

## 2. From the U.S. Perspective

The terminology ‘selection invention’ has not been frequently referred to in U.S. Courts,<sup>72</sup> which instead use the expression ‘genus/species’. However, Federal Circuit has also decided on this matter.

### a) *Markush Claim – Olanzapine Decision*<sup>73</sup>

In its *Olanzapine* decision, the Federal Circuit restated that “anticipation is a question of fact, including whether or not an element is inherent in the prior art and the prior art reference must disclose each and every feature of the claimed invention, either explicitly or inherently”.<sup>74</sup> The defendants argued that ‘Chakrabarti’ anticipated the patent in view of *In re Petering*<sup>75</sup> and *In re Schaumann*.<sup>76</sup> In *In re Petering* the Court held that a prior art reference disclosing a limited genus of twenty compounds rendered every species within the genus unpatentable. In *In re Schaumann*, the Court held that when a small genus places a claimed species in the possession of the public, the species was obvious even if the genus were not small enough to reject. However, in his opinion Judge Rader distinguished the *Olanzapine* case, where Chakrabarti disclosed millions of compounds, from the above two cases, where limited numbers of specific preferences, namely ‘some 20 compounds’, or ‘14 compounds’ were disclosed, respectively. He noted that Chakrabarti in the *Olanzapine* case had not “expressly spelled out a definite and limited class of compounds that enabled a person of ordinary skill in the art to at once envisage each member of this limited class”.<sup>77</sup> Judge Rader also stated that “one would have to depart from the teaching of the article and recombine the components of the specific illustrative compounds *with hindsight*” to make the olanzapine starting from the Chakrabarti disclosure<sup>78</sup>

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72 But see *Eli Lilly and Company v Zenith Goldline Pharmaceuticals, Inc.*, 364 F.Supp 2d 820, 897 (S.D. Ind. 2005) (stating that selection inventions, also referred to as “improvement patents,” are a normal consequence of technological progress and are expressly provided for by statute. 35 U.S.C. § 101 (“Whoever invents . . . any new and useful . . . composition of matter, or any . . . *improvement thereof* . . . may obtain a patent therefor . . .”)) (emphasis added).

73 *Eli Lilly and Company v Zenith Goldline Pharmaceuticals, Inc.*, 471 F.3d 1369 (Fed. Cir. 2006) (hereinafter, ‘Eli Lilly’). In fact, this was the first decision among three jurisdictions which upheld the validity of *Olanzapine* patent.

74 *Id.*, at 1375.

75 *In re Petering*, 301 F.2d 681 (C.C.P.A. 1962).

76 *In re Schaumann*, 572 F.2d 312 (C.C.P.A.1987).

77 *Eli Lilly*, *supra* note73, at 1376.

78 *Id.*, at 1377.

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.<sup>80</sup>

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.<sup>81</sup>

### 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<sup>82</sup> (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*.<sup>83</sup> It had been well established, without distinguishing between novelty and non-obviousness,<sup>84</sup> 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*.<sup>85</sup>

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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).