do in an inventive manner.”*

39. See also T1195/00 Alcan International Ltd (24 May 2004) and T0803/01 Novartis (9 September 2003). It is perfectly true that in all these cases, the objection to the patent was that the product was obvious. It does not seem to have occurred to anyone to argue that even if there was an inventive step, the application was defective under article 83 of the EPC because it did not

*“disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art”.*

40. It is however remarkable that if the principle applied by the judge is good law for revocation proceedings in the United Kingdom, no one has ever thought of applying it to the identical language applicable to opposition proceedings in the EPO. Biogen should therefore not be read as casting any doubt upon the proposition that an inventor who finds a way to make a new product is entitled to make a product claim, even if its properties could have been fully specified in advance and the desirability of making it was obvious.

41. What the judge has done is to make the requirements for sufficiency under section 72(1)(c) differ according to the nature of the inventive step. If it is to “describe a new and non-obvious compound which has a beneficial effect”, the judge acknowledges (at paragraph 263) that one way of making it will be sufficient. But the case is otherwise if the inventive step is to find a way of making an obvious compound. In my opinion, however, there is nothing in section 72(1)(c) which connects the requirements of sufficiency to the inventive step. What needs to be disclosed sufficiently to enable it to be performed is the invention as defined in the claim. That remains the same, whatever may have been the inventive step.

42. It is however difficult not to sympathise with the judge’s feeling that the distinction between Professor Murray [in Biogen](#) and Lundbeck in this case owes little to any difference in their original contributions to their respective arts. Professor Murray may have been unlucky in not being able to make a product claim for the isolated DNA molecule. It was only because he was driven to identifying the product which he claimed by reference to the way it was made that the method of manufacture became relevant both to the extent of the monopoly and the question of sufficiency. A simple product claim has no such difficulties.

43. Product claims have had a chequered history. Under the Statute of Monopolies 1623 a patent could be granted only for a “manner of new manufactures.” By the end of the 19th century it was a matter of some controversy whether a new material could be claimed: compare Lord Davey in *Acetylene Illuminating Co Ltd v United Alkali Co Ltd* 22 RPC 145, 153 with Lord Shaw in *British Thomson-Houston Co Ltd v British Insulated and Helsby Cables Ltd* 42 RPC 180, 207. It would appear that some chemical product claims were granted, because in 1916 the Comptroller-General of Patents, Mr W. Temple Franks, who was a member of a committee chaired by Lord Parker of Waddington appointed to advise on amendments to the Patents and Designs Act 1907, commented unfavourably upon them. In the course of a memorandum “on German use of our Patent Law”, in which he elaborated on the way the Germans “have carefully studied and most astutely used every provision of our Patent and Trade

Mark Laws for the furtherance of their trade”, he made these observations:

*“Another point to be noticed in connection with the use made by the Germans of our patent procedure is their use of what are called ‘product claims’. These claims are claims to any new product per se irrespective of the process by which it is made and are in the form eg ‘as a new product the dyestuffs made as above or by any other process’. The consequence of such claims especially in chemical manufacture is that the inventor of a process producing a new chemical product is enabled to attack as infringements products produced not only by the process discovered by him but by any other method. These are, in my opinion, in the majority of instances, obstructive and injurious claims, and they very largely aid the establishment of a monopoly in the case of chemical manufacture as they prevent research and invention on analogous lines by other persons.”*

44. The 1907 Act was amended in 1919 by inserting a new section 38A:

*“In the case of inventions relating to substances prepared or produced by chemical processes or intended for food or medicine, the specification shall not include claims for the substance itself except when prepared or produced by the methods or processes of manufacture particularly described and ascertained or by their obvious chemical equivalents...”*

45. But the 1947 Departmental Committee on the Patents and Designs Act (Cmd 7206) recommended the removal of this restriction. The Committee said (at paragraph 93):

*“It has been strongly urged that this limitation on the claiming of new substances should be removed as not being in accordance with modern technological developments. It has been argued that the real invention lies in the discovery of a new substance, with new and useful properties, and that the process of manufacture often involves little novelty in itself. Many valuable new substances are produced by synthesising a large number of possible compounds by known methods and then determining which of the new substances have useful properties.”*

46. Parliament accepted this recommendation and section 38A was repealed and not replaced by the Patents Act 1949. The 9th edition (1951) of Terrell on Patents said that it was “an important change in the law.” It remains the law today: see section 60(1) of the 1977 Act. There are obviously arguments of public policy on both sides: the Kawasaki Steel Corporation line of cases shows that sometimes the “real invention” does not lie in the discovery of the new substance but in finding a process of manufacture. But Parliament has chosen to allow product claims and the jurisprudence of the EPO, which we have always regarded as carrying great weight, shows that such claims can be made in the latter case as well. It is too late to have regrets about the breadth of the monopoly which such claims confer.

47. I would therefore allow Lundbeck’s appeal against the revocation of claims 1 and 3 and dismiss the

claimants’ appeals against the judge’s refusal to revoke claim 6.

**Lady Justice Smith :**

48. I agree with both judgments.

**Lord Justice Jacob :**

49. I agree that Lundbeck’s appeal should be allowed for the reasons given by Lord Hoffmann. However since we are differing from the Judge and this case involves some questions of general importance I will briefly state some of them in my own language.

50. First novelty. This involves a pure question of construction, namely whether the claim covers the (+) enantiomer when in the racemate. In my opinion it obviously does not – the patentee was plainly not intending to cover the racemate. How much more than 50% of the (+) enantiomer must be present for a product to fall within the claim is simply a moot point as far as this case is concerned.

51. As regards obviousness I have little to add to what Lord Hoffmann has said. In essence Mr Thorley’s argument was that the skilled man could have come by the invention by doing a short and simple experiment. But one could say that, with hindsight, of many an invention. It is not enough that an experiment revealing an invention would have been short and simple. There has to be a reason why the skilled man would have carried it out. Normally that would require at least an expectation that something might come out of it. Otherwise, short and simple though it would have been, doing the experiment would have been pointless. The claimant’s expert, Dr Newton, suggested there was a point, saying “the reaction looked promising”. But the Judge rejected that evidence. And there was clearly material upon which he could do so. That is an end of the obviousness case.

52. I turn to sufficiency. There is a very short answer to this point. The claim is to the (+) enantiomer. That is novel and non-obvious. 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.”

53. Where then, lay the Judge’s error? He reasoned thus: that the (+) enantiomer existed was known. So all that Lundbeck “invented” - contributed to the art - was a particular way of making it. So its patent claim should be correspondingly limited. Were it otherwise, Lundbeck would effectively get a monopoly to any way of making the (+) enantiomer – ways which it had not invented. Hence the claim was insufficient.

54. But any product claim is apt to give the patentee “more than he has invented” – and in two ways. Firstly such a claim will have the effect of covering all ways of making the product including ways which may be inventive and quite different from the patentee’s route. Secondly it will give him a monopoly over all uses of the patented compound, including uses he has never thought of.

55. I elaborate on the second point a little. A patent can only be granted for a novel substance if the patentee specifies a use for it (absent this he has simply not made an invention at all – has added nothing to human knowledge). But once he has specified a use, his claim to the substance will cover any use. For instance he may invent a new glue, specified in his claim by its chemical composition. If that glue turns out to be useful for some entirely different purpose, e.g. as a plasticiser, he has a monopoly over that too – more than he “invented”.

56. It works the other way round too. If a substance is old, it may not be repatented as such just because the later inventor has found an entirely different use. An old but good example of this is *Shell v Esso* [1960] RPC 35 where the prior art disclosed a fuel with an additive for preventing corrosion of fuel tanks and the patentee wanted a claim to a fuel with the same additive for the quite different purpose of increasing octane rating and prevention of fouling of plugs and valves. The patentee had to disclaim those parts of his claimed range with overlapped with the prior art range. (It now may be possible for a patentee to do somewhat better by the use of the kind of claim approved by the Enlarged Board in *MOBIL/Friction reducing additive GO2/88*, namely “the use of that compound in a composition for a particular purpose”).

57. The fact that compound claims may give a patentee “more than he deserves” has not in practice proved to be much of a problem. Their certainty and pragmatic value has proved itself over the years. What matters for present purposes is that the concept “that the patentee should not have more than he deserves” does not form part of the statutory test for sufficiency.

58. The other consideration which moved the judge was this: that the claim was to a desired compound. He thought the position would be different if the technical contribution lay in “the provision of the new and useful compound.” Here, that the compound would be useful was already known, so the monopoly should not extend to it.

59. It is of course the case that, as the [Technical Board of Appeal said in \*Exxon/ Fuel Oils T409/91\*](#) at 3.3:

*“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.”*

In the context of substance claims the technical contribution includes provision of the substance itself – one that could not be provided before. Merely because it was wanted before does not diminish the technical contribution.

60. Some careful thinking is called for in considering claims to desirable ends. There are different sorts of these. I quite agree that a patentee may not normally frame his claim simply by reference to known desirable properties of a product – what is sometimes called a “free beer” claim. The Guidelines for Examination at the EPO put it this way:

*“4.1 The area defined by the claims must be as precise as the invention allows. As a general rule, claims which*

*attempt to define the invention by a result to be achieved should not be allowed, in particular if they only amount to claiming the underlying technical problem.”*

and:

*“4.10 Result to be achieved*

*The area defined by the claims must be as precise as the invention allows. As a general rule, claims which attempt to define the invention by a result to be achieved should not be allowed, in particular if they only amount to claiming the underlying technical problem. However, they may be allowed if the invention either can only be defined in such terms or cannot otherwise be defined more precisely without unduly restricting the scope of the claims and if the result is one which can be directly and positively verified by tests or procedures adequately specified in the description or known to the person skilled in the art and which do not require undue experimentation (see *T 68/85, OJ 6/1987, 228*).”*

61. So, for example, if a man finds a particular way of making a new substance which is 10 times harder than diamond, he cannot just claim “a substance which is 10 times harder than diamond.” He can claim his particular method and he can claim the actual new substance produced by his method, either by specifying its composition and structure or, if that cannot be done, by reference to the method (see *Kirin-Amgen* at [90-91]) but no more. The reason he cannot claim more is that he has not enabled more – he has claimed the entire class of products which have the known desirable properties yet he has only enabled one member of that class. Such a case is to be contrasted with the present where the desirable end is indeed fully enabled – that which makes it desirable forms no part of the claim limitation.

62. Those examples form two extremes – there may be cases in between where the invention may lie in appreciating that a particular combination of desirable properties is of special value. The validity of that sort of claim will be particularly sensitive to the context of the teaching of the patent and the prior art.

63. Finally I should say a word about *Biogen*. I can well understand that certain passages, taken out of context, can be read as supporting the Judge’s decision. But none of them was concerned with a case like this: a novel, non-obvious and enabled product claim. In the end one comes back to the short answer with which I started this topic. Founded as it is on the plain words of the statute I do not see how it can be refuted.

64. Accordingly, like Lord Hoffmann, I would allow Lundbeck’s appeal and dismiss that of the respondents.

-----