b) Enantiomer Invention – Escitalopram Decision[79]

The District Court found that the alleged prior art did not disclose 'substantially pure' Escitalopram and did not enable the person skilled in the art to obtain the product since the separation technique at the time of the invention was relatively new and unpredictable, and that the inventor himself failed to separate the enantiomer several times.[80]

Stating that it did not find errors in the District Court's conclusion, the Federal Circuit reconfirmed that since the prior art, which in effect even *did state* Escitalopram, *did not enable* the person skilled in the art to obtain the enantiomer, it *did not anticipate* the claimed invention.[81]

3. From the UK Perspective: "Parting from IG Rule"

A specific rule for selection inventions was developed from the early twentieth century on in the UK as established by Maugham J in *I.G. Farbenindustrie's A.G.'s Patent* case[82] (hereinafter "*IG Rule*"). This *IG Rule* stated three traditional requirements for the selection invention in the UK as follows: i) a selection patent to be valid must be based *on some substantial advantage* to be secured by the use of the selected members (the phrase will be understood to include the case of a substantial disadvantage to be thereby avoided); ii) *the whole of the selected members* must *possess the advantage* in question; iii) the selection must be in respect of *a quality of a special character* which can fairly be said to *be peculiar to the selected group*.[83] It had been well established, without distinguishing between novelty and non-obviousness,[84] until the *Olanzapine* decision, where the Court declared the end of the rule's life. As a result, when the invention can be found novel in the first place, it does not have to be considered any longer whether it is a valid selection invention according to the *IG Rule*.[85]

79 Forest Labs., Inc. v. Ivax Pharms., Inc., (hereinafter, 'Forest Labs.') 501 F.3d 1263 (Fed. Cir. 2007).
80 *Id.,* at 1265.
81 *Id.,* at 1268-69.
82 I.G. Farbenindustrie's AG's Patent 47 R.P.C. 289, 322-3 (1930).
83 *Id.*
84 *See Infra* note 96 and accompanying text.
85 *See e.g.,* Robert Fitt, *Selection Patents and Markush Claims in Europe,* 20 Biotech. L. Rep. 17, 18 (2010).

a) Markush Claim – Olanzapine Decision

(1) Patent Court Decision[86]

Floyd J noted that the Markush formula in the *Olanzapine* case was capable of encompassing many millions of compounds, and that the effect of this disclosure was at issue.[87] While citing the relevant EPO Boards of Appeal decisions, Floyd J confirmed that a prior disclosure did not take away the novelty of a claim to a specific compound unless the compound was disclosed in "individualized form" and attention would have focused on compounds actually described.[88] Floyd J further referred to the three general propositions of the *IG Rule* for selection inventions. However, he rejected this three steps test,[89] applied the standard approach to testing novelty, and held that the patent was novel.[90]

(2) Court of Appeal Decision[91]

Jacob LJ in his opinion firmly rejected the argument that "every chemical class disclosure discloses each and every member of the class" for two reasons: i) being an *a priori* consideration and ii) not being consistent with the jurisprudence of the Boards of Appeal of the European Patent Office, particularly the *Hoechst Enantiomers* decision.[92] With respect to the *a priori* consideration, he argued as follows:

> "An old question and answer runs as a follows: "Where does a wise man hide a leaf? In a forest." It is, at least faintly, ridiculous to say that a particular leaf has been made available to you by telling you that it is in Sherwood Forest. Once identified, you can of course see it. But if not identified you know only the generality: that Sherwood Forest has millions of leaves".[93]

This argument was in line with the separate judgement of Lord Neuberger.[94] While citing the EPO's Board of Appeal decision, Jacob LJ reiterated that "an anticipation

86 Dr Reddy's Laboratories Ltd v Eli Lilly & Company Ltd(hereinafter, 'Dr Reddy's Lab, Patent Court'),R.P.C. 19 (2008) (U.K.).
87 *Id.,* at para 79.
88 *Id.,* at paras 91-94; *See also supra* note 57, at 600 (In the Olanzapine*, Federal Court of Justice,* the court clearly stated that its position is in line with the EPO and UK jurisprudence, and referred to this part of the UK decision).
89 *See supra* note 82 and accompanying text.
90 Dr Reddy's Lab, Patent Court, *supra* note 86, at paras 109, 139; *See also* Brian Cordery et al., *Patent cases in 2008-Review of Patent Cases in English Courts in 2008,* 38 C.I.P.A. J. 110, 112 (2009).
91 Dr Reddy's Laboratories Ltd v Eli Lilly & Company Ltd (hereinafter, 'Dr Reddy's Lab, Court of Appeal'), EWCA Civ 1362 (2009), available at http://www.bailii.org/ew/cases/EWCA/Civ/2009/1362.html.
92 T 0296/87, O.J.EPO 195, 1990.
93 Dr Reddy's Lab, Court of Appeal, *supra* note 90*,* at paras 25-30.
94 *Id.,* at para 108.

is an 'individualised description' of the later claimed compound or class of compounds".[95]

Jacob LJ said that the "selection invention" rule of *I.G. Farbenindustrie's Patent* was developed to avoid a finding of anticipation, did not draw a distinction between lack of novelty and obviousness, and was too strict because it is difficult to show that a group (compound) has a 'substantial advantage' over the whole prior class without an enormous amount of experiments.[96] Jacob LJ determined that the IG rule was just 'a part of legal history', but not part of the living law (post-1977 law).[97] Lord Neuberger noted that this issue was "not dissimilar from the enantiomer/racemate issue"[98] and recognized the difficulty in the application of the I.G. rule where the prior class of compounds was very large.[99]

b) Enantiomer Invention – Escitalopram Decision

While citing *Synthon BV v Smithkline Beecham Plc*[100] , Lord Hoffmann restated that to anticipate a patent, the prior art must disclose the claimed invention and enable the ordinary skilled person to perform it, and that it is settled jurisprudence in the EPO[101] that disclosure of a racemate does not in itself amount to disclosure of each of its enantiomers.[102] Regarding the plaintiff's argument that claim 1 is not only directed to the isolated enantiomer, Lord Hoffmann said that the claim did not include an unresolved part of the racemate, based on the title of the patent ('new enantiomers and their isolation') and the knowledge of a person skilled in the art.[103] Jacob LJ stated further that this was a pure question of construction, and that how much more than 50% of the (+) enantiomer must have been present for a product in order to fall within the claim was, simply a moot point in the validity court.[104] The Patent Court already had held that the claims were novel, and there was no further discussion in the upper court. Since the challenge based on lack of

95 *Id.,* at para 30.
96 *Id.*, at paras 36-39; This issue also may be discussed at *infra III.C.3.a)(2.)*.
97 *Id.*, at para 37; *See also* Mannual of Patent Practice – UK Patents Act 1977, paragraph 3.89-3.90 (July 2010).
98 Generics v Lundbeck, the House of Lords, (hereinafter, 'Generics, the House of the Lords') R.P.C.13 (2009) (U.K.).
99 *Id.*, at paras 103-104.
100 Synthon BV v Smithkline Beecham Plc, the House of Lords, Oct. 20, 2005, R.P.C. 10, (2006)(U.K.).
101 Generics v Lundbeck (hereinafter, 'Generics, Court of appeal'), R.P.C. 19 (2008) (U.K.); Lord Hoffmann also cited the decisions T 296/87 (OJ 1990, 19, point 6.2), T 1048/92 and T 1046/97.
102 *Id.,* at para 9.
103 *Id.*, at paras 10-13.
104 *Id.,* at para 50.

novelty had failed in both courts below, it was not renewed before the House of Lords.[105]

4. Summary

Whereas a specific prior art disclosure can take away the novelty of a generic claim, making it unpatentable, the reverse situation is more complicated.[106] In Germany, it seems that the Federal Court of Justice parts from the Fluoran decision, where a Markush claim disclosure in the prior art would be enough to be a novelty-destroying prior reference, and even selection of one out of two would be novel, unless the selected compound was enabled in the prior art. In the U.K., while the court declared its own old I.G. Rule on selection inventions as a part of history, a selection invention no longer has to satisfy this Rule, making it easier to meet the novelty requirement. In the U.S., the novelty requirement for an enantiomer was reconfirmed as having to be enabled by the invention, and for an invention claimed as Markush type it seems to depend on the finite number of class or compounds, which shifts the discussion to whether the non-obviousness requirement is met. Overall, thanks to the much lowered bar of novelty in major jurisdictions, challenging novelty of a selected class (compound, enantiomer) out of a Markush type disclosure, or even out of two genus (racemate) has become more difficult than ever.

C. Nonobviousness Requirement

1. From the German Perspective

a) Markush Claim – Olanzapine Decision[107]

The Federal Court of Justice held that olanzapine was not obvious to the person skilled in the art over neither 'Chakrabarti' document nor other prior art in any other manner.[108]

Interestingly enough, while doing so, the Federal Court of Justice confirmed that its position was not in line with the EPO's to determine obviousness, in "only"

105 Generics, the House of the Lords, *supra* note 98, at paras 11, 43, 65 (also noting that the patentee would not have intended to cover racemate.).
106 1 Donald S. Chisum, Chisum on Patents § 3.02[2][a]- [b] (2010).
107 Since the Federal Patent Court did not excessively discussed about the inventive step of the invention, the Federal Court of Justice decision would only be addressed under this section; *See also* Olanzapine, Federal Patent court, *supra* note46, at 4811.
108 *See* Olanzapine, Federal Court of Justice, *supra* note 57, at 601.