File Name: *Angiotech Pharmaceuticals v. Conor Medsystems*
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WORLD PATENT COURT

CONOR MEDSYSTEMS INCORPORATED

APPELLANT

-V. –

ANGIOTECH PHARMACEUTICALS INCORPORATED AND OTHERS

RESPONDENT

Counsel for the Appellant:
The Rt. Hon. Professor Sir Robin Jacob

Counsel for the Respondent:
The Rt. Hon. Professor Lord Hoffmann

DATE: November 29, 2011

ROTHSTEIN J. (ORALLY)—

[1] This is a very difficult and close case. Justice Pumfrey and Lord Justice Jacob on one side. Lord Hoffmann and the Dutch District Court on the other. I am in the least enviable chair in this room today. I have to tell one of them that I think they are wrong.

[2] However, I have been instructed to reach a decision on the basis of the arguments I have heard and the prior judgments, rather than reserving judgment and escaping. So I shall deliver short reasons for judgment now. I shall finalize the reasons in writing and make them available next week.

[3] Before I go on, I want to say that it is a high honour for me to have been asked to participate in this unique event. When I received the invitation, I said to my wife Sheila, "Did you ever think in your wildest dreams that I would be judging a moot court between two world icons of intellectual property law?" and she said, "Marshall, you aren't in my wildest dreams". Be that as it may, it is an honour to be here.

[4] In this appeal the starting point was a very wide ranging patent. But in the end, what emerges is a claim for a particular device and whether the patent for that claimed invention is or is not valid.

[5] The object of the device is to treat a condition known as restenosis. The relevant claim, claim 12, is said to cover something new and inventive, a stent coated

with taxol for treating or preventing restenosis. It is one of a number of claims which are typical in that they start broadly and progressively claim narrower variations in the hope that at least one of them will be valid and will catch any possible infringement.

[6] Because of the course this litigation has taken, I think it is necessary to reiterate some basic principles of patent law. The issue is patent validity. To be valid, a patent must disclose and describe an invention that is new, industrially applicable or useful, and unobvious. I shall say a word about each of these elements.

[7] The need to disclose an invention sufficiently is often described as the quid pro quo for the patent monopoly. Society gets to know about the invention from its specification so that others can make it after the patent expires or can build on the teaching of the patent while it is still extant to make or do something else.

[8] The subject-matter of the patent must be an invention – that is, the kind of thing for which a patent could be granted. It must be something intrinsically patentable, not a mere discovery, principle or abstract theorem.

[9] The invention must be new, that is, not known and not available to the public.

[10] And the invention must be industrially applicable or useful, that is, it does or is soundly predicted to do something practical. Society does not grant patents for things that do not work or cannot be put to practical use. Patents are for those who apply ideas to do something practically useful for society.

[11] And finally, non-obviousness: an invention must be for something inventive - that is, something the person skilled in the art would not have figured out from the prior art.

[12] The overarching policy of patent law is, to paraphrase Lord Neuberger in *Human Genome Sciences Inc v Ely Lilly & Co*[1]., to provide a temporary monopoly as an incentive to invent, while at the same time facilitating the dissemination of the innovation through its publication in the patent. The purpose behind each element of patent validity I have mentioned points toward that overarching policy: but each element has its own different variant of that policy, and it is important to keep each element in its place.

[13] It has been agreed throughout these proceedings, including this appeal, that the only relevant attack on the patent in this case is that it is obvious or lacks any inventive step. It is therefore only to the issue of obviousness that this judgment is directed.

[1] [2011] UKSC 51, at para. 99.

[14] All the judges found the patent difficult to read, and with that I agree. But no judge said that it was impossible to understand the patent. It was just a matter of interpretation. I agree that, although difficult, the patent can be understood by a person skilled in its art.

[15] The question then is whether the claim in issue is obvious to such a person. And I think the best way to proceed is to follow the generally accepted obviousness inquiry template outlined by Lord Justice Oliver in *Windsurfing International v Tabur Marine*[2], as updated into five steps by Lord Justice Jacob in *Pozzoli v BDMO*[3].

[16] The first step of the inquiry is easily answered. Who is the notional person skilled in the art? There is no controversy that, so far as the patent is concerned with the problem of restenosis, the skilled person would be a team engaged in research aimed at treating or preventing restenosis after angioplasty. It would include an interventional cardiologist and a pharmacologist familiar with drugs that inhibit the proliferation of blood cells, including drugs for treating cancer.

[17] The second step is to identify the common general knowledge of that team. By the mid 1980's cardiologists knew that coronary artery disease could be treated by drugs, coronary bypass surgery and angioplasty, that is, using a balloon to

[2] [1985] R.P.C. 59.
[3] [2007] EWCA Civ 588, at para. 23.

expand the channel of a coronary artery. A problem with angioplasty was that a relatively high proportion of patients experienced a gradual closure of the channel after the original procedure, caused by the proliferation of blood cells. This closure is called restenosis. To counteract it, coronary stents could be inserted into the diseased artery to hold it open, but even then restenosis occurred at a significant rate.

[18] Some research had been directed toward local delivery of drugs to reduce the proliferation of blood cells, including through a drug-releasing stent, but no particular drug had been identified as a specially effective solution. It was common general knowledge among pharmacologists with interests in cancer that taxol prevented cancerous cells from dividing and thus from proliferating, but that toxicity and other side effects occurred with the use of taxol. That then was the combined common general knowledge of the relevant skilled team.

[19] The third step is to construe the claim in question and identify its alleged inventive concept. Counsel disagreed on the identification of the inventive concept. Sir Robin argued that the concept was merely that a taxol coated stent might work. Lord Hoffmann however said the concept was that a taxol coated stent not only might work, but that it would work.

[20] Claim 12 is for a stent coated with taxol for treating or preventing restenosis. It is not for a stent that merely might work to treat or prevent restenosis; it

is for one that would so work. To turn it into a claim that taxol only might work would change its meaning by reference to what appears in the specification.

[21] I accept that a specification may help clarify any ambiguities in a claim and thus its inventive concept. However, in my opinion, the meaning of a claim cannot be narrowed or expanded by what appears in the rest of the specification; nor therefore may the scope of the inventive concept be so narrowed or expanded.

[22] There is clearly scope to argue that the specification discloses only the research possibilities of a taxol-coated stent, and that much was needed before one could assert or soundly predict that such a stent would in fact treat or prevent restenosis. Counsel indeed presented persuasive arguments for and against this proposition. The point is certainly important in considering the state of the prior art when comparing it with the inventive concept to see what advance, if any, the inventor made. It is also important in inquiring about the claim's industrial applicability or utility, or for other aspects of patentability such as the sufficiency of the disclosure. I however resist the temptation to consider it when defining the nature of the inventive concept itself. That concept must be found in the words of the claim alone.

[23] I turn then to the fourth step: to identify the differences if any between the state of the art and the inventive concept of the claim. It is here where the specific pieces of prior art become relevant. Sir Robin argued that the prior art suggested that

anti-proliferative drugs could possibly work to treat restenosis, and that taxol was a known anti-proliferative. There were four specific papers cited in the evidence before the trial judge and are at the centre of the obviousness inquiry. He essentially argues that this prior art taught that it was at least obvious to try a taxol coated stent to treat restenosis; Lord Hoffmann says the opposite. Sir Robin submits that the alleged invention provided no advance beyond the prior art; Lord Hoffmann says that the invention was for a taxol coated stent, which none of the prior art had focused on as being particularly suitable for the treatment or prevention of restenosis.

[24] I have read the treatment of these papers in the judgments below but time precludes my going through each of them in detail now. Some papers dealt with stents; some dealt with anti-proliferative drugs; some even mentioned taxol in passing; but none suggested that taxol would work any better than any other anti-proliferative drug.

[25] Counsel also referred to the CAM assay, which also figured largely in the discussion in the lower courts when discussing what the inventor had really invented. The CAM assay was a test the inventor conducted to assess the effects of a number of compounds on anti-angiogenesis and appears in the patent specification. The assay is in fact central to the inventor's invention, which was that one way to stop cell proliferation is anti-angiogenesis: that is, stopping blood vessels from growing in the first place. Taxol was the most effective drug the test revealed to stop angiogenesis,

and the results of the CAM assay enabled the inventor to predict that its use on a stent would prevent restenosis.

[26] But if the inventive concept is to be found in the claim alone, it is irrelevant, in testing for obviousness, to inquire whether the CAM assay reveals that taxol does or only might work. The result might be important to an inquiry whether the CAM assay enabled the inventor soundly to predict his inventive concept, but that inquiry would go to whether the invention is useful or industrially applicable. But that ground of invalidity is not at issue in this appeal.

[27] In my opinion none of the prior art discloses that taxol is particularly effective in treating restenosis more than any other anti-proliferative compound. This is not surprising because the prior art did not point out the importance of anti-angiogenesis as a means of anti-proliferation, nor the worth of taxol in anti-angiogenesis. I do not mean to suggest that patents can be granted simply because someone has discovered why or how something works. If something does work, it does not matter, for the purpose of patent law, why it works or whether an inventor's theory about this is right. I mention the inventor's theory merely to indicate why the prior art had not suggested taxol as a particularly effective solution to the problem of restenosis. The persons skilled in the art had not appreciated that anti-angiogenesis was the most promising means to stop cell proliferation.

[28] This brings me to the fifth and final step of the inquiry: did the differences that have been identified constitute steps which would have been obvious to the team skilled in the art, or did they require some degree of inventiveness? It is here that the obvious-to-try test becomes relevant. Would the prior art cause the skilled team to think it obvious that taxol-coated stents would work, or to try taxol-coated stents to see if they would work?

[29] The prior art does not point directly to the concept in claim 12, and one paper indeed points away from it. So the prior art and the state of knowledge of the skilled team would not directly have made it obvious to the skilled team that the taxol-coated stent should work. There was no reason to select taxol more than any other possible candidate.

[30] Would then this prior art make it obvious to try taxol-coated stents to see if they would treat restenosis? This requires all the facts of the case to be considered. As Lord Justice Kitchin, as he is now, said in *Generics et al. v. H. Lundbeck A/S*[4], the weight to be attached to each factor will have regard to all the circumstances, including the motive to find a solution to the problem the patent addresses, the number and extent of possible avenues of research, the effort involved in pursuing them and the expectation of success.

[4] [2007] EWHC 1040 at para. 72.

[31] One should nevertheless proceed cautiously. Obviousness-to-try cannot be seen as a panacea for infringers or those who wish to invalidate patents. The patent system is intended to provide economic encouragement for practical research and development. This cautions against the adoption and application of too liberal an approach to the obvious-to-try test.

[32] For these reasons I am attracted to the test adopted by Lord Justice Jacob in *St Gobain PAM v Fusion Provida Ltd*:

> The obvious to try test really only works where it is more or less self evident that what is being tested ought to work.[5]

[33] Thus for a finding that something was obvious to try, there must be evidence to convince a judge on a balance of probabilities that something was more or less self evident to try to obtain the invention. The possibility that something *might* turn up is not enough.

[34] In my opinion, there was no expectation of success in this case in the sense that the purported invention was more or less self evident from the prior art. The Wolff publication does not describe the taxol coated stent as being particularly suitable for the treatment of restenosis; Kopia simply lists taxol among other drugs with no preference given to it; Katsuda does not suggest that taxol is suitable for local

[5] [2005] EWCA Civ 177, at para. 35.

delivery in the treatment of restenosis; and the Holy Grail paper, as the words suggest, gave no indication of whether a taxol coated stent would be the preferred treatment for restenosis. And so the conclusion must be that the invention was not obvious to try.

[35] The result is that the prior art does not demonstrate that the use of taxol as a coating for stents was obvious or very plain as a means to combat restenosis, nor that it was obvious or very plain to the skilled team to try it for this purpose over any other suggested drug.

[36] It is not a matter of whether this is a fair result overall or whether the court likes the result. Or whether the patent was lengthy and complex and was significantly amended. Or that other drugs were included before the amendments were made. Or that the inventor could have tested taxol more before claiming it as a treatment for restenosis, or could have filed a stronger application at some later point in time. Or that other defences that were not advanced may have been successful.

[37] In the end, although this is a close case, I find that the invention here is not obvious and the patent cannot be invalidated on that ground. The appeal to the World Patent Court is dismissed.