

nonobvious the separation, the more likely the enantiomers are nonobvious over the racemate,<sup>212</sup> which seems to be confirmed in all three jurisdictions.<sup>213</sup>

## 2. Overcoming Obviousness

### a) *Teach away*

A prior art reference can be said to teach away from the invention when it “is discouraged from following the path set out in the reference, or would be led in a direction divergent from the path taken by the applicant.”<sup>214</sup> This is one significant factor to consider when determining obviousness<sup>215</sup> and is a common response to a validity attack on the grounds of obviousness.<sup>216</sup> Teaching away from the prior art reference was one of the main findings in the *Olanzapine* decision in three jurisdictions.<sup>217</sup>

### b) *Unexpected Results*

Showing unexpected substantially improved results can be a way of overcoming a *prima facie* case of obviousness.<sup>218</sup> For instance, an unexpected result would be a superiority of the invention in a characteristic which is shared with the prior art compounds. For a species claim, the superior unexpected activity over the genus can rebut a *prima facie* obviousness rejection against structural similarity. For enantiomer inventions, increased pharmacological activity can be an unexpected result. In addition, the Court in *Ortho-McNeil* also considered other factors like solubility as unexpected results.<sup>219</sup>

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212 See Spenner, *supra* note 116, at 489; see also Generics, the House of Lords, *supra* note 98, at para 61-65.

213 See *supra* III.C.1.b), III.C.2.b), and III.C.3.b).

214 *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

215 See e.g., Durham, *supra* note 28, at 111.

216 See e.g., Lance Leonard Barry, *Teaching a Way is not Teaching Away*, 79 J. Pat. & Trade-mark Off. Soc’y 867, 867 (1997).

217 See generally *supra* III.C.

218 See *In re Sony*, 54 F.3d 746, 750-751 (Fed. Cir. 1995).

219 See *Ortho-McNeil*, *supra* note 208, at 754-55 (holding that it would not have been expected that an enantiomer is “twice as potent, about ten times more soluble, and appreciable less toxic” than its racemate.).

### c) Other Secondary Considerations

Apart from unexpected results, scepticism of experts, long felt need, failures of others, copying, licensing, commercial success, and others are recognised in the U.S. as secondary considerations for nonobviousness.<sup>220</sup> The Federal Circuit exploited these considerations explicitly in the *Olanzapine* decision. Commercial success of selection inventions, however, is less likely to play a role as a secondary consideration.<sup>221</sup>

## 3. Considerations

### a) Person Skilled in the Art in the *Olanzapine* Decision

As discussed in III.B, the Courts provide special criteria for the novelty assessment of chemical inventions, especially enantiomer inventions, based on the “unpredictability” of chemical inventions. Since their effect is difficult to predict, a reasonable expectation of success plays an important role.

Picking up on the facts of the *Olanzapine* decision, the structural difference of olanzapine (-ethyl) from the closest compound (-methyl) is only one-carbon-shorter alkyl, and a prior art reference disclosed that this shorter alkyl substitution in position 2 of the thiophene ring appeared to increase the activity.<sup>222</sup> The German Federal Court of Justice held that this finding did not change the result since only very few substituents having a methyl group at the 2-position had been prepared because of the bad activity.<sup>223</sup> In this regard, this paper would like to argue that it might not have been easily judged whether the prior art sufficiently encouraged a person skilled in the art to substitute ethyl group for the methyl. This is because the level of skill of the person skilled in the art would be regarded differently from the Court’s finding, especially today.

Jacob LJ rejected defendant Dr. Reddy’s Labs’ argument that one skilled in the art would not bother with SAR (Structure-Activity Relationship) but press on with the actual Chakrabarti compounds because the skilled person was an academic who

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220 See generally, Martin J. Adelman, et al., *Cases and Materials on Patent Law* 343-347, (3d ed, 2009); See also Forest Labs *supra* note 79, at 1267.

221 See *supra* III.B.1.a)(1).

222 See *Olanzapine*, BGH, *supra* 112, at para 55.

223 *Id.* (noting that only 10 out of 48 compounds have no substituents at all (*Cf.* preferred group of compounds in prior art was one of compounds having halogen atom) and 8 out of above 10 have ‘ethyl’ group in position 2 of the thiophene ring.).