III. Jurisprudence on the patentability requirements for selection inventions

Under this title, it will be discussed what the courts in three major jurisdictions have decided about the patentability requirements of selection inventions, with a view to the recent *Olanzapine* and *Escitalopram* decisions.

A. Facts of the Cases

1. Facts in Olanzapine

The patent in suit was Eli Lilly's patent (EP 0,454,436, US 5,229,382) on a single chemical compound olanzapine, which is a widely prescribed anti-psychotic agent used for the treatment of schizophrenia. The most pertinent prior art reference disclosed a general formula covering theoretically many millions of individual compounds; identified around 100 compounds by name and 15 compounds prepared; but did not disclose olanzapine specifically. Another prior art document disclosed Structure-Activity-Relationship observations of a group of compounds and several closely neighboring compounds to olanzapine, but neither enabled nor even disclosed olanzapine.

The questions at issue were the effect of a particular kind of disclosure, namely, a "Markush" formula which could cover many millions of compounds, the consideration of structural similarity of compounds, and whether a person skilled in the art can modify or supplement the prior art reference's teaching to determine the disclosure of prior art. In the UK, the law of novelty in the context of selection patents was particularly debated in relation to its *IG Rule*.[39]

2. Facts in Escitalopram

The challenged patent was EP 0,347,006 (U.S. RE34,712) belonging to Lundbeck on the (S)-enantiomer of citalopram (Escitalopram), a selective serotonin reuptake inhibitor anti-depressant. The most relevant prior art reference was a patent disclosing a general formula of the racemate mixture of (S)- and (R)- enantiomers.

39 *See infra* III.B.3.

The main issues for debate were whether the prior disclosure of racemate allowing a person skilled in the art clearly to recognize two enantiomers was enough to destroy the novelty of an enantiomer, and it should have been enabled in the prior art. In the UK, whether or to what extent a claim directed to more than one product or process should have been enabled by the description, known as "Biogen insufficiency" was argued as well.

B. Novelty Requirement

1. From the German Perspective: "Parting from Fluoran"

Selection patents have been granted in Germany from the nineteenth century on.[40] After the introduction of claims directed to chemical compounds *per se* on January 1, 1968, however, there has been much discussion about whether the general principles of German Patent Law can be directly applied to chemical compound patents.[41] Before the *Olanzapine* decision of the Federal Court of Justice, chemical selection inventions from the genus had not been considered as novel, since the general formula was regarded as disclosing the individual species according to the *Fluoran* decision.[42] Before the *Olanzapine* decision, this approach regarding the generic disclosure[43] was opposite to the position of the EPO Boards of Appeal. The Federal Court of Justice confirmed its new position on this issue in the *Escitalopram* decision, the first decision on the patentability of an enantiomer.[44]

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40 *See* Volker Vossius, *Selection Inventions in Chemistry According to German Patent Law – A problem of Novelty*, 59 J. Pat. Off. Soc'y 180, 180-181 (1977).

41 *Id.*

42 Fluoran, *supra* note 26.

43 *See e.g.,* T 651/91, available at http://legal.european-patent-office.org/dg3/biblio/t910651du1.htm (confirming that a generic disclosure does not normally take away the novelty of any specific example falling within that disclosure. The board further added that a disclosure could be generic even where it only left open the choice between two alternatives).

44 Wolrad Prinz zu Waldeck und Pyrmont, *BGH: Enantiomer eines bekannten Razemats kann patentiert warden- „Escitalopram "(BGH : enantiomer of a known racemate can be patented – " Escitalopram "),* (Gewerblicher Rechtsschutz und Urheberrecht, Praxis im Immaterial- und Wettbewerbsrecht) [GRUR-Prax], 13 (2010) (stating that the Escitalopram decision seems to show that the Court continues its new line regarding the concept of disclosure stated in its Olanzapine decision.).