

United Kingdom

Recent patent law developments: a new test for obviousness and a statement on the principles for determining industrial applicability

Two recent patent decisions by the English Court of Appeal and the House of Lords have substantially changed and clarified the law in regard to obviousness. First, the Court of Appeal ruling in *Pozzoli SpA v BDMO SA* restated the test for obviousness as originally formulated in 1986 in *Windsurfing International v Tabur Marine*, which previously defined the law of obviousness. Second, the House of Lords decision in *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc* clarified the test for obviousness even further and will arguably lead to more patents being upheld. In addition, in an area of law with little precedent, in *Eli Lilly & Co v Human Genome Sciences Inc* the High Court provided a detailed examination of the requirement that an invention be capable of industrial application in order to be patentable.

The Pozzoli Case

In the seminal *Pozzoli Case*, the Court of Appeal reformulated the *Windsurfing* test for obviousness and made it clear that there may be circumstances in which the inventive concept cannot be identified. In such circumstances, the court held that the sensible solution would be to determine the features of the claim to decide the differences between what is claimed and the prior art. In other words, the court held that trial judges should disregard disagreements about the inventive concept that develop into an unnecessary satellite debate and instead focus on the actual differences between the features of the patent and the features of the known matter, which is what actually matters.

Background

Pozzoli SpA owned a European patent entitled “container for a plurality of discs, particularly compact discs” – in

layman’s terms, a CD container that could hold two CDs. Pozzoli brought an action against BDMO SA and Moulage Industriel de Perseigne SA on the basis that they had infringed Pozzoli’s European patent for a CD packaging. BDMO had combined plastic trays with cardboard covers and distributed them in the United Kingdom, while Moulage had manufactured and marketed packaging for discs and distributed them. BDMO and Moulage manufactured a product called a ‘double push tray’ which consisted of a single piece of moulded plastic. At trial, the High Court held Pozzoli’s patent to be invalid and obvious in view of the common general knowledge. Further, the High Court held that if the patent were valid, it would not have been infringed by the double push tray. Pozzoli appealed to the Court of Appeal.

Obviousness test reformulated

Lord Justice Jacob, rendering the judgment for the Court of Appeal, started by setting out the traditional test for assessing obviousness as defined in *Windsurfing*. Under this test, the court:

- identifies the inventive concept;
- assumes the mantle of the normally skilled but unimaginative addressee in the art at the priority date and imputes to him the common general knowledge in the art at that date;
- identifies any differences which exist between matters cited as being “known and used” and the alleged invention; and
- asks itself whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled person or whether they require any degree of invention.

The judge determined that the *Windsurfing* test required some restatement and elaboration. Specifically, he thought that the court should look at the mantle of the normally skilled but unimaginative addressee in the art before looking at the inventive concept, since it was only through the eyes of the skilled person that one would properly understand what such a person would understand the patentee to have meant, and thereby set about identifying the inventive concept. Next, he thought that the first step actually involved two steps: identification of the attributes of the notional ‘person skilled in the art’ and a second identification of the common general knowledge. It bears mention that Jacob had shown an inclination to nail down the nature of the notional person skilled in the art – in an earlier decision in 2004 (*Rockwater Ltd v Technip France SA*) he described the person skilled in the art as “very boring – a nerd”.

In regard to the new second step, Jacob stated that in identifying the inventive concept, what mattered was the difference between what was claimed and the prior art, as it was those differences which determined the step to be considered at stage four. He noted that if a disagreement about the inventive concept of a claim began to get too involved, the sensible way to proceed would be to forget it and simply work on the features of the claim.

Therefore, the reformulated *Windsurfing* test requires that the court:

- identify the notional person skilled in the art (the ‘nerd’) and then identify the relevant common general knowledge of that person;
- identify the inventive concept of the claim in question or, if that cannot readily be done, construe it;
- identify what, if any, differences exist between the matter cited as forming part of the state of the art and the inventive concept of the claim or the claim as construed; and
- viewed without any knowledge of the alleged invention as claimed, decide whether those differences constitute steps which would have been obvious to the person skilled in the art or whether they require any degree of invention.

In this case, the court held that Pozzoli’s patent would not have been infringed even if it had not been obvious (which it was). However, the real lesson of this case is less in the decision about Pozzoli’s patent and more in the reformulation of the test for obviousness. Where the inventive concept cannot be identified, the sensible way would be simply to work out the features of the claim to

decide the differences between what was claimed and the prior art. What matters in the obviousness test is to consider those differences.

More on obviousness

In *Conor Medsystems Inc v Angiotech Pharmaceuticals Inc*, the House of Lords provided welcome clarification on the test for obviousness and arguably brought UK practice closer to that in Europe. The House of Lords reversed the decision of the High Court and the Court of Appeal that Angiotech’s patent for taxol-coated stents for the prevention of tissue growth around the stent was invalid for obviousness. The House of Lords held that both lower courts had incorrectly identified the inventive step of the patent by ignoring the clear wording of the claims in issue and ascribing too much weight to the description of the invention contained in the specification.

Background

Angiotech and the University of British Columbia were joint owners of a European patent which claimed, among other things, a stent coated with taxol for “treating or preventing recurrent stenosis”. The stent produced under the patent was very successful. At the patent’s priority date taxol was already known as an anti-cancer drug. Conor attempted to revoke Angiotech’s patent on the grounds of obviousness based on an earlier US patent owned by Angiotech which described a stent coated with polymer containing the drug taxol. When Angiotech filed this patent in the United States, it was well known that if a bare metal stent was used to keep a coronary artery open, damage to the inner lining of that artery caused a reaction during the healing process which could ultimately result in a build-up of tissue around the stent (known as restenosis), which in turn could cause angina.

Inventive concept

Conor argued that the inventive concept in the Angiotech patent was merely the idea of coating a stent with taxol to deal with restenosis and that the patent taught nothing further than taxol was “worth a try”. In Conor’s view, this “worth a try” teaching added nothing to the existing knowledge in the subject area. Further, Conor argued that it was common ground that taxol was, like many other anti-proliferative drugs, worth a try and therefore obvious. It was not necessary for Conor to show it was obvious actually to use taxol to treat restenosis because the patent did not teach that it would work. Lord Hoffman thought that this argument was an illegitimate amalgam of the requirements of inventiveness and either sufficiency or support, or both. He stated that it

was the claimed invention which had to involve an inventive step and that an invention was, on the face of it, what was claimed by the patentee and not just what was stated or described in the specification of a patent. In this case, the inventiveness was in Angiotech's claim that the product would have a particular property – namely, to prevent or treat restenosis. The question of obviousness was whether it was obvious to use a taxol-coated stent for this purpose. In Lord Hoffman's opinion, the invention is the product specified in a claim and the patentee is entitled to have the question of obviousness determined by reference to its claim and not some vague paraphrase based upon the extent of the disclosure in the description. He noted that there is no requirement in the European Patent Convention or the UK Patents Act 1977 that the specification must demonstrate by experiment that the invention will work or explain why it will work.

Obviousness

Lord Hoffman noted that it was hard to see how the concept that something was worth a try or might work could be described as an invention to such an extent that a patentee should be awarded a patent. He agreed that a patent cannot be granted for an idea which is mere speculation. In addition, in principle he could see no reason 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 a patent will work.

Lord Hoffman thought that neither the trial judge nor the Court of Appeal answered what he considered to be the correct question: whether it was obvious to use a taxol-coated stent to prevent restenosis. In Lord Hoffman's view, it was not obvious.

This decision should be seen as pro-patentee, which is arguably a rare occurrence before the UK courts. It would seem that as long as so-called speculative patents disclose enough information to make the efficacy of the claimed product plausible, there is no reason why the obviousness of the claimed invention should be subject to a different or more enhanced test.

Industrial applicability

In *Eli Lilly & Co v Human Genome Sciences Inc*, the High Court set out the principles that UK courts should apply when considering whether a given patent possesses the necessary quality of industrial applicability. The case is noteworthy as few cases have ever clearly defined what is needed to meet the industrial applicability criterion.

Background

Eli Lilly applied to have Human Genome Sciences Inc's patent (for a nucleotide and amino acid sequence of a novel member of the TNF ligand superfamily which it called Neutrokin-) revoked. Eli Lilly contended, among other things, that the prediction of Neutrokin-'s uses was wholly speculative and that Human Genome filed its application for patent protection without knowing:

- the biological activity or function of Neutrokin-;
- the identity of any receptor; or
- the conditions which it causes or the diseases which it might be used to treat.

This gave rise to the first fundamental attack on the patent and one which, the court noted, had received relatively little judicial consideration in the United Kingdom. Eli Lilly said that the specifications failed to disclose an invention capable of industrial application.

Decision

While the court ultimately held that Human Genome's patent was invalid on the grounds of obviousness, insufficiency and lack of industrial applicability, Justice Kitchen laid down the following principles for the courts to apply when considering whether a given patent possesses industrial applicability:

- The notion of industry should be broadly construed. However, it need not necessarily be conducted for profit and a product which is shown to be useful to cure a rare or orphan disease may be considered capable of industrial application even if it is not intended for use in trade.
- The capability of industrial exploitation must be derivable by the skilled person from the description read with the benefit of the common general knowledge.
- The description must disclose a practical way of exploiting the invention in at least one field of industrial activity.
- There is a need to disclose in definite technical terms the purpose of the invention and how it can be used to solve a given technical problem. Moreover, there must be a real prospect of exploitation which is derivable directly from the specifications, if not already obvious from the nature of the invention or the background art.
- Conversely, the requirement will not be satisfied if what is described is merely an interesting research result that might yield a yet-to-be identified industrial application.

- It follows that the purpose of granting a patent is not to reserve an unexplored field of research for the applicant.
- If a substance is disclosed and its function is essential for human health, then the identification of the substance having that function will immediately suggest a practical application. If, on the other hand, the function of that substance is not known or is incompletely understood, and no other practical use is suggested for it, then the requirement of industrial applicability is not satisfied.
- Using the claimed invention to find out more about its own activities is not in itself an industrial application.
- It is no bar to patentability that the invention was found by homology studies using bioinformatics techniques, although this may have a bearing on how the skilled person would understand the disclosure.

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