HOUSE OF LORDS SESSION 2007–08

[2008] UKHL 49

on appeal from: [2007]EWCA Civ 5

OPINIONS

OF THE LORDS OF APPEAL

FOR JUDGMENT IN THE CAUSE

Conor Medsystems Incorporated (Respondents) *v* Angiotech Pharmaceuticals Incorporated and others (Appellants)

Appellate Committee

Lord Hoffmann
Lord Scott of Foscote
Lord Walker of Gestingthorpe
Baroness Hale of Richmond
Lord Neuberger of Abbotsbury

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LORD HOFFMANN

My Lords,

1. Angiotech Pharmaceuticals Inc, a Canadian company, and the University of British Columbia are joint proprietors of European patent 0 706 376 which claims, among other things, a stent coated with taxol for "treating or preventing recurrent stenosis". For convenience I shall call the patentees Angiotech. Conor Medsystems Inc (Conor), an American competitor, applied in both the United Kingdom and the Netherlands for revocation of the patent on the ground that the claimed invention was obvious. In the United Kingdom, before Pumfrey J and the Court of Appeal (Mummery, Tuckey and Jacob LJJ), it succeeded. In the Netherlands, before the District Court of The Hague (Robert van Peursem, Edgar Brinkman and Walter van Straalen) it failed. Angiotech appeals to your Lordships' House and says that the Dutch court was right and that the patent should be declared valid.

2. Since the decision of the Court of Appeal, Angiotech and Conor have reached a settlement. Conor does not oppose Angiotech's appeal. But a patent confers proprietary rights in rem and the validity of a patent cannot be established simply by a judgment in default of opposition. Your Lordships therefore invited the Comptroller General of Patents to assist the court in presenting what appeared to him to be the arguments against the validity of the patent. The House followed the procedure adopted by the Court of Appeal in a similar situation in *Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] EWCA Civ 1715. Angiotech agreed to pay the Comptroller's costs and the Comptroller instructed Mr Tappin to appear before the House. I have, as I am sure your Lordships will agree, found his written and oral submissions of great assistance.

3. There is still no European Patent Court. A European patent takes effect as a bundle of national patents over which the national courts have jurisdiction. It is therefore inevitable that they will occasionally give inconsistent decisions about the same patent. Sometimes this is because the evidence is different. In most continental jurisdictions, including the European Patent Office ("EPO"), cross-examination is limited or unknown. Sometimes one is dealing with questions of degree over which judges may legitimately differ. Obviousness is often in this category. But when the question is one of principle, it is desirable that so far as possible there should be uniformity in the way the national courts and the EPO interpret the European Patent Convention ("EPC"). In this case, as Pumfrey J made clear in his judgment, there is a question of principle at stake. It is about how you identify the concept embodied in the invention which may constitute the "inventive step" for the purposes of article 56 of the EPC and section 1(1)(b) of the Patents Act 1977.

4. The subject matter of the patent is a stent, a tubular metal scaffold inserted into an artery to keep it open. It is used in connection with angioplasty, one of the great modern advances in the treatment of sclerosis of the coronary arteries. A catheter carrying a balloon is inserted into the arterial system from outside ("percutaneously"), usually at the groin, and manoeuvred through the arteries to the point at which the coronary artery has become constricted or "stenosed". There the balloon is expanded to push back the artery walls and enlarge the channel. The insertion of a stent will prevent the walls from collapsing when the catheter and balloon are withdrawn.

5. A serious problem with this form of intervention was that the injury caused to the inner layer of the artery by the insertion of the stent often produced an exaggerated healing response, characterised by the proliferation of smooth muscle cells forming new tissue which once again constricted the arterial channel. This is called restenosis. It affected between a third and a half of patients in whom stents had been inserted and no one knew what to do about it.

6. There was however no shortage of suggestions and in 1993, more or less at the same time as the priority date of the patent in suit, a group of Dutch scientists of high repute in the field published a two-part article entitled *Pharmacological Approaches to the Prevention of Restenosis Following Angioplasty: The Search for the Holy Grail?* (Drugs 46(1) 18-52; 46(2) 249-262). Many people thought that the proliferation of smooth muscle cells in restenosis was analogous to the proliferation of

cells in cancer tumours and might be treated by anti-proliferative drugs. Others favoured antithrombotic agents such as heparin, antiplatelet agents like aspirin, anti-inflammatories, calcium antagonists and lipid-lowering drugs. The article described two theories about how the process of restenosis took place. Both involved several stages at which different forms of pharmacological intervention might be appropriate.

7. The summary at the start of the second part of the article, which dealt with future possibilities, said:

> "[D]espite 15 years of clinical experience and research in the field of restenosis prevention, this has not yet resulted in the revelation of unequivocal beneficial effects of any particular drug. Other newer approaches likely to receive more attention in the future include anti-bodies to growth factors, gene transfer therapy and antisense oligonucleotides. Whether there is a feasible monotherapy, whether we have to focus on a drug combination, or whether we are only searching for the 'Holy Grail' remain to be answered."

8. Meanwhile in Vancouver, a young medical student named William Hunter was studying angiogenesis, the process by which capillary blood vessels grow, under a Dr Arsenault, who had made it his particular area of research. It occurred to Dr Hunter that one approach to unwanted cell proliferation might be the inhibition of angiogenesis, because most cell tissue cannot grow more than 200 or so microns without blood. (Tumour cells are different; they are notoriously able to grow without a supply of oxygen from the blood but they are not the normal cause of restenosis). In 1991, during his third year at medical school, Dr Hunter met Dr Machan, who had experience in cardio-vascular intervention and the use of stents. As a result of their discussions, they decided to try to find an anti-angiogenic agent which could be used to inhibit or prevent tissue growth in restenosis. To fund the research, Drs Hunter, Arsenault and Machan formed Angiotech and obtained a grant from the Science Council of British Columbia.

9. They tested various drugs for anti-angiogenic properties by an assay using chick embryos (the chorioallantoic membrane or "CAM" assay). This was an established test, although perhaps not very sophisticated or discriminating. One of the drugs tested, in February 1993, was paclitaxel, a recently-discovered anti-proliferative derived

from the Pacific yew tree, which was much in the news as a possible cancer treatment. Dissolved in cremophor for pharmacological use, it was marketed under the trade name of taxol. On the CAM assay, it appeared to have remarkable anti-angiogenic properties. Dr Hunter said it was effective to inhibit angiogenesis even in minute concentrations.

10. On 19 July 1993 Angiotech applied for a US patent which is the priority document for the patent in suit. The title of the patent is "Anti-angiogenic compositions and methods of use" and the patent, at least as originally applied for, is by no means confined to their use on stents. The primary emphasis is on the use of anti-angiogenics for the treatment of cancer. This was a bold claim because most anti-angiogenics such as taxol were anti-proliferatives and their use for treating cancer was well known. But their use on stents comes next, as is made clear by the introductory paragraph of the description:

> "The present invention relates generally to compositions and methods for treating cancer and other angiogenic-dependent diseases, and more specifically, to compositions comprising anti-angiogenic factors and polymeric carriers, stents which have been coated with such compositions, as well as methods for utilizing these stents and compositions."

11. In the European Patent Office, the patent was opposed after grant on the ground, among others, that use for cancer treatment was either not new or obvious. As a result of a decision of the Opposition Division, the claims for treating cancer and other diseases were abandoned and the patent confined to the use of taxol on stents. Claim 1 as amended was for a stent coated with taxol, claim 11 to a stent according to claim 1 for treating a "narrowing of a body passageway" and claim 12 for a stent according to claim 11 "for treating or preventing recurrent stenosis". It is this last claim which is in issue in these proceedings.

12. The Angiotech stent has been a great commercial success. It has the largest share of the market in drug eluting stents, which have very considerably reduced the incidence of restenosis.

13. The action for revocation was commenced by Conor on 18 February 2005. In its amended grounds of invalidity it was said that the alleged invention was obvious having regard to three items of prior art:

PCT Patent Application WO 91/12779 (Wolff) PCT Patent Application WO 93/11120 (Kopia) and an abstract of a paper by Katsuda and others delivered at a symposium in Rome in 1988 (Katsuda). I shall return to the prior art at the end of this opinion.

14. At the end of July and in early August 2005 Angiotech served reports from Professor Cumberland of Sheffield, an expert on cardio-vascular intervention, and Professor Calvert of Newcastle-on-Tyne, an oncologist. Conor's experts were Professor Rogers, a cardio-vascular specialist at Harvard, and Professor Lemoine, an oncologist at Barts. A reading of these reports suggests that the only issue over which the experts proposed to lock horns at the trial was whether it would have been obvious at the priority date to coat a stent with taxol to prevent or treat restenosis. Professor Rogers said that he would have consulted an oncologist about a suitable anti-proliferative drug. Professor Lemoine said that taxol was at the time a highly publicised new drug for cancer treatment. He would have recommended it and Professor Rogers said he would have found it attractive. On the other side, Professor Cumberland said that he would have seen no reason to select taxol out of the huge variety of possible solutions then under consideration and Professor Calvert said that, on account of its toxic properties, he would actually have advised against it.

15. That seemed a fairly straightforward issue and Angiotech no doubt prepared for trial clutching the Holy Grail paper as the best possible evidence that there was at the time no obvious solution to restenosis. But then events took a different turn. In a skeleton argument served at the end of September 2005, Mr Thorley QC, for Conor, denied that the inventive step disclosed by the specification was to coat the stent with taxol. It was, he said (at paragraph 62), much less precise; the inventive concept —

> "purportedly resides in the idea of seeking to treat or prevent restenosis by coating a stent with a taxol/polymer composition. The disclosure is of no more than this. The idea is not shown to work (either in humans or in animals), nor to work to any particular extent, nor to work with any particular polymer nor with any particular amount of drug. The invention thus lies in the idea of trying some, one or more, taxol/polymer combinations to determine whether restenosis can thereby be treated. It is at this level of generality that inventiveness must be assessed."

16. On the basis that the patent taught no more than that taxol was worth trying, he submitted that it added nothing to existing knowledge. It was common ground that taxol was, like many other anti-proliferative drugs, worth a try. And that was obvious. It was not necessary for Conor to show that it was obvious actually to use taxol to treat restenosis because the patent did not teach that it would work.

17. I shall say at once that in my opinion this argument was an illegitimate amalgam of the requirements of inventiveness (article 56 of the EPC) and either sufficiency (article 83) or support (article 84) or both. It is the claimed invention which has to involve an inventive step. The invention means prima facie that specified in the claim: see section 125(1) of the 1977 Act. In the present case, the invention specified in claim 12 was a stent coated with taxol. There was no dispute that this was a new product. The question should therefore simply have been whether it involved an inventive step. As in the case of many product claims, there was nothing inventive in discovering how to make the product. The alleged inventiveness lay in the claim that the product would have a particular property, namely, to prevent or treat restenosis. (Compare *Pharmacia Corp v Merck & Co Inc* [2002] RPC 775). So the question of obviousness was whether it was obvious to use a taxol-coated stent for this purpose. And this, as I have said, was the question to which the experts addressed themselves.

18. Mr Thorley, however, sought to avoid this question by watering down the claimed invention by reference to what he said were inadequacies in the specification. It did not contain information about human or animal tests which showed that it would work or provide enough information about doses and so forth to enable the skilled person to work it. It was therefore nothing more than an idea that taxol might work and any skilled person would have known that.

19. In my opinion, however, the invention is the product specified in a claim and the patentee is entitled to have the question of obviousness determined by reference to his claim and not to some vague paraphrase based upon the extent of his disclosure in the description. There is no requirement in the EPC or the statute that the specification must demonstrate by experiment that the invention will work or explain why it will work. As the Dutch court said (at paragraph 4.17):

> "…it is not required in the view of the court that experimental data concerning such use of taxol stents in

humans and the actual prevention of restenosis be included in the patent to further substantiate [the claim]."

20. There seems to have been no dispute about what the experts thought the teaching of the patent to be. In cross-examination, Mr Thorley put to Professor Cumberland:

"Q. The teaching on page 12, lines 33-38 [of the patent in suit] , is that an anti-angiogenic composition can be used to treat restenosis. Correct, professor?

A. Either prevent or treat.

Q. Prevent or treat."

21. That speaks in general terms of anti-angiogenic compounds and it is true that the headline story in the specification was that preventing angiogenesis was the route by which one could prevent cell proliferation. But the specification also makes it clear that taxol is the favoured anti-angiogenic. Example 2, headed "Analysis of Various Agents for Anti-angiogenic Activity", describes the results of testing various anti-angiogenics by the CAM assay. It gives top marks to taxol:

"In summary, this study demonstrated that 48 hours after taxol application to the CAM, angiogenesis was inhibited. The blood vessel inhibition formed an avascular zone which was represented by three transitional phases of taxol's effect. The central, most affected area of the avascular zone contained disrupted capillaries with extravasated red blood cells; this indicated that intercellular junctions between endothelial cells were absent. The cells of the endoderm and ectoderm maintained their intercellular junctions and therefore these germ layers remained intact; however, they were slightly thickened. As the normal vascular area was approached, the blood vessels retained their junctional complexes and therefore also remained intact. At the periphery of the taxol-treated zone, further blood vessel growth was inhibited which was evident by the typical redirecting or 'elbowing' effect of the blood vessels…Taxol-treated avascular zones also revealed an abundance of cells arrested in mitosis in all three germ layers of the CAM; this was unique to taxol since no previous study has

> illustrated such an event. By being arrested in mitosis, endothelial cells could not undergo their normal metabolic functions involved in angiogenesis. In comparison, the avascular zone formed by suramin and cortisone acetate do not produce mitotically arrested cells in the CAM; they only prevented further blood vessel growth into the treated area. Therefore, even though agents are anti-angiogenic, there are many points in which the angiogenesis process may be targeted.
>
> We also observed the effects of taxol over the 48 hour duration and noticed that inhibition of angiogenesis occurs as early as 9 hours after application. … Also, we observed the revascularization process into the avascular zone previously observed. It has been found that the avascular zone formed by heparin and angiostatic steroids became revascularized 60 hours after application. In our study, taxol-treated avascular zones did not revascularize for at least 7 days after application implying a more potent long-term effect."

22. It is true that the specification said very little about the details of how or why taxol would be efficacious in preventing restenosis. It clearly saw the solution for restenosis in terms of preventing angiogenesis, but offered no proof that this was right. In cross-examination, Mr Thorley put to Professor Cumberland (Day 3, p.517):

> "Q. The disclosure that a compound is anti-angiogenic would be of no assistance to you in concluding whether that compound would actually work to inhibit the proliferation of smooth muscle cells?
>
> A. That is correct, at that time, yes."

23. That again meant that the patentee appeared to be at risk of a finding of insufficiency. On the other hand, if (as turned out to be the case) the invention did work, it would not matter why. The reason may have had nothing to do with anti-angiogenesis. The specification would be sufficient if, for whatever reason, taxol coated stents possessed the claimed property of preventing or treating restenosis.

24. Likewise, Mr Thorley elicited a string of admissions from Professor Cumberland about whether the specification provided enough information to enable the skilled person to make a suitable stent:

> "Q. There is no data in this patent which demonstrates that any of those compounds actually worked to treat restenosis?
>
> A. That is correct.
>
> Q. The patent does not address the question of whether any of the compounds will inhibit the proliferation of smooth muscle cells?
>
> A. That is correct.
>
> Q. It does not address the question of whether local administration of any of the compounds will cause unmanageable side-effects?
>
> A. I think that is correct, yes.
>
> Q. The patent does not address the question of the dose of drug that will be needed to prevent or cure restenosis?
>
> A. That is true.
>
> Q. lt does not address the question of the period of time for which the drug should rest at the location in question?
>
> A. True. That is correct."

25. At this point, Mr Waugh objected that these questions appeared to go to the question of sufficiency rather than obviousness. The judge disagreed, saying afterwards in his judgment (at paragraph 27) that this evidence showed that the disclosure was merely a speculative idea. In my opinion, however, Mr Waugh's point was well taken. The questions had nothing to do with whether claim 12 involved an inventive step.

26. In his judgment, Pumfrey J accepted Mr Thorley's argument. He said:

> "61. In summary, therefore, the Claimant's case is that it is sufficient for the purposes of invalidating the claims of the patent in suit that the interventional cardiologist, in consultation with someone of skill and experience in the field of anti-mitotic drugs of one sort or another, would see paclitaxel (taxol) as worth experimentation. The

Patentees' case is that the properties of taxol are such that the skilled person would not think that it was suitable for local administration in a drug-eluting stent. The Patentees' contentions centre on the toxic character of taxol. It is therefore necessary at this point to deal with a particular question which has vexed this case. Is it sufficient for Conor to show that taxol is an obvious candidate for testing on a drug-eluting stent in addition to the material specifically identified in Wolff, or is it necessary to show that taxol is an obvious, or the obvious, material to use in a drug-eluting stent for administration to human beings? Put another way, is the patent vulnerable only if it can be shown that the skilled person would have an expectation of success sufficient to induce him to incorporate taxol in a drug-eluting stent, or is it sufficient that without any expectation of success he would test or screen taxol?

62. In my judgment, this question is to be answered by assessing the contribution to the art disclosed by the specification. For the reasons that I have given above, I am satisfied that the disclosure of the specification is that taxol may be incorporated in a stent. It does not suggest that such a stent would be safe or that such a stent would work to prevent restenosis. I think it is fair to say that the sum of the disclosure of the specification is that taxol should be incorporated in a drug-eluting coating on a stent with a view to seeing whether it works to prevent restenosis and whether it is safe. If it is obvious to the skilled person that taxol should be incorporated in a drug-eluting coating on a stent with a view to seeing whether it prevents restenosis and is safe, then the claim is invalid, the specification having made no contribution to the art. It is obviously preferable to identify the correct question before assessing the evidence. In this case, the profound difference between the parties as to the nature of the inventive step has led them to identify as relevant very different factors.

64. The claim is to a physical device, that is, to a stent upon which is a drug-eluting coating loaded with taxol and optionally with other active ingredients as well. If, as I consider is the case here, the specification provides directions to make such a stent, but provides no data or other material suggesting that such a stent is in fact suitable for the treatment of restenosis, then success in

> preventing restenosis is not, in my view, a relevant consideration when assessing the obviousness of constructing such a stent. I accept immediately that there must be some motive [for] making such a stent: but a sufficient motive is the testing of such a stent to see if it has potential in the treatment of restenosis. In the present case, therefore, I reject Mr Waugh's contention that the definite object in view is the treatment or prevention of restenosis. The object in view is the testing of a taxol-loaded stent to see if it is of any use in the treatment or prevention of restenosis: that is all the specification provides."

27. For the reasons I have given, I am afraid that I cannot agree with this analysis. In my opinion it is absolutely clear that the teaching of the specification, so far as it supported claim 12, was that a taxol-coated stent would prevent or treat restenosis. I agree with the opinion of the Dutch court (at paragraph 4.17):

> "…[T]he patentee sufficiently clearly indicates in the patent that it is advantageous to use taxol (inter alia but also specifically for restenosis) and states as reason for this that taxol…scores well in the CAM assay to demonstrate its anti-angiogenic effect, bearing in mind that the patentee saw the solution for restenosis in the use of an anti-angiogenic factor."

28. The question was whether that was obvious and not whether it was obvious that taxol (among many other products) *might* have this effect. It is hard to see how the notion that something is worth trying or might have some effect can be described as an invention in respect of which anyone would be entitled to a monopoly. It is therefore perhaps not surprising that the test for obviousness which Pumfrey J devised for such an "invention" was whether it was obvious to try it without any expectation of success. This oxymoronic concept has, so far as I know, no precedent in the law of patents.

29. It is true that a patent will not be granted for an idea which is mere speculation, unsupported by anything disclosed in the specification. Article 84 of the EPC says that the claims must be "supported by the description" and this requirement is reproduced in section 14(5)(c) of the 1977 Act. So in *Re Prendergast's Applications*

[2000] RPC 446, the applicant attempted to patent the use of two known pharmaceuticals to treat —

> "battle fatigue, combat stress reaction, post-traumatic stress disorder in civilian and military emergency situations, neurological symptoms associated with chemical warfare and nausea associated with chemical or biological warfare."

30. The specification contained no information whatever to support the claim that the products in question would have any effect on these ailments. Neuberger J upheld the Comptroller's rejection of the claim on the ground that it was not supported by the description.

31. In this case, however, the patent had been granted by the EPO and article 84 was therefore no longer in issue. There is also a line of authority in the EPO in which claims to broad classes of chemical compounds alleged to have some common technical effect have been rejected under article 56 (obviousness) when there was nothing to show that they would all have that technical effect. The leading case is *AGREVO, Case No T 0939/92*, which was a product claim for a class of chemical compounds alleged to be useful as herbicides. But there was nothing in the description to justify the assertion that all the compounds in the class would have herbicidal properties. The Board of Appeal decided that the claims were not insufficient (the skilled man would have been able to make all the compounds claimed) but failed for lack of an inventive step because there was nothing inventive in simply making the compounds. The invention, if any, would lie in the discovery that they were herbicides. The Board of Appeal said (at paragraph 2.5.4):

> "…[A] technical effect which justifies the selection of the claimed compounds must be one which can be fairly assumed to be produced by substantially all the selected compounds..."

32. At paragraph 2.6.2 the Board acknowledged that a patentee does not have to have tested every compound to see whether it has the claimed effect: "reasonable predictions of relations between chemical

structure and biological activity are in principle possible, but that there is a limit beyond which no such prediction can be validly made."

33. The case of *Johns Hopkins University School of Medicine Case No T 1329/04* deals with the question of whether the use which may be made of the claimed product (ie that which may constitute the inventive step) must be stated in the specification or can be proved by later evidence. The claim was to a DNA sequence encoding a protein "having GDF-9 activity". Again, as in AGREVO, there was nothing inventive in simply making the DNA sequence. The inventive step, if any, would lie in a disclosure that it coded for a useful protein . But the specification disclosed no more than speculation about how GDF-9 activity might be useful. The examining division rejected the application on the ground that such speculation did not go beyond what was obvious and refused to take into account subsequently published material showing specific properties of GDF-9.

34. The Board of Appeal pointed out (at paragraph 10) that in the specification various effects were "tentatively and presumptively" attributed to GDF-9. It went on:

> "[T]he issue here is…how much weight can be given to speculations in the application in the framework of assessing inventive step, which assessment requires that facts be established before starting the relevant reasoning. In the board's judgment, enumerating any and all putative functions of a given compound is not the same as providing technical evidence as regard a specific one…[T]here is not enough evidence in the application to make at least plausible that a solution was found to the problem which was purportedly solved."

35. The Board then went on to consider whether this deficiency could be remedied by evidence coming into existence after the application:

> "12. The appellant filed post-published evidence… establishing that GDF-9 was indeed a growth differentiation factor. This cannot be regarded as supportive of an evidence which would have been given in the application as filed since there was not any. The said post-published documents are indeed the first disclosures

> going beyond speculation. For this reason, the post-published evidence may not be considered at all. Indeed, to do otherwise would imply that the recognition of a claimed subject-matter as a solution to a particular problem could vary as time went by. Here, for example, had the issue been examined before the publication date of the earliest relevant post-published document, GDF-9 would not have been seen as a plausible solution to the problem…and inventive step would have had to be denied whereas, when examined thereafter, GDF-9 would have to be acknowledged as one such member. This approach would be in contradiction with the principle that inventive step, as all other criteria for patentability, must be ascertained as from the effective date of the patent. The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve. Therefore, even if supplementary post-published evidence may in the proper circumstances also be taken into consideration, it may not serve as the sole basis to establish that the application solves indeed the problem it purports to solve."

36. These cases are in my opinion far from the facts of this case. The specification did claim that a taxol coated stent would prevent restenosis and Conor did not suggest that this claim was not plausible. That would have been inconsistent with the evidence of its experts that taxol was just the thing to try. It is therefore not surprising that implausibility was neither pleaded nor argued. The same was true of the proceedings in the Netherlands (see paragraph 4.17 of the judgment).

37. The Court of Appeal upheld the judgment of Pumfrey J on the ground that the patent contained no "disclosure" saying that taxol was specially suitable for preventing restenosis. Again, I agree that the description, though offering a theory (its anti-angiogenic properties) as to why taxol would prevent restenosis, did not offer any evidence that this would turn out to be true. If it had not turned out to be true, the patent would have been insufficient. But there is in my opinion no reason as a matter of principle why, if a specification passes the threshold test of disclosing enough to make the invention plausible, the question of obviousness should be subject to a different test according to the amount of evidence which the patentee presents to justify a conclusion that his patent will work.

38. The issue in the Court of Appeal appears to have been whether the teaching of the patent was that a taxol-coated stent would prevent or treat restenosis. Jacob LJ disagreed with the view of the Dutch court, which I have already quoted, that that was precisely what the patent said. He said that the Dutch court had formed its view "with the hindsight knowledge that taxol stents work". I do not think that this is a fair criticism. The Dutch court was not addressing itself to whether taxol worked, or whether the specification proved that it would work, but to whether the specification taught that it should be used. And it did so by reference to the disclosure of the success of taxol in the CAM assay and the specific references to taxol in the claims. Jacob LJ considered that there was nothing in these points. After reading part of the passage about the CAM assay which I have quoted above, he said:

> "But this is miles away from indicating that taxol is a particularly suitable anti-angiogenic for a drug eluting vascular stent or that the CAM assay is a test for a drug which will actually work to prevent restenosis in a drug eluting vascular stent."

39. If, by using the word "indicating", Jacob LJ meant "proving", then of course I agree. The specification did not prove that taxol would work. If, however, he meant that it did not claim that taxol would work, then I would regard it as a very narrow approach to the meaning of the patent, more suitable to old-fashioned statutory construction than to what the skilled practitioner in cardio-vascular intervention would have understood. It was, as appears from Mr Thorley's question to Professor Cumberland, common ground that that the teaching of the patent was to use an anti-angiogenic factor on a stent to prevent or treat restenosis. The disclosure of the results of the CAM assay taught that taxol was the best anti-angiogenic. I do not understand what more the patentee could have said.

40. In the event, therefore, neither the judge nor the Court of Appeal answered what I consider to have been the correct question, namely, whether it was obvious to use a taxol-coated stent to prevent restenosis. One can however, deduce the answer which Pumfrey J would have given to this question from the way in which he formulated the issue which he had to decide. It was, at the end of the passage I have quoted:

> "is the patent vulnerable only if it can be shown that the skilled person would have an expectation of success sufficient to induce him to incorporate taxol in a drug-eluting stent, or is it sufficient that without any expectation of success he would test or screen taxol?"

41. The judge answered this question in the second sense, from which I think it can be inferred that he would have rejected the attack on the patent if he had answered it in the first and in my opinion correct sense. That, in my view would have been inevitable. Of the three cited items of prior art, both Wolff and Kopia are concerned with methods of delivery. In the case of Wolff, it is by a drug eluting stent and in the case of Kopia it is by chemical means. But neither of them identifies taxol as particularly suitable. Wolff does not mention it except by implication in a generic reference to anti-proliferatives and although Kopia does mention it, it is one of an undifferentiated number of drugs which could be tried. The disclosures leave one in no better position than a reader of the Holy Grail article, namely, with the knowledge that the solution may lie somewhere in the large number of drugs which could be tried. Katsuda, the last item of prior art, discloses in vitro work which showed that taxol prevented mitogenic proliferation (ie growth by cell division) of smooth muscle cells. That also seems to me insufficient to make it obvious that taxol would prevent restenosis.

42. In the Court of Appeal, Jacob LJ dealt comprehensively with the question of when an invention could be considered obvious on the ground that it was obvious to try. He correctly summarised the authorities, starting with the judgment of Diplock LJ in *Johns-Manville Corporation's Patent* [1967] RPC 479, by saying that the notion of something being obvious to try was useful only in a case in which there was a fair expectation of success. How much of an expectation would be needed depended upon the particular facts of the case. As Kitchin J said in *Generics (UK) Ltd v H Lundbeck A/S* [2007] RPC 32, para 72:

> "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."

43. But Jacob LJ rejected this approach (at paragraph 48) on the grounds that "this is not an 'obvious to try' case of the Johns-Manville type" because "the patent has not in any way demonstrated that taxol actually works to prevent restenosis." I agree with the Dutch court that patent law does not require such a demonstration. It was not a sufficient reason for not applying the ordinary principles of obviousness to the claimed invention. I would therefore allow the appeal.

LORD SCOTT OF FOSCOTE

My Lords,

44. I have had the advantage of reading a draft of the opinion of my noble and learned friend Lord Hoffmann. I am in agreement with it and for the reasons he gives I too would allow the appeal.

LORD WALKER OF GESTINGTHORPE

My Lords,

45. 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 his opinion, and for the reasons that he gives I would allow this appeal. I am doubtful whether I can usefully add anything. But I venture to add a few remarks on the notion of "obvious to try," and its relevance to this appeal.

46. Its origin was in the judgment of Diplock LJ in *Johns-Manville Corporation's Patent* [1967] RPC 479, a case about a method for production of asbestos cement. After referring to two items of prior art Diplock LJ said at p 495:

> "It is enough that the person versed in the art would assess the likelihood of success as sufficient to warrant actual trial. . . . The Superintending Examiner and the Patents Appeal Tribunal were both of opinion that, filtration

> processes being common to many industries, these documents, although addressed primarily to the mining and paper industries respectively, were likely to be read by those concerned with the asbestos cement industry, and that such readers would have realised that here was a newly-introduced flocculating agent which it was well worth trying out in their own filtration process. I can see no grounds which would justify this court in reversing this concurrent finding by two expert tribunals."

Diplock LJ was not here expounding a technical doctrine. On the contrary, he was at pains to stress the need to avoid generalisation. A little earlier in his judgment he had said (at pp 494-495):

> "I have endeavoured to refrain from coining a definition of 'obviousness' which counsel may be tempted to cite in subsequent cases relating to different types of claims. Patent law can too easily be bedevilled by linguistics, and the citation of a plethora of cases about other inventions of different kinds. The correctness of a decision upon an issue of obviousness does not depend upon whether or not the decider has paraphrased the words of the Act in some particular verbal formula. I doubt whether there is any verbal formula which is appropriate to all classes of claims."

47. *Johns-Manville* was decided over forty years ago, and was concerned with a fairly low-tech process. During the last forty years the volume of high-tech research has increased enormously, especially in the fields of pharmaceuticals and biotechnology. The resources committed to research are enormous, because the potential rewards in world-wide markets are so great. Competition is fierce. In this climate "obvious to try" has tended to take on a life of its own as an important weapon in the armoury of those challenging the validity of a patent.

48. The process has been vividly described in observations made out of court by Sir Hugh Laddie, Patents – what's invention got to do with it? (Chapter 6 in Intellectual Property in the New Millenium, p.93):

> "When patents and patent applications succumb to invalidity attacks, obviousness is the most common cause. This inevitably generates friction between the community

> of patentees and applicants on the one hand and patent offices and national courts on the other. A company which has spent millions of dollars on research and has produced a valuable new drug will be understandably irritated when, say, a court declares the patent invalid for obviousness, thereby opening up the market to competitors who are free to copy. That irritation is likely to be particularly acute when the raison d'être of the patent system is said to be the economic encouragement of research and development.
>
> The problems can be approached by considering first the concept of 'obvious to try'. The classic statement of this principle is set out in the judgment of the Court of Appeal in *Johns-Manville Corporation's Patent*. It was said that a development should be treated as obvious if 'the person versed in the art would assess the likelihood of success as sufficient to warrant actual trial'. Statements to similar effect have been made by the EPO.
>
> On its face, this produces an unworkable or irrational test. If the reward for finding a solution to a problem and securing a monopoly for that solution is very high, then it may well be worthwhile for large players to examine all potential avenues to see if one gives the right result, even though the prospects of any one of them succeeding are much less than 50/50. What makes something worth trying is the outcome of a simple risk to reward calculation. Yet, if the reward is very large, the avenues worth trying will be expanded accordingly. So, the more commercially attractive the solution and the more pressing the public clamour for it, the harder it will be to avoid an obviousness attack. In those circumstances a solution which is quite low down a list of alternatives, all of which are more or less worth trying, will fail for obviousness; a consequence which is consistent with the decision in *Brugger v Medic-Aid*."

Sir Hugh goes on to suggest that as technology advances rapidly, this is a serious and growing problem.

49. In the Court of Appeal in this case Jacob LJ (paras 39-45) made some comments to the same general effect, with a useful anthology of citations from different jurisdictions.

50. This background helps to explain the question which the judge asked himself (at the end of para 61 of his judgment), including the reference to testing a product "without any expectation of success" (which Lord Hoffmann refers to as an "oxymoronic concept"). The judge sought to answer the question (para 62) by assessing the contribution to the art made by the specification, and decided (para 64) that the only real contribution was a proposal for testing (and no more). In this way arguments that would normally be regarded as relevant to insufficiency crept into a challenge on the ground of obviousness.

51. Your Lordships all concur, as I do, in Lord Hoffmann's view that the judge and the Court of Appeal took too narrow a view of the specification of the patent in suit, probably because they attached insufficient weight to the CAM assay. What that assay demonstrated fell far short of what might have been demonstrated (and was in due course demonstrated) by clinical trials in treating restenosis after angioplasty. The CAM assay was not a last-minute last-ditch point taken in reply in the Court of Appeal. It had not been much discussed in the judge's judgment because it was not then regarded as a contentious issue.

52. So the patent has finally been upheld in your Lordships' House. I have to say that in my view the inventors and those who drafted the specification have to some extent brought the tribulations of this litigation on themselves. As the judge said (para 12):

> "The patent is a very long document, containing some 37 pages of description and 34 pages of figures. Very little of it is about restenosis and stents."

That is putting it quite mildly. The inventors were carrying on research work with various substances which held out the prospect of exciting medical advances, not only in preventing restenosis but also in the treatment of cancer. They understandably wished to cover as much ground as possible in the specification. But in doing so they risked making it so unfocused as to end up with nothing capable of resisting a challenge to its validity.

53. The European Patent Office focuses on the need for an invention to solve a particular technical problem: see for instance *AGREVO*, Case-T0939/92, paras 2.4 to 2.4.2. So far as the focus was on stents, there was a particular technical problem, clearly highlighted in the "Holy

Grail" paper published in 1993. The specification, fairly construed, did put forward a taxol-eluting stent as the answer to this problem. But that teaching had to be disentangled from so much extraneous matter that it nearly got lost.

BARONESS HALE OF RICHMOND

My Lords,

54. For the reasons given by my noble and learned friend, Lord Hoffmann, with which I agree, I too would allow this appeal.

LORD NEUBERGER OF ABBOTSBURY

My Lords,

55. I have had the benefit of reading in draft the opinions of my noble and learned friends Lord Hoffmann and Lord Walker of Gestingthorpe. I agree with them that this appeal should be allowed. Although the decision represents a significant development in United Kingdom patent law, and we are differing from the views of highly experienced Judges in that field, I do not think there is anything that I can usefully add to the reasons given by Lord Hoffmann, or to the additional remarks of Lord Walker, with both of whom I entirely agree.