

Actavis v Novartis: the Conor effect and technical obviousness

Dr Matthew Royle, patents associate at Taylor Wessing LLP, reviews the England and Wales High Court judgment

In *Conor v Angiotech* [2008] UKHL 49, the House of Lords decided that, contrary to decisions of the High Court and the Court of Appeal, Angiotech's patent for a taxol-eluting stent was not obvious. Lord Neuberger described the decision as 'a significant development in United Kingdom patent law'. First-instance judgments decided in the light of *Conor* are now being handed down. It is the interpretation of *Conor* in these judgments that will give the first indication as to its true significance.

One such judgment is *Actavis v Novartis* [2009] EWHC 41 (Ch). It is interesting to review this decision and to assess the judicial interpretation of *Conor*. In addition to reviewing *Conor*, Mr Justice Warren commented on technical obviousness, the could/would approach to obviousness and *Pozzoli v BDMO* [2007] EWCA Civ 588.

Ultimately, Warren J held that the patent was not obvious based on motive and expectation of success but nevertheless held that the patent was technically obvious and so was invalid. The decided case law was considered fully, but this decision demonstrates that obviousness is highly fact-dependent and that different factors will be key in each case. It is difficult to suggest a rigid set of general rules that will be applicable in all cases and often it will be necessary simply to consider the statutory test: is the invention

obvious to the skilled man having regard to the state of the art? This article reviews the way in which Warren J approached the question of obviousness in *Actavis* and the effect that the decision in *Conor* had on this approach.

The facts

The patent in suit covered a sustained release formulation of fluvastatin. The drug, which is marketed by Novartis as Lescol, is a statin and is used for lowering cholesterol levels in the blood by inhibiting an enzyme involved in the production of cholesterol. At the priority date of the patent, fluvastatin was known and was being marketed in an immediate release formulation.

Actavis brought revocation proceedings against the patent, arguing that the patent was obvious over the common general knowledge. They also argued obviousness over two pieces of prior art and insufficiency. However, since neither of these attacks was successful and each was considered only very briefly in the judgment, they will not be considered further here.

The only novel aspect of the formulation disclosed in the patent was a sustained release pharmaceutical composition. It was, therefore, necessary for Warren J to ask whether or not there was any invention in producing such a formulation.

Obviousness

Warren J reviewed the decision of the House of Lords in *Conor* in some detail and concluded that the resolution of the question by the House of Lords in *Conor* did not assist his decision, only their approach to the question of obviousness.

While Warren J did not disagree with Lord Neuberger's comments that *Conor* was a significant development in patent law, he commented that 'it was difficult ... to read Lord Hoffmann as seeing himself doing anything other than applying well-established law to clear facts'. However, he identified two points in *Conor* that would have wider application:¹

1. The question of obviousness should be determined by reference to the claim.
2. The 'obvious to try' test was useful where there was a 'fair expectation of success' and not only in cases where it was 'more-or-less self evident that what is being tested ought to work'.

These two points did not assist in this case. He held that there was no real issue in determining obviousness by reference to anything other than the claim, as there had been in *Conor*. Moreover, even if the obvious-to-try test applied where there was a fair expectation of success, the expectation of success in this case still fell well below that standard and therefore the test was not relevant.

Warren J referred to the following quote from Mr Justice Kitchin in *Generics v Lundbeck* [2007] RPC 32 at para 72, which had been quoted with approval by Lord Hoffmann in *Conor*. It is this quote that best summarises the current law of obviousness and the approach taken by Warren J in this judgment:

'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 light of all the relevant circumstances. These may

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include such matters as 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.'

Warren J's consideration of whether or not a sustained-release formulation was obvious focused on two of the factors highlighted in this quote: whether or not there was a motive to develop a sustained-release formulation and whether there was an expectation of success. Different factors might prove to be important in other cases but on the facts of this case these two factors were key and were relied on by Novartis as a defence to the claim of obviousness.

In fact, Warren J noted that these alternative bases were incompatible. If no motive existed to take a particular route then the skilled man would not consider the prospects of success. If the skilled man considered the prospects of success of a particular route then he must have had motive to follow that particular route even if he did not, in the end, proceed because he was uncertain as to the outcome. He would lack the expectation of success but the motive to consider that route would have nevertheless existed. From this, motive would seem to be a lower hurdle than expectation of success.

Warren J considered a number of factors that were said either to provide motivation to develop a sustained-release formulation or to dissuade the skilled team from following that route. Having considered these various factors, Warren J decided that

there was a motive to produce a sustained-release formulation but there was 'nothing approaching certainty or even a strong expectation that it would achieve success in the sense of producing such a formulation which releases *in vivo* over a period of 3 hours or more and which had improved clinical efficacy'.

Having identified two points of general applicability from *Conor*, it is arguable that Warren J did not determine obviousness with reference to the claim. He construed the claim to a sustained-release formulation as relating to the formulation's *in vitro* release profile but then determined the expectation of success not only by reference to the *in vivo* release profile but also by comparison to the existing formulation. It is difficult to identify either of these features within the claim and so it could be argued that Warren J judged obviousness with reference to a vague paraphrase of what is disclosed in the specification and not simply to the claim. This was not the quasi-insufficiency argument of *Conor*, though, and the decision did not rely on the extent of the disclosure in the specification. Furthermore, the claim is to a 'pharmaceutical composition', which clearly indicates that the formulation should work *in vivo*. The motive and expectation of success would both also be affected by comparison to the existing formulation. After all, it would not be sensible (or obvious) to try a formulation that would not compete with the existing product or to develop a product at great expense when the existing product was more than adequate.

Following the approach outlined in Kitchin J's quote, Warren J decided that the prospects of success in producing a sustained-release formulation was the single most important factor and that because this was uncertain the patent was not obvious.

Technical obviousness

Despite this finding the patent was revoked for obviousness in any event because it was a mere workshop variation of the type envisaged in *Hoechst Celanese v BP*.² The formulation was technically obvious.

The basis of Warren J's finding of technical obviousness was that anyone is entitled to repeat the prior art with obvious modifications. The example quoted in *Hoechst* is that of the 5¹/₄" plate. Assuming that 5" plates are known and that the skilled man would be able to make them, producing a 5¹/₄" plate would not be inventive and neither would the method of doing so. It would be a mere workshop variation with no inventive merit. Such variations might commonly be made for commercial reasons but are not entitled to patent protection.

Of course it is possible to argue that there is no reason for taking such a step and that therefore it should be considered to be inventive. In the same passage in *Hoechst*, Mr Justice Laddie stated that '[b]efore a step from the prior art can be held to be obvious there must be some reason why the man skilled in the art would wish to take it'. This has been held not to be the case. In *Pharmacia v Merck* [2001] EWCA Civ 1610 at para 124, Lord Justice Aldous, having quoted Laddie J's statement in *Hoechst*, made it clear that 'a step from the prior art, albeit made without reason, can still be obvious', although later in that judgment he clarified that lack of a reason to take a particular step is a factor that should be taken into account.

In this case an 'absence of motivation [did] not prevent claim 1 from being technically obvious'. Although Warren J had earlier held that there was motive to produce a sustained-release formulation, on the basis that no one would have considered a sustained-release formulation, he concluded that the skilled man would appreciate that the production of a sustained-release formulation was technically obvious.

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Could/would approach

Novartis argued that the question that the court should ask (and that it was common practice for the EPO to ask) was whether the skilled man *would* have taken a particular approach rather than whether he *could* have taken a particular approach. While the skilled man could have produced a sustained-release formulation there was no evidence that he would have done so. Warren J recognised that it might be appropriate to consider the could/would approach in a situation where the skilled man was addressing a problem ‘but where there is no problem ... which is sought to be addressed by the patent, it is essential to go back to the words of the statute’.⁴ This was such a case where no problem was addressed in the patent and therefore the could/would question was not relevant.

Lions in the path and paper tigers

Actavis sought to rely on *Pozzoli* as authority for the argument that the only problem addressed in the patent was the water solubility of fluvastatin and that because this was not actually a problem the invention was obvious. Warren J therefore considered whether or not it was necessary to address a problem in the patent before that problem can meet an obviousness attack.

In *Pozzoli*, Lord Justice Jacob explained that it could be novel and inventive to overcome a prejudice that exists in the mind of the skilled man.

‘Patentability is justified because the prior idea which was thought not to work must, as a piece of prior art, be

taken as it would be understood by the person skilled in the art. He will read it with the prejudice of such a person. So that which forms part of the state of the art really consists of two things in combination, the idea and the prejudice that it would not work or be impractical. A patentee who contributes something new by showing that, contrary to the mistaken prejudice, the idea will work or is practical has shown something new. He has shown that an apparent “lion in the path” is merely a paper tiger. Then his contribution is novel and non-obvious and he deserves a patent.’

Jacob LJ also questioned whether or not the prejudice would come into play if the skilled man did not have the idea in the first place. Effectively, unless the idea would have occurred to the skilled man (ie, it is obvious), it cannot be relevant that there exists a prejudice that would prevent the skilled man from actually taking the step. This is similar to the incompatibility of the arguments relating to the motive and expectation of success recognised by Warren J and discussed above. Once the skilled man only recognises the prejudice he has had the idea and if he has had the idea then it is obvious. A lion in the path argument therefore appears to be inconsistent with an argument that the idea was not obvious in the first place.

In any event, *Pozzoli* was not authority for the proposition that Novartis was not able to rely on problems not identified in the patent as a defence to an obviousness attack and therefore did not assist Actavis.

Ultimately, Warren J held that the solubility of fluvastatin was not enough of a problem that it would convince the skilled man not to go down the route of a sustained-release formulation. There was no lion in the path.

Has *Conor* made a difference?

Obviousness depends on the relevant circumstances in each particular case. Previous case law will only ever offer a rough guide, as no case will have exactly the same considerations. This was what Warren J found to be the case with *Conor*. He gleaned the points of principle but did not find a consideration of the facts of the case useful in reaching his decision.

Warren J’s rejection of the arguments based on could/would, lions in the path and obvious to try were all based on the multifactorial approach advocated by Kitchin J in *Generics v Lundbeck*. Even the factors listed there – motive, number of avenues available, effort involved and expectation of success – are not exhaustive and no doubt further relevant matters will be identified in future cases, depending on the specific facts of each case.

In this case, *Conor* appears to have had little effect on the decision. The effect of *Conor* on future cases is not clear and will depend on the facts of each case. What is clear is that when considering obviousness it is important to remember Jacob LJ’s words in the Court of Appeal in *Conor*:⁴ ‘... one can over-elaborate a discussion of the concept of “obviousness” so that it becomes metaphysical or endowed with unwritten doctrines, sub-doctrines or even sub-sub-doctrines ... In the end the question is simply “was the invention obvious?”’

¹ See paras 161 and 163 of the judgment

² [1997] FSR 547 at 573

³ At para 293

⁴ At para 319

⁵ At para 27

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