HOUSE OF LORDS SESSION 2005–06
[2005] UKHL 59

on appeal from:[2003] EWCA Civ 861

OPINIONS

OF THE LORDS OF APPEAL

FOR JUDGMENT IN THE CAUSE

Synthon BV (Appellants)
v.
Smithkline Beecham plc (Respondents)

Appellate Committee

Lord Bingham of Cornhill
Lord Hoffmann
Lord Walker of Gestingthorpe
Baroness Hale of Richmond
Lord Brown of Eaton-under-Heywood

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LORD BINGHAM OF CORNHILL

My Lords,

1. I have had the privilege of reading in draft the opinion of my noble and learned friend Lord Hoffmann. I am in full agreement with it and would, for the reasons he gives, allow the appeal and restore the decision of Jacob J.

LORD HOFFMANN

My Lords,

The invention

2. Paroxetine is a compound used to treat depression and related disorders. It has for some time been marketed in the form of its hydrochloride hemihydrate salt under the name Paxil or Seroxat. These proceedings arise out of the more or less simultaneous discovery in about 1997 by the appellants Synthon BV, a Dutch pharmaceutical company, and the respondents, Smithkline Beecham plc ("SB"), a UK pharmaceutical company, that a different paroxetine salt, paroxetine methanesulfonate ("PMS"), has properties which make it more suitable for pharmaceutical use. It is more stable, less hygroscopic and much more soluble, so that it can be prepared in higher concentrations.

The Synthon disclosure

3. On 10 June 1997 Synthon filed an international application under the Patent Cooperation Treaty for a patent which claimed a broad class of sulfonic acid salts including PMS. This was published on 17 December 1998. The specification said that a known useful salt of paroxetine was the hydrochloride in various forms but that each of them had, to a greater or lesser extent, disadvantages for safe handling and formulation. The object of the invention was to provide a compound with improved characteristics. It then set out, by reference to a formula with a number of variables, a class of compounds which were said to exhibit good stability and high solubility. These included PMS.

4. The specification, as is customary in patents for chemical compounds, then narrowed its focus to a preferred group within the class which was said to exhibit a very high degree of solubility and then, by way of illustration, to a particular compound in that group. That compound was PMS, which features in the first example of the preparation of a salt of paroxetine suitable for pharmaceutical use. Under the heading "Example 1", the specification describes how to make PMS in crystalline form.

5. The notion of crystalline form may require some explanation. The same substance may exist in different solid forms, depending upon the arrangement of its molecules. In crystalline form the molecules arrange themselves in an organised pattern called a lattice which gives the crystal a distinctive shape. On the other hand, in an amorphous form or an oil, the molecules are randomly distributed and the substance has no particular shape. Some substances have only one crystalline form. They are called monomorphic. But others have a variety of patterns into which the molecules may arrange themselves. They are polymorphic. Different crystalline forms can be distinguished by a number of conventional tests. Infra-red radiation (IR) will result in a spectrum of readings of absorbance which are characteristic of that particular crystal. X-ray diffraction (XRD) will likewise give a characteristic series of readings. The IR and XRD readings are the crystal's fingerprint. Some compounds form one or more types of crystals which include, as part of their crystalline structure, molecules of the solvent from which the crystal has been precipitated. They are called solvates or, if the solvent is water, hydrates.

6. Example 1 teaches how to make PMS from a solution of paroxetine, prepared in accordance with a procedure disclosed in a previous US patent, by adding methane sulphonic acid. This is the standard method of producing a salt by adding an acid to a base. In the example, crystallisation is obtained by the use of a seeding crystal which induces precipitation of crystals from the solution. This is said to produce a 99.5% yield of crystals having a 98% purity. The characteristics of the crystals are described in Table 1, giving their melting point (142° to 144°C), DSC (differential scanning calorimetry) curve, IR spectrum and NMR (nuclear magnetic resonance) readings which map the hydrogen and carbon atoms in the structure of the crystal. A note after Table 1 draws attention to the fact that "the compounds of the invention are crystalline, with defined melting points, DSC curves and IR spectra" but that they may be polymorphic and exist in other crystalline forms. The crystals of the acid addition salts with organic sulphonic acids, like PMS, are "substantially free of bound organic solvents", that is to say, they are not solvates, but some "may contain crystallisation water and also unbound water, that is to say water which is other than water of crystallisation." The particular example in Table1, however, is said to be a crystal of 98% purity and therefore not a hydrate.

7. Example 1, as I have said, requires a seeding crystal to start the process of crystallisation and is preceded by a description of how such a seeding crystal had been obtained. It involved dissolving paroxetine in hot ethanol, adding methanesulfonic acid, cooling and then freezing the mixture and evaporating it to reduce it to an oil. After being left for a month, a waxy solid was obtained, part of which was dissolved in EtOAc and the rest used to precipitate crystals from the solution in a freezer.

The SB patent

8. After Synthon had filed its application but before it was published, SB filed a document dated 6 October 1998 which gave it priority for a UK patent application filed on 23 April 1999. The patent was published on 10 May 2000 as UK Patent No 2 336 364. SB, like Synthon, appears at first to have thought that PMS was a novel compound. The SB specification began by saying that it had been surprisingly discovered. The title of the patent is "Paroxetine Salt". But during the course of prosecution, it appeared that there was prior art in which PMS had been identified as one of many paroxetine salts suitable for a method of treatment patented in the United States. SB therefore

confined its claim to a particular form of crystalline PMS. It is described in claim 1, upon which other claims are dependent:

> "Paroxetine methanesulfonate in crystalline form having inter alia the following characteristic IR peaks: 1603, 1513, 1194, 1045, 946, 830, 776, 601, 554, and 539 ± 4cm $^{-1}$.; and/or the following characteristic XRD peaks: 8.3, 10.5, 15.6, 16.3, 17.7, 18.2, 19.8, 20.4, 21.5, 22.0, 22.4, 23.8, 24.4, 25.0, 25.3, 25.8, 26.6, 30.0, 30.2, and 31.6 ± 0.2 degrees 2 theta."

9. It will be seen that the claim identified a particular crystalline form by reference to its IR and XRD peaks. If, as the specification said was possible, PMS turned out to be polymorphic, no other forms of crystal were claimed. And it is of particular importance to notice that the IR peaks in claim 1 are different from those in Table 1 of the Synthon application. A person skilled in the art, reading both documents, would think that they identified different polymorphs.

10. Although the specification does not spell out the advantages of PMS or sulfonate salts in general in the way that the Synthon application does, the specification makes it clear that the inventive step was the discovery of the sulfonate salt of paroxetine as an alterative to the hydrochloride salt.

11. The specification suggests a variety of solvents which may be used for dissolving paroxetine before mixing it with commercially available methanesulfonic acid and goes on to say that "the salt may be isolated in solid form by conventional means from a solution thereof obtained as above." Examples of non-crystalline and crystalline solids are given. As for the crystalline form, the specification says:

> "A crystalline salt may be prepared by various methods such as directly crystallising the material from a solvent in which the product has limited solubility or by triturating for example with ethers such as diethyl ether or otherwise crystallising a non-crystalline salt. A number of solvents may be used for the crystallisation process including those that are useful industrially; eg paroxetine methanesulfonate may be crystallised from a relatively

crude feedstock such as is commonly produced during the final stage of the chemical synthesis of paroxetine."

A number of other alternative methods are then given over the following pages. But there is no suggestion that any of them involved an inventive step. They are all described as involving commonly used solvents and conventional methods (eg "vigorous stirring is particularly useful").

The proceedings

12. On 7 March 2001 Synthon commenced proceedings to have the SB patent revoked on the ground that the crystalline form of PMS described in claim 1 was not new. Section 1(1)(a) of the Patents Act 1977 provides that a patent may be granted only for an invention which is new. Section 2(1) provides that an invention shall be taken to be new if it does not form part of the state of the art. Section 2(2) and (3) define 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.
>
> (3) The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say—
>
> (a) that matter was contained in the application for that other patent both as filed and as published; and
>
> (b) the priority date of that matter is earlier than that of the invention."

13. Synthon do not rely on section 2(2). They accept that the crystalline form of PMS identified in claim 1 of the patent in suit had not been "made available to the public", whether by description or in any other way, before the priority date. They rely on section 2(3), claiming that the invention in claim 1 was disclosed by their own patent application.

14. In order to make good their case, Synthon had to satisfy the judge on two points. The first was that their application disclosed the invention which had been patented as claim 1. I shall call this requirement "disclosure". The second was that an ordinary skilled man would be able to perform the disclosed invention if he attempted to do so by using the disclosed matter and common general knowledge. I shall call this requirement "enablement". If both these requirements are satisfied, the invention is not new. I shall later have to discuss the law on disclosure and enablement and the relationship between them in some detail, but for the moment that is enough to explain the course which the proceedings took before the judge.

15. For the purposes of disclosure, Synthon relied upon the fact that their application disclosed the existence of PMS in crystalline form. An immediate difficulty, however, was that the differences in the IR spectra suggested that it was not the same crystalline form as was claimed in the patent. Synthon nevertheless pressed on with experiments designed to show that they also satisfied the requirement of enablement. That means, as I have said, that the ordinary skilled man would be able to perform the invention. Synthon, however, left nothing to chance and engaged Sir Jack Baldwin FRS, Waynflete Professor of Chemistry in the University of Oxford and one of the foremost organic chemists in the world, together with Dr Robert Adlington, whom Professor Baldwin described as the best practical organic chemist he had ever worked with, to conduct the experiments. They were given in a sealed bottle a sample of the mixture of paroxetine dissolved in ethanol mixed with methanesulfonic acid mixed with ethanol described in the Synthon application as having been used to make seeding crystals and asked to reproduce the experiment. The result was a complete failure. The method failed to produce any crystals at all. Eventually, after a good deal of skilled manipulation of a kind not described by Synthon's application, Professor Baldwin and Dr Adlington produced some crystals. These turned out not to have the IR spectrum predicted by Synthon in Table 1. Instead, they had the spectrum described in the patent in suit.

16. Faced with these results Synthon had to retreat and regroup. When it came to the trial, they advanced new arguments. First, they called evidence to show that the IR spectrum in Table 1 of their application was the result of a mistaken reading in their own laboratory. They submitted that the totality of the evidence, including the IR readings of the crystals obtained by Professor Baldwin, showed that PMS was monomorphic. Any PMS crystal would have the characteristics described in the patent in suit. The judge accepted this submission. He therefore found that a disclosure of a crystalline form of PMS necessarily meant that it would be the form described in the patent, even though a person who had read the patent and set out to make the form described in the application might have thought he was making something different.

17. Secondly, Synthon put forward a new argument on enablement. They said that although the method described in the application did not produce seeding crystals, that did not mean that the ordinary skilled man would not be able to crystallise PMS. The trouble with the described method turned out to be that it had used an unsuitable solvent. Ethanol produced a reaction which inhibited crystallisation. But the ordinary skilled man, if not confined to a particular solvent, would try another. Crystallisation was an art rather than an exact science and commonly involved some routine trial and error before results were achieved. For these propositions, Synthon relied mainly upon the evidence of SB's own expert, Dr Ward. They also relied, as evidence of what would have been thought within the abilities of the ordinary skilled man, upon the terms of SB's own specification, which described the process of crystallisation as conventional and capable of being effected with a variety of solvents and in a number of different ways. They abandoned reliance upon any particular method disclosed by their application and relied upon it only for the information it contained about the chemistry of PMS which the skilled man might find useful in choosing solvents and methods of crystallisation.

18. Jacob J accepted this argument as well. He found that the reader of the application, seeking to crystallise PMS, would be able to overcome any problems within a reasonable time. The crystals he made would then inevitably be the crystals described in the patent in suit. The judge therefore held that the matter contained in the application did disclose the existence of the very product which was the subject of the SB patent and that the making of that product was enabled. The patent was therefore invalid.

The law

19. Before I discuss what the Court of Appeal made of these findings, I must say something about the law. I have said that there are two requirements for anticipation: prior disclosure and enablement.

(a) Disclosure

20. The concept of what I have called disclosure has been explained in two judgments of unquestionable authority. The first is Lord Westbury LC in *Hill v Evans* (1862) 31 LJ(NS) 457, 463:

> "I apprehend the principle is correctly thus expressed: the antecedent statement must be such that a person of ordinary knowledge of the subject would at once perceive, understand and be able practically to apply the discovery without the necessity of making further experiments and gaining further information before the invention can be made useful. If something remains to be ascertained which is necessary for the useful application of the discovery, that affords sufficient room for another valid patent."

21. The second authoritative passage is in the judgment of the Court of Appeal (Sachs, Buckley and Orr LJJ) in *General Tire and Rubber Co v Firestone Tyre and Rubber Co Ltd* [1972] RPC 457, 485-486:

> "To determine whether a patentee's claim has been anticipated by an earlier publication it is necessary to compare the earlier publication with the patentee's claim…If the earlier publication…discloses the same device as the device which the patentee by his claim…asserts that he has invented, the patentee's claim has been anticipated, but not otherwise. …
>
> When the prior inventor's publication and the patentee's claim have respectively been construed by the court in the light of all properly admissible evidence as to technical matters, the meaning of words and expressions used in the art and so forth, the question whether the patentee's claim is new…falls to be decided as a question of fact. If the

> prior inventor's publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty…The prior inventor, however, and the patentee may have approached the same device from different starting points and may for this reason, or it may be for other reasons, have so described their devices that it cannot be immediately discerned from a reading of the language which they have respectively used that they have discovered in truth the same device; but if carrying out the directions contained in the prior inventor's publication will inevitably result in something being made or done which, if the patentee's claim were valid, would constitute an infringement of the patentee's claim, this circumstance demonstrates that the patentee's claim has in fact been anticipated.
>
> If, on the other hand, the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee's claim, but would be at least as likely to be carried out in a way which would not do so, the patentee's claim will not have been anticipated, although it may fail on the ground of obviousness. To anticipate the patentee's claim the prior publication must contain clear and unmistakeable directions to do what the patentee claims to have invented…A signpost, however clear, upon the road to the patentee's invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee."

22. If I may summarise the effect of these two well-known statements, the matter relied upon as prior art must disclose subject-matter which, if performed, would necessarily result in an infringement of the patent. That may be because the prior art discloses the same invention. In that case there will be no question that performance of the earlier invention would infringe and usually it will be apparent to someone who is aware of both the prior art and the patent that it will do so. But patent infringement does not require that one should be aware that one is infringing: "whether or not a person is working [an] ... invention is an objective fact independent of what he knows or thinks about what he is doing": *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76, 90. It follows that, whether or not it would be apparent to anyone at the time, whenever subject-matter described in the prior disclosure is capable of being performed and is

such that, if performed, it must result in the patent being infringed, the disclosure condition is satisfied. The flag has been planted, even though the author or maker of the prior art was not aware that he was doing so.

23. Thus, in *Merrell Dow*, the ingestion of terfenadine by hay-fever sufferers, which was the subject of prior disclosure, necessarily entailed the making of the patented acid metabolite in their livers. It was therefore an anticipation of the acid metabolite, even though no one was aware that it was being made or even that it existed. But the infringement must be not merely a possible or even likely consequence of performing the invention disclosed by the prior disclosure. It must be necessarily entailed. If there is more than one possible consequence, one cannot say that performing the disclosed invention will infringe. The flag has not been planted on the patented invention, although a person performing the invention disclosed by the prior art may carry it there by accident or (if he is aware of the patented invention) by design. Indeed, it may be obvious to do so. But the prior disclosure must be construed as it would have been understood by the skilled person at the date of the disclosure and not in the light of the subsequent patent. As the Technical Board of Appeal said in *T/396/89 UNION CARBIDE/high tear strength polymers* [1992] EPOR 312 at para 4.4:

> "It may be easy, given a knowledge of a later invention, to select from the general teachings of a prior art document certain conditions, and apply them to an example in that document, so as to produce an end result having all the features of the later claim. However, success in so doing does not prove that the result was *inevitable*. All that it demonstrates is that, given knowledge of the later invention, the earlier teaching is capable of being adapted to give the same result. Such an adaptation cannot be used to attack the novelty of a later patent."

24. Although it is sometimes said that there are two forms of anticipatory disclosure: a disclosure of the patented invention itself and a disclosure of an invention which, if performed, would necessarily infringe the patented invention (see, for example, Laddie J in *Inhale Therapeutic Systems Inc v Quadrant Healthcare Plc* [2002] RPC 21 at para 43) they are both aspects of a single principle, namely that anticipation requires prior disclosure of subject-matter which, when performed, must necessarily infringe the patented invention.

25. As I have indicated by reference to the quotation from *UNION CARBIDE*, it is this requirement that performance of an invention disclosed in the prior art must *necessarily* infringe the patent which distinguishes novelty from obviousness. If performance of an invention disclosed by the prior art would not infringe the patent but the prior art would make it obvious to a skilled person how he might make adaptations which resulted in an infringing invention, then the patent may be invalid for lack of an inventive step but not for lack of novelty. In the present case, the Synthon application is deemed to form part of the state of the art for the purposes of novelty (section 2(3)) but not for the purpose of obviousness (section 3). As Synthon rely solely upon section 2(3) matter as prior art, they do not rely and cannot succeed on obviousness.

(b) Enablement

26. Enablement means that the ordinary skilled person would have been able to perform the invention which satisfies the requirement of disclosure. This requirement applies whether the disclosure is in matter which forms part of the state of the art by virtue of section 2(2) or, as in this case, section 2(3). The latter point was settled by the decision of this House in *Asahi Kasei Kogyo KK's Application* [1991] RPC 485.

27. *Asahi's* case was decided on the assumed facts that there had been a prior disclosure of the same invention (a particular polypeptide) but that neither the disclosed information nor common general knowledge would have enabled the skilled man to make it. The House therefore did not have to consider the test for deciding what degree of knowledge, skill and perseverance the skilled man was assumed to have. But the concept of enablement is used in other contexts in the law of patents (see *Biogen Inc v Medeva Plc* [1997] RPC 1, 47) and in particular as a ground for the revocation of a patent under section 72(1)(c): "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". The question of what will satisfy this test has been discussed in a number of cases. For example, in *Valensi v British Radio Corporation* [1973] RPC 337, 377 Buckley LJ said:

> "The hypothetical addressee is not a person of exceptional skill and knowledge, that he is not to be expected to exercise any invention nor any prolonged research, inquiry or experiment. He must, however, be prepared to display a

> reasonable degree of skill and common knowledge of the art in making trials and to correct *obvious* errors in the specification if a means of correcting them can readily be found."

There is also a valuable and more extended discussion in the judgment of Lloyd LJ in *Mentor Corporation v Hollister Incorporated* [1993] RPC 7. In the present case the Court of Appeal was reluctant to say that the test of enablement of a prior disclosure for the purpose of anticipation was the same as the test of enablement of the patent itself for the purpose of sufficiency. But I can think of no reason why there should be any difference and the Technical Board of Appeal has more than once held that the tests are the same: see *ICI/Pyridine Herbicides* [1986] 5 EPOR 232, para 2; *COLLABORATIVE/Preprorennin* [1990] EPOR 361, para 15. In my opinion, therefore, the authorities on section 72(1)(c) are equally applicable to enablement for the purposes of sections 2(2) and (3). There may however be differences in the application of this test to the facts; for example, because in the case of sufficiency the skilled person is attempting to perform a claimed invention and has that goal in mind, whereas in the case of prior art the subject-matter may have disclosed the invention but not identified it as such. But no such question arises in this case, in which the application plainly identified crystalline PMS as an embodiment of the invention.

(c) Keeping the concepts distinct

28. It is very important to keep in mind that disclosure and enablement are distinct concepts, each of which has to be satisfied and each of which has its own rules. As Laddie J said in relation to sufficiency in *University of Southampton's Applications* [2005] RPC 220, 236:

> "In my view, devising an invention and providing enabling disclosure are two quite different things. Although both may be necessary to secure valid protection, as section 14 of the Act shows, they relate to different aspects of the law of patents. It is very possible to make a good invention but to lose one's patent for failure to make an enabling disclosure. The requirement to include an enabling disclosure is concerned with teaching the public how the invention works, not with devising the invention in the first place".

29. For a similar point, see Jacob J in *Beloit Technologies Inc v Valmet Paper Machinery Inc* [1995] RPC 705, 739. Of course the same disclosure may satisfy both requirements. The prior art description may be sufficient in itself to enable the ordinary skilled man, armed with common general knowledge of the art, to perform the subject-matter of the invention. Indeed, when the prior art is a product, the product itself, though dumb, may be enabling if it is "available to the public" and a person skilled in the art can discover its composition or internal structure and reproduce it without undue burden: see the decision of the Enlarged Board of Appeal in *Availability to the Public* [1993] EPOR 241, para 1.4.

30. Nevertheless, in deciding whether there has been anticipation, there is a serious risk of confusion if the two requirements are not kept distinct. For example, I have explained that for the purpose of disclosure, the prior art must disclose an invention which, if performed, would necessarily infringe the patent. It is not enough to say that, given the prior art, the person skilled in the art would without undue burden be able to come up with an invention which infringed the patent. But once the very subject-matter of the invention has been disclosed by the prior art and the question is whether it was enabled, the person skilled in the art is assumed to be willing to make trial and error experiments to get it to work. If, therefore, one asks whether some degree of experimentation is to be assumed, it is very important to know whether one is talking about disclosure or about enablement.

31. An example of laying oneself open to misunderstanding in this way is the famous statement by Lord Westbury LC in *Hill v Evans* (1862) 31 LJ(NS) 457, 463, which I have quoted above. Lord Westbury said that the person skilled in the art must be able practically to apply the discovery "without the necessity of making further experiments and gaining further information before the invention can be made useful". Was he referring to disclosure or enablement? I rather think he meant disclosure and was saying the same as the Court of Appeal did later in *General Tire* when it said that the prior disclosure must have planted the flag on the invention. On the other hand, by speaking of the man skilled in the art being "able practically to apply the discovery" he certainly gave the impression that he was talking about enablement, and was so understood by Lord Reid in *C Van der Lely NV v Bamfords Ltd* [1963] RPC 61,71, when he said, correctly in relation to enablement:

> "Lord Westbury must have meant experiments with a view to discovering something not disclosed. He cannot have meant to refer to the ordinary methods of trial and error which involve no inventive step and are generally necessary in applying any discovery to produce a practical result."

32. Likewise, the role of the person skilled in the art is different in relation to disclosure and enablement. In the case of disclosure, when the matter relied upon as prior art consists (as in this case) of a written description, the skilled person is taken to be trying to understand what the author of the description meant. His common general knowledge forms the background to an exercise in construction of the kind recently discussed by this House in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 9. And of course the patent itself must be construed on similar principles. But once the meanings of the prior disclosure and the patent have been determined, the disclosure is either of an invention which, if performed, would infringe the patent, or it is not. The person skilled in the art has no further part to play. For the purpose of enablement, however, the question is no longer what the skilled person would think the disclosure meant but whether he would be able to work the invention which the court has held it to disclose.

33. There is also a danger of confusion in a case like *Merrell Dow Pharmaceuticals Inc v H N Norton & Co Ltd* [1996] RPC 76, in which the subject-matter disclosed in the prior art is not the same as the claimed invention but will, if performed, necessarily infringe. To satisfy the requirement of disclosure, it must be shown that there will necessarily be infringement of the patented invention. But the invention which must be enabled is the one disclosed by the prior art. It makes no sense to inquire as to whether the prior disclosure enables the skilled person to perform the patented invention, since ex hypothesi in such a case the skilled person will not even realise that he is doing so. Thus in *Merrell Dow* the question of enablement turned on whether the disclosure enabled the skilled man to make terfenadine and feed it to hay-fever sufferers, not on whether it enabled him to make the acid metabolite.

Applying the law to the facts

(a) Disclosure

34. Did the Synthon application disclose an invention which, if performed, would infringe the SB patent? Because it covered a class of chemicals defined by reference to a formula, it disclosed a myriad of compounds, each of which may be regarded as an invention. But that does not matter if one of those inventions was the crystalline PMS claimed in the patent.

35. There seems to me no doubt that the application disclosed the existence of PMS crystals of 98% purity and claimed that they could be made. Whether in fact they could be made is the question of enablement which I shall come to in a moment. But their existence and their advantages for pharmaceutical use were clearly disclosed in the application. And on the basis of the judge's finding of monomorphism, a PMS crystal of 98% purity must necessarily have all the characteristics of the crystals claimed in the patent, including the IR and XRD spectra.

36. Does it matter that the disclosure attributed to PMS crystals an IR spectrum which, on the judge's findings, was wrong? In my opinion it does not. Of course if the crystals were polymorphic, it would be necessary to specify an IR spectrum or some other way of distinguishing between them. The skilled person, having made his crystals, might find that they infringed the patent or they did not, depending upon which kind he had made. If there had been more than one polymorph, he would not have infringed if he had made the one disclosed by the application. But when the crystals are monomorphic, the IR spectrum is a superfluous part of the description. It may be that the skilled person, having successfully made what the application describes, namely PMS crystals of 98% purity, would be puzzled, perhaps even disconcerted, to find that their IR spectrum turned out to be different from what he had been led to believe. But he would have made the crystals and they would necessarily infringe the patent.

37. In some contexts one might say that the IR spectrum in the application was a *falsa demonstratio* which did not prevent the described compound, upon the true construction of the application, from being simply pure crystalline PMS, in the way one might conclude, from various details and circumstantial evidence that a witness was

describing a particular motor car, even though his reading of the number plate was inaccurate. That is a perfectly legitimate way of approaching the question. But it is, I think, more easily answered if one remembers the general principle that anticipation requires a prior disclosure which, if performed, would infringe the patent. The subject-matter described was crystalline PMS and a skilled person who performed that invention, though he might, if he had read the patent, think that he was not going to infringe it, would inevitably do so.

(b) Enablement

38. Once one has decided that the disclosure in the application was crystalline PMS and that the IR spectrum was superfluous and irrelevant, the question of enablement is whether the skilled person would have been able to make crystalline PMS. If he did, he would necessarily have made the product claimed in the patent. There is no dispute that the disclosure enabled him to make PMS. The issue is whether he would have been able to get it to crystallise. That is a question of fact, involving the application of the standards laid down in cases like *Mentor Corporation v Hollister Incorporated* [1993] RPC 7 to the evidence of the nature of the problem, the assistance provided by the disclosure itself and the extent of common general knowledge. Synthon, as I have said, got off to a bad start by specifying, in their main example, a solvent which proved unsuitable for crystallisation. Nevertheless, the judge found that the skilled man would have tried some other solvent from the range mentioned in the application or forming part of his common general knowledge and would have been able to make PMS crystals within a reasonable time. This is a finding of fact by a very experienced judge with which an appellate court should be reluctant to interfere: compare *Biogen Inc v Medeva Plc* [1997] RPC 1, 45.

The Court of Appeal

39. The Court of Appeal (Aldous, Sedley and Rix LJJ), in a judgment given by Aldous LJ, reversed the judge's decision. As will appear, I have not found it easy to understand the judgment; I shall have to look at some passages in detail, but the main source of my difficulty is that, with great respect to Aldous LJ, who is an acknowledged master of patent law, the questions of disclosure and enablement are so intermingled that it is often difficult to say which of them he is talking about.

40. After referring to some of the authorities, Aldous LJ said:

> "The dispute between the parties essentially involves a dispute of fact, namely what is explicitly and implicitly disclosed in the application. Thereafter, the court has to decide whether that disclosure is sufficient to make the invention of the patent available."

41. If that means that there are two questions: first, did the application disclose, explicitly or implicitly, an invention which would, if performed, infringe the patent and secondly, was that invention enabled, then of course I would agree. After setting out the arguments of the parties and saying that clear guidance could be obtained from the *General Tire* and *UNION CARBIDE* cases (to which I have referred above) the judge went on:

> "There are no clear and unmistakeable directions to make PMS as claimed in claim 1 of the patent as required by the *General Tire* case. The general teaching of the application does not mention PMS. It is one of a number of compounds described by reference to formulae. The only specific reference is in example 1. That describes a different form. It follows that the skilled person would not expect to produce the PMS claimed in claim 1 by carrying out the general teaching of the application. If he attempted to carry out example 1, he would fail to obtain crystalline PMS. He would therefore not know that there was only one form of crystalline PMS and that was not the form described in the application."

42. I find this passage particularly confusing. What are the "clear and unmistakeable directions to make PMS as claimed in claim 1"? Is this disclosure (ie identifying crystalline PMS as a desirable compound) or does it refer to enablement? If it refers to enablement, does it mean that the disclosure itself must enable? That cannot be right because, as I have said, the disclosure may consist entirely of putting a compound on the market and enablement may be found in the ordinary skilled man's ability to analyse and reproduce it. Likewise, if the problem is crystallisation, the enablement may be found in the armoury of the ordinary skilled man with little, if any, assistance from the disclosure. Then, why does it matter that it is one of a number of compounds identified in the invention and that it is mentioned at a certain point in

the application? The question is whether it is disclosed. To say that the application discloses a different form begs the question because there is no different form. Disclosure of crystalline PMS was disclosure of the patented product. The fact that the skilled man, surveying the result of his labours, would have thought he had made a product different from that described in the application seems to me irrelevant.

43. The judge next said:

> "Further the teaching is not such that skilled persons would at once perceive, understand and be able practically to apply the invention claimed in claim 1 of the patent without the necessity of doing further experiments. If they sought to produce PMS they would believe that the application led to a different form."

44. Again, it seems to me that what they would have believed they were doing when they sought to produce crystalline PMS is as irrelevant as what the takers of terfenadine thought was happening in their livers. Making crystalline PMS would have resulted in the form described in the patent. The judge then went on:

> "If they sought to carry out the specific directions of production, they would fail … The general statements in the application relied on did not disclose any particular method of production of any particular product. To suggest that they did when the specific method did not work is, I believe, fanciful. "

45. These sentences appear to be about enablement. But the judge then immediately went on to cite the passage in the *UNION CARBIDE* case (quoted above) about it being necessary that the prior disclosure should be of an invention which, if performed, will inevitably result in infringement of the patent. But that principle is, as I have explained, concerned with the scope of the disclosure in the prior art; whether it has planted the flag. It is not concerned with the question of enablement.

46. The judge later said:

> "The suggestion that the disclosure in the application was equivalent to that in the patent is not correct. As one would expect both contain general statements on production, but they are different. Perhaps with knowledge of the patent, it would be possible to extract the idea to make crystalline PMS and a process to do it other than that in example 1."

47. There was in my opinion no need to have knowledge of the patent or anything else to "extract the idea to make crystalline PMS". The idea of making crystalline PMS and its advantages in terms of purity, stability and so forth were plainly disclosed in the application. Whether the skilled person would have been enabled to make it is a separate point.

48. Finally, the judge contrasted the two disclosures:

> "The patent is directed at PMS, whereas the application is directed at a large number of compounds both in the general statements and in the preferred form. Secondly, the general statements as to how PMS can be obtained differ from those relating to the compounds in the application. Thirdly, the examples in the patent give detailed instructions as to how crystalline PMS can be made, whereas the equivalent example in the application does not work. Fourthly, the patent claims a different crystalline form of PMS to that described in the application."

49. Of these four points, the second and third are relevant to enablement but the first and fourth are, for the reasons I have explained, irrelevant.

50. I am therefore left in some uncertainty as to whether or not the Court of Appeal thought that Synthon had failed on the requirement of disclosure, that is, whether they had failed to plant the flag on crystalline PMS as described in the patent. If that was the finding, I think it was wrong.

51. I turn therefore to the question of enablement. As I have said, Jacob J relied in part upon his general findings that the processes by which crystallisation is initiated are "far from precisely understood" and "something of an art – part of the skills of an organic chemist". He found support in the attitude taken by the SB patent itself and the evidence of Mr Ward, from whom he quoted the following passage:

> "Q. If you were looking at [the application] and considering making paroxetine mesylate, you would certainly start with the examples. That is right, is it not?
>
> A. Yes, yes, I certainly would.
>
> Q. But you certainly would not feel bound by them, would you? You would expect to make paroxetine mesylate using a variety of other reactions and conditions?
>
> A. Yes, I think I would.
>
> Q. And crystallise it successfully?
>
> A. That is perhaps another matter. I think I might be inclined to say 'Once I have actually got some sort of crystals, then I might investigate a better way of making crystalline material'. In order to get your seeds, then it might be sensible to do what is in the document rather than go shooting off and doing your own thing.
>
> Q. I think we agree you would start with the examples. You start with the examples. Let us suppose that you perform [the example in the application] and it does not work. What do you do next?
>
> A. I think I would do the sort of thing I have mentioned in my expert report. I would look at the chemistry that I was trying to carry out and say 'Well, maybe I need to make some changes'. I think I have suggested the sort of changes I would make. I might well readjust the stoichiometry, the molar equivalents.
>
> Q. And you might get a hint that that might be a good idea from looking at [the example], would you not?
>
> A. You might and you might not. I am not necessarily convinced by that. In my experience of making salts of bases, it is sometimes actually advantageous to make the first sample with an excess of acid. This is frequently done with things like hydrochloride salts. I am not necessarily convinced that you would necessarily always go down in molarity.
>
> Q. You might go up?

A. You might go up, yes. You might change the concentration; you might change the solvent.

Q. But these would all be straightforward changes, and you would expect, fairly quickly, to succeed, based on what is in this document?

A. I would certainly have an expectation of success, yes."

52. Having quoted this evidence, Aldous LJ said that it —

> "does not establish that the application contains the clear and unmistakeable directions to make the claimed form of PMS".

Again I find it difficult to say whether the judge is concerned with disclosure or enablement. The reference to "the claimed form of PMS" suggests that he is still preoccupied with the difference in IR readings, which is a matter of disclosure and is, as I have said, irrelevant. The judge went on to say that Mr Ward was one of the inventors of the patent and had "more knowledge of making PMS than the skilled person would have had". That is true, but Jacob J was well aware of the dangers of reasoning from what a highly skilled person would do (he said of the evidence of Sir Jack Baldwin: "one is concerned with the ordinary skilled man or team, not world champions") and the fact that Mr Ward discovered the properties of PMS does not mean that he could not give evidence of what would be conventional practice in dealing with problems of crystallisation. He agreed that the kind of experimentation being put to him consisted of "straightforward changes".

53. The main reasons for the Court of Appeal's rejection of the judge's finding of fact appear from para 56 of the judgment of Aldous LJ:

> "The crucial question was not whether the skilled addressee would expect success, but whether the application made available PMS as claimed. There was no attempt to ask Mr Ward whether there were directions in the application which, if followed, would produce the claimed form of PMS. No doubt that was because the

> answer would have been 'No'. Once it had been established that example 1 did not disclose a successful route to PMS as claimed in the patent, the skilled addressee might have adopted obvious modifications. But such an approach is not permissible when considering novelty."

54. This passage again suggests to me a serious confusion between disclosure and enablement. The evidence of Mr Ward was relied upon solely for the purpose of proving enablement. But the reference at the end to "obvious modifications" being impermissible is a reference to the requirement that the prior art must have planted the flag on the patented invention, which is a principle of disclosure. On that question Mr Ward's evidence about making crystals could have nothing to contribute.

55. Paragraph 56 again leaves me in doubt about whether the Court of Appeal thought that the prior art did not disclose the invention or whether it did so but was not enabled. If it was the former, then, as I have said, I think that they were wrong. If it was the latter, then I do not think that they have offered adequate reasons for disturbing the judge's finding of fact. I would therefore allow the appeal and restore the decision of Jacob J.

LORD WALKER OF GESTINGTHORPE

My Lords,

56. I have had the privilege of reading in draft the opinion of my noble and learned friend Lord Hoffmann. I agree with it and for the reasons which he gives I would allow this appeal. I add some brief comments of my own which are no more than footnotes.

57. The law of patents is wholly statutory, and has a surprisingly long history. It has been wholly statutory since the Statute of Monopolies 1623, an important landmark in constitutional history because of its effect in curbing the royal prerogative. It is a field of law in which statutory change (although important in its cumulative effect, especially in reflecting international treaty obligations) has been a process, not of

revolution, but of slow evolution. Bankruptcy law and, until recently, the law of rating are comparable in this respect. In these fields the courts have shown an inclination to enrich the bare simplicity of the statutory text with their own explanatory commentary. But from time to time this process is interrupted by periods of reappraisal. In the law of patents the doctrine of "pith and marrow" is one example of such a reappraisal: see *C Van der Lely NV v Bamfords Ltd* [1963] RPC 61, 75, 77, 79, 80. Another example is the so-called protocol (or *Improver*) questions: see *Improver Corp v Remington Consumer Products* Ltd [1990] FSR 181, 189 and the recent decision of this House in *Kirin-Amgen Inc v Hoechst Marion Roussel Ltd* [2005] RPC 169, 191 (para 52). This sort of judicial exposition is more than what the old cases called glossing the statute. 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.

58. 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. The concepts which Lord Hoffmann addresses in his opinion are "disclosure" and "enablement". He emphasises that these are distinct concepts, each of which has its own function and rules. Nevertheless the composite expression "enabling disclosure" (which originated, it seems, in the United States of America) has been in frequent use in this country for at least fifteen years. One of the first reported instances may be found in the judgment of Falconer J in *Genetech Inc's (Human Growth Hormone) Patent* [1989] RPC 613, 629:

> "… what has come to be called an 'enabling disclosure', that is to say, one sufficient, in the case of a claim to a chemical compound, to enable those skilled in the art to make the compound claimed"

This passage was referred to and approved by Lord Oliver in *Asahi Kasei Kogyo KK's Application* [1991] RPC 485, 539. It is worth looking to see how this composite expression is derived from, and fits in with, the statutory provisions.

59. The most relevant provisions of the Patents Act 1977 are sections 1, 2, 3, 5 and 14. Section 72 (Grounds for revocation of a patent) is also

relevant but only as confirmation of the substance of the earlier sections. The effect of section 1 (1)(a) and (b) is that a claimed invention will not be recognised as such unless it is (a) new and (b) involves an inventive step. These requirements (whose negatives are generally labelled as "anticipation" and "obviousness") are spelled out in sections 2 and 3 of the Act.

60. Section 2 defines novelty in negative terms of not being part of "the state of the art" (in other words a claimed invention lacks novelty if it already forms part of the state of the art) and section 3 defines an inventive step in terms of not being obvious, but with a qualified reference to the state of the art:

> "An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art by virtue only of section 2(2) above (and disregarding section 2(3) above)."

The reader is thus sent back to section 2(2) and (3):

> "(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.
>
> (3) The state of the art in the case of an invention to which an application for a patent or a patent relates shall be taken also to comprise matter contained in an application for another patent which was published on or after the priority date of that invention, if the following conditions are satisfied, that is to say –
>
> (a) that matter was contained in the application for that other patent both as filed and as published; and
>
> (b) the priority date of that matter is earlier than that of the invention."

61. Section 5 relates to priority dates, and refers to an invention being "supported by matter disclosed" in an earlier application, wording which is (at the lowest) consistent with the concept of enabling disclosure. Section 14 relates to applications for patents. By sub section (2) an application must contain (among other things):

> "a specification containing a description of the invention, a claim or claims and any drawing referred to in the description or any claim."

Sub section (3) provides:

> "(3) 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."

This subsection does not actually use the expression "enabling disclosure" but it comes far closer to it than any other statutory provision. It is clear beyond argument that the specification in a patent application must contain an enabling disclosure in the sense in which that expression has been used by the court at latest since *Genetech* in 1989.

62. One of the issues which arose in the past is how far enabling disclosure is to be regarded as implicitly required in statutory provisions expressed in different terms from section 14, that is in the concept of the state of the art, which is of central importance to section 2 (anticipation) and (in a modified form) section 3 (obviousness). Where the state of the art consists of claims in existing patent specifications the material in those claims will almost by definition contain an enabling disclosure – that is the disclosure of something which is indeed an invention, together with a sufficiently clear and complete description of the invention to enable it to be performed by a person skilled in the art. The same will be true of material disclosed in claims in patent applications. But the state of the art has a much wider range of meaning. As well as material contained in introductory or narrative parts of patent specifications or in technical publications it can include non-technical matter such as the illustrated magazine articles in *Van der Lely* or the primitive prototype windsurfing board built (and used in public) by a

twelve year old boy in *Windsurfing International Inc v TaburMarine (Great Britain) Ltd* [1985] RPC 59.

63. What emerges from the authorities, to my mind, is that enabling disclosure is a compendious summary of two distinct statutory requirements, which arise (as a pair) in two different statutory contexts: explicitly in section 14 (requirements for a patent application) and implicitly (as decided by the Court of Appeal in *General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd* [1972] RPC 457 and by this House in *Asahi*) in determining the state of the art, whether for the purposes of anticipation (section 2(2) and (3)) or obviousness (section 2 as restricted by section 3). This produces a degree of symmetry in the law and avoids divergence from the practice of the European Patent Office.

64. Nevertheless the expression must be handled with some care. The practical importance of keeping the two requirements distinct will vary with the factual situation. In the case of a low-tech invention (for instance a simple agricultural machine such as the hay rake with ground-driven wheels in *Van der Lely*) the simple disclosure of the invention will probably be enough to enable the skilled person to perform it. By contrast in the case of a high-tech invention in the field of pharmaceutical science the bald assertion of the existence of the invention may have to be accompanied by detailed disclosure enabling the skilled person to perform it. But in testing the adequacy of the enablement it may be assumed that the skilled person will have to use his skill, and may have to learn by his mistakes (see Lord Reid's reference to "trial and error" in *Van der Lely* [1963] RPC 61,71).

65. I respectfully concur in Lord Hoffmann's analysis of all the factual issues raised in this appeal. I agree that the appeal should be allowed and the order of Jacob J restored.

BARONESS HALE OF RICHMOND

My Lords,

66. I am most grateful to my noble and learned friend, Lord Walker of Gestingthorpe, for his explanation of how it comes about that the "state of the art" involves both disclosure and enablement. I am also most grateful to my noble and learned friend Lord Hoffmann for his exposition of how those separate concepts of disclosure and enablement should be applied to the facts of this case. For the reasons that they give, I too would allow this appeal.

LORD BROWN OF EATON-UNDER-HEYWOOD

My Lords,

67. I have had the privilege of reading in draft the opinions of my noble and learned friends Lord Hoffmann and Lord Walker of Gestingthorpe. I agree with them both and would, for the reasons given by Lord Hoffmann, allow the appeal and restore the decision of Jacob J.