

The Federal Circuit addressed that Ivax only emphasized the evidence that was favourable to their desired outcome without addressing the evidence favourable to Forest, such as the failure of the inventors to resolve citalopram without undue experiments, and so on.¹²⁵ Judge Lourie concluded that it was not obvious to the person skilled in the art. Considering this decision was given several months after KSR, this decision is interesting because the Federal Circuit did not address more than the ordinary view regarding obviousness while relying on the District Court's finding based on *Graham v. John Deere Co.*¹²⁶

3. From the UK Perspective

a) Markush Claim – Olanzapine Decision

(1) Patent Court Decision

Floyd J employed the structure approach of the obviousness test in *Windsurfing v. Tabur Marine* case,¹²⁷ found the 'skilled addressee' as a team of scientists with a particular interest in finding anti-psychotics, led by a medicinal chemist having access to other disciplines such as pharmacology and toxicology,¹²⁸ found 'common general knowledge' as medicinal chemistry including structure-activity-relationships, psychological disorders and associated side effects,¹²⁹ and held the patent was not obvious over all prior arts argued.¹³⁰ Considering determination of what a person skilled in the art perceived at the filing date was crucial to determine obviousness,¹³¹ this court seems to start from the very basic element. In addition, he found that 'commercial success' is not helpful in deciding obviousness, since the fact alone did not support obviousness if olanzapine was technically obvious.¹³² He emphasised that the commercial success was not because the third parties had

125 *Id.*, at 1268.

126 *Graham v. John Deere Co.*, 383 U.S. 684 (1966).

127 *Windsurfing International Inc. v Tabur Marine (GB) Ltd.* R.P.C. 59 (1985) (Gt Brit.). (4 step tests to the obviousness: (1) (a) Identify the notional "person skilled in the art" (b) Identify the relevant common general knowledge of that person; (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it; (3) 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; (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?").

128 *Dr Reddy's Lab*, Patent Court, *supra* note 86, para 140.

129 *Id.*, paras 141-148.

130 *Id.*, paras 149-184.

131 *See also* Spenner, *supra* note 116, at 477.

132 *Dr Reddy's Lab*, Patent Court, *supra* note 86, para 185.

not appreciated the advantages of olanzapine, but because the basic patent covering olanzapine had prevented the manufacture and sale of olanzapine.¹³³

(2) Court of Appeal Decision

Jacob LJ stated that the objection of obviousness could be made where there was ‘no real technical advance’ in the art, since the patent monopoly could be justified by the technical contribution to the art.¹³⁴ While endorsing Jacob LJ’s position on this issue, Lord Neuberger noted that whether the selection was arbitrary, or whether the teaching of prior art established that the selection achieved ‘a particular technical result’, should be asked.¹³⁵ If there was not technical advance, it was just an arbitrary selection which was obvious. However, since olanzapine provided its superior therapeutic effect to the prior arts, and selection from almost millions of compounds could not be regarded as random,¹³⁶ it was nonobvious over the prior arts.

b) Enantiomer Invention – Escitalopram Decision

(1) Court of Appeal Decision

Before this Court, whether the so-called amino diol route for resolving the racemate would have been obvious was an issue.¹³⁷ Lord Hoffmann stated that the appeal court might reverse the trial judge’s finding when the error of principle occurred that the judge failed to consider whether it was obvious for the skilled person to try the reaction to see if it worked, like in the *Biogen*¹³⁸ case.¹³⁹ While stating Kitchen J applied the state of law correctly to the facts of this case, Lord Hoffmann shortly rejected the nonobviousness argument. Regarding the plaintiff’s argument that a person skilled in the art could have come to the invention by doing a short and simple experiment, Jacob LJ rejected this argument stating that by itself is not enough ; as one could say that ‘with hindsight’ of many inventions; and as it was

133 *Id.*, para 186.

134 Dr Reddy’s Lab, Court of Appeal, *supra* note 91, at paras 40-52.

135 *Id.*, at para 109.

136 *Id.*, at paras 54-57, 98-101, 109-115.

137 Generics, Court of appeal, *supra* note 101, at para 14.

138 *Biogen Inc v. Medeva Plc* (hereinafter “*Biogen*”), Oct. 31, 1996, UKHL 18, 1996; R.P.C. 1, 1997.

139 Generics, Court of appeal, *supra* note 101, at para 23.

not enough motivation for a skilled person to carry it out. Therefore, the invention was not obvious.

(2) *The House of Lords Decision*

Since attack based on obviousness failed in both courts below, it was not a big issue before the House of Lords. On the other hand, Lord Neuberger summarized basic knowledge about enantiomers which had long been known as follows: i) two enantiomers could have different properties from each other; ii) a racemate's therapeutic effect might be mainly dependent on one enantiomer; iii) the other enantiomer might have toxic or side-effects; iv) the only way to tell which one had which effect was to separate one from another and to compare; iv) however, above was not possible to predict yet.¹⁴⁰ He continued that the notion to obtain a pure therapeutic form from a racemate is obvious, but to obtain a pure form is not obvious, and it was particularly difficult to separate (S)-citalopram from the racemate.¹⁴¹ Thus it seems that Lord Neuberger weighted the difficulty of separation of racemates to determine obviousness.

4. Summary

These decisions show that the courts share and consider various factors to determine obviousness, such as level of knowledge of persons skilled in the art, structural similarity, motivation to carry it out, unexpected beneficial properties (a real technical advance), teach-away, previous failures, hindsight issue, reasonable expectation of success (arbitrariness), and so on. For example, similar to the 'obvious-to-try' doctrine, Jacob LJ stated that enough motivation and a simple statement that the experiment would have been short and simple was not sufficient. Also as Jacob LJ tried to warn against the hindsight bias, the German Federal Court of Justice stated that only from a retrospective view, one could be sure what was the closest prior art. However, regarding whether there was enough motivation to separate the enantiomer, the U.S. Federal Circuit seemed to have a different view from the German Federal Court of Justice, and this issue will be discussed further at IV.B.

140 Generics, the House of Lords, *supra* note 98, at para 61.

141 *Id.*, paras 61-65.