

b) *Enantiomer Invention – Escitalopram Decision*

The Federal Patent Court held that it was obvious to resort to the method of chiral chromatography to separate the enantiomers.

The Federal Court of Justice agreed that a person skilled in the art had reason at the date of priority to attempt to produce or isolate the citalopram's enantiomers since it was known that one enantiomer can have a better effect and other might have the opposite or side effect.¹¹³ However, based on the fact that there was no obvious way to obtain the escitalopram at the date of priority; that it was not certain which way would provide industrially useful scale production; that there was not enough motivation to choose the method; that there was uncertain expectation of success; and that there were many failures to separate it, the Court held that the invention is not obvious.¹¹⁴

2. From the U.S. Perspective

Nonobviousness has been a much more difficult requirement to meet than the novelty requirement,¹¹⁵ and in the U.S., after the KSR decision, it has been hotly discussed whether this Supreme Court decision has changed the law of obviousness.¹¹⁶

a) *Markush Claim – Olanzapine Decision*

The U.S. Federal Circuit held that several prior art references, in fact, *taught away* from exploring the compounds which did not possess an electron-withdrawing group in one benzene ring, where olanzapine exactly has a hydrogen atom.¹¹⁷ On the one hand, he recognized the *structural similarity* with a compound which has an ethyl group ('ethyl-olanzapine') instead of a methyl group of olanzapine; on the other hand, Judge Rader addressed that patentability for a chemical compound did not depend only on structural similarity, but also accounted for the unexpected

113 Escitalopram, Federal Court of Justice, *supra* note 24, at paras 37-38; *But see also Id.*, paras 39-41 (noting that there was no overwhelming need to separate the enantiomer.).

114 *Id.*, paras at 42-65.

115 See e.g., Miles J. Sweet, *The Patentability of Chiral Drugs Post-KSR: The More Things Change, the More They Stay the Same*, 24 Berkeley Tech. L.J. 129, 136 (2009).

116 See e.g., Jonathan M. Spenner, *Obvious-to Try Obviousness of Chemical Enantiomers in View of Pre-and Post-KSR Analysis*, 90 J. Pat. & Trademark Off. Soc'y, 477, 478-479 (2008).

117 Eli Lilly, *supra* note 73, at para 40.

beneficial significant properties which might render the invention to be nonobvious.¹¹⁸ After he noted the similarity with the case of *Yamanouchi Pharm. Co., Ltd. V. Danbury Pharmacal*,¹¹⁹ Inc., he also stated that the defendants did not sufficiently show the motivation for a person skilled in the art to select the above ‘ethylolanzapine’ as a lead which did not contain an electron-withdrawing group.¹²⁰ This analogy is interesting, since in *Yamanouchi* an entire complex combination was required; selecting and combining separate parts of two embodiments followed by further chemical reactions to produce the patented compound; however, there was only a single difference between the compounds in the prior art (ethyl group) and that in the patent at issue (methyl group). While citing *Yamanouchi* again, the Judge stated that to make the combination as a whole be obvious is not the mere identification in the prior art of each component, but rather a motivation to select the reference and to combine them in the particular claimed manner to reach the claimed invention.¹²¹ One may consider this was even so because it was held before *KSR v. Teleflex* in 2007.¹²² The court held that it was not obvious based on the above ‘teaching away’ and extensive ‘secondary considerations of nonobviousness’ such as; (i) a long-felt and unmet need; (ii) failure of others; (iii) industry acclaim; and (iv) unexpected results.

b) *Enantiomer Invention – Escitalopram Decision*

The District Court found that the alleged prior art did not provide a reasonable expectation of success to obtain the enantiomer for similar reasons to those of enablement regarding the same prior art.¹²³ The Court also found that one of ordinary skill in the art at the time of the invention would generally have been motivated to develop new compounds rather than undertake the difficult and unpredictable task of resolving a known racemate.¹²⁴

118 *Id.*, at paras 42-44.

119 *Yamanouchi Pharm. Co., Ltd. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1344 (Fed. Cir. 2000) (holding that [The ANDA filer] did not show sufficient motivation for person skilled in the art at the time of invention to take any necessary steps to reach the patented invention from the prior arts).

120 Eli Lilly, *supra* note 73, at para 45.

121 *Id.*, at para 47.

122 *KSR Int'l Co. v. Teleflex Inc.*, (hereinafter, ‘KSR’) Apr. 30, 2007, 127 U.S. 1727 (2007) (holding that TSM(teaching, suggestion, and motivation test) test provides helpful insights, unless it is applied too rigidly).

123 Forest Labs., *supra* note 79, at 1267.

124 *Id.*; *Contra* German Federal Court of Justice’s position at III.C.1.b); *Contra* Jonathan J. Darrow, *The Patentability of Enantiomers: Implications for the Pharmaceutical Industry*, 2 STAN. TECH. L. REV. paras 21 and 39 (2007).

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.