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.).

### *a) Markush Claim – Olanzapine Decision*[45]

#### *(1) Federal Patent Court Decision*[46]

The *Olanzapine* patent was held invalid mainly based on anticipation by a prior art reference[47] (hereinafter 'Chakrabarti') that disclosed a genus of compounds as a general formula[48] covering olanzapine and 45 individual compounds. However, Chakrabarti disclosed explicitly neither the olanzapine itself nor indication thereof. The Federal Patent Court referred to the "electric plug-in connection" decision of the Federal Court of Justice :[49]

> "According to the decision "*Elektrische Steckverbindung*" (electric plug-in connection), the disclosure of a previously published document is not limited to a literal description, but also comprises modifications that are obvious to the skilled person from the whole context of the document, in such a manner that they will become evident to him when carefully studying them and focussing more on their obvious meaning than on the words, i.e. when "*reading between the lines*", *even if he is not aware of that*.[50]"

Applying this rule, the Court stated that the "novelty of a chemical compound is to be regarded as anticipated if the skilled person can derive from the prior publication a clear indication to this specific compound, i.e. if he will read this compound between the lines without difficulty, and if due to this indication he will be capable of obtaining said substance without difficulty".[51] In addition, the court explicitly mentioned that it was not required that this substance had *de facto* already been produced in line with the *α-Aminobenzylpenicillin* case[52] and the *Fluoran* case.

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45 In a nut shell, the Federal Patent Court revoked the Olanzapine patent. The patentee appealed to the Federal Court of Justice. While this appeal was pending, the patentee applied to the Düsseldorf District Court for preliminary injunction for infringement of the Olanzapine patent by a competitor, which was denied. The patentee filed an appeal also against this decision, whereupon surprisingly enough and for the first time in history, the Düsseldorf Court of Appeal granted the injunction, although the patent had been revoked in the first instance, and the first instance decision had not yet been reversed by the Federal Court of Justice. The Federal Court of Justice finally held that the Olanzapine patent was valid.

46 Bundespatentgericht (BPatG) [Federal Patent Court] Jun. 4, 2007, *Neuheitsschädliche Vorwegnahme einer chemischen Verbindung zur Herstellung eines Arzneimittels (Novelty-destroying anticipation of a chemical compound for the preparation of a medication)*, Neue Juristische Online Zeitschrift [NJOZ], 4786, 2007 (Ger.); Case number 3 Ni 21/04 combined with case number 3 Ni 41/06. (hereinafter, "*Olanzapine, Federal Patent Court*")..

47 This prior art is the scientific article: Chakrabarti et al., *4-Piperazinyl-10H-thieno[2,3-b][1,5]benzodiazepines as Potential Neuroleptics*, 23 J. Med. Chem. 878, 878-884 (1980).

48 See Olanzapine, Federal Patent Court, *supra* note 46, at 4796-97 (the defendant argued Chakrabarti does not disclose the general formula of the Markush formula type, but the court disagreed. ).

49 Bundesgerichtshof [BGH] [Federal Court of Justice] Jan. 17, 1995, GRUR, 330, 1995 (Ger.).

50 *See* Olanzapine, Federal Patent Court, *supra* note 46, at 4792.

51 *Id.*

52 Bundesgerichtshof [BGH] [Federal Court of Justice] May 30, 1978, GRUR, 696, 698, 1978 (Ger.).

According to *Fluoran*, it is decisive when determining novelty, whether a person skilled in the art will be capable of implementing the invention relating to this compound and of preparing the compound without difficulty, on the basis of the indications given with regard to the contested compound of the prior publication.[53]

The Court noted that in this case, a skilled person would be able to obtain all necessary information[54] to manufacture olanzapine from Chakrabarti, and therefore it is a novelty-destroying disclosure of olanzapine.[55] The Court stated that based on the further disclosures of Chakrabarti such as structure and activity relationship, three directly neighboring compounds, and manufacturing procedure, olanzapine was anticipated by Chakrabarti.[56]

*(2) Federal Court of Justice Decision*[57]

In contrast to the holding of the Federal Patent Court, the Federal Court of Justice held in the appeals decision that it was not necessary to determine in what form a person skilled in the art can perform a certain general teaching, *using his technical knowledge, or how he can modify this teaching*, if necessary.[58] The important point is *exclusively what a person skilled in the art derives from the prior publication as the content of the specific (general) teaching*.[59] The court went on that the deciding factor was rather what can be "*directly and unambiguously" derived from a document*, from the point of view of a person skilled in the art, which is in line with the jurisprudence of the Boards of Appeal of the European Patent Office.[60]

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53 See Olanzapine, Federal Patent Court*, supra* note 46, at 4798.

54 The court illustrated this information as follows: lead structure of formula I, a group of only 12 compounds, 3 specific compounds immediately "neighboring" olanzapine, neuroleptic activity of compounds which is useful for treating diseases such as schizophrenia.

55 *See* Gerhard Barth, et al., *The Olanzapine Patent Dispute: German Court Grants a Preliminary Injunction on a Patent Invalidated by the First-Instance Federal Patent Court*, 27 Biotech. L. Rep. 532, 532-533 (2008).

56 *See* Olanzapine, Federal Patent Court, *supra* note 46, at 4795-96 (e.g.: … between these three directly adjacent compounds, there is one gap which is to be filled by olanzapine...).

57 Bundesgerichtshof [BGH] [Federal Court of Justice] (hereinafter, "Olanzapine, Federal Court of Justice") Dec.16, 2008, IIC 596, 2009 (Ger.).

58 *Id.*, at 599.

59 *Id.*

60 *Id.*; The Federal Court of Justice cited the relevant BoA decision as follows: 1982 OJ 296 – Diastereomers/ BAYER; 1984 OJ 401 – Spiro compounds/CIBA GEIGY; 1988 OJ 381 – Xanthines/DRACO; 1990 OJ 195 – Enantiomers/HOECHST; decision dated 19 February 2003, T 94-/98 – Diastereomers of 3-cephem-4-carboxylic acid-1-(isopropoxycarbonyloxy) ethyl ester/HOECHST; *See also* Peter Meier-Beck, Die *Rechtsprechung des Bundesgerichtshofs zum Patent und Gebrauchsmusterrecht im Jahr 2008[The jurisprudence of Federal Court of Justice for patent and utility model law in 2008]*, GRUR 893, 895 (2009) (Ger.).

The Court stated that the determination of what was not explicitly mentioned in the characteristics of the claim and in the text of the specification but was obvious for a person skilled in the art to implement the teaching being protected and therefore did not require any special disclosure is, not aimed at supplementing the disclosure with the technical knowledge. The purpose is not different from the determination of the meaning of a claim, i.e. that technical information which a person skilled in the art derives from the source with the background of his technical knowledge.[61] Citing the *Elektrische Steckverbindung* decision, the Court held that modifications would only be allowable, if the modifications were so obvious to the person skilled in the art, in the overall context of the document, that they were easily evident to him when reading the document attentively, paying attention less to the words than to their meaning, so that he essentially 'reads them along' in his thoughts.[62]

The Court, then, applied this principle to the chemical compound invention as follows: "The *decisive factor is whether the concrete compound is disclosed* or not, and for this purpose, information that easily enables the person skilled in the art to specifically implement the invention relating to this chemical compound, i.e. to obtain the specific substance, is required".[63] The Court clarified its position against the *Fluoran* decision by explaining that the *Fluoran* case was held under the Patent Act of 1968 and that the Court did not adhere to this decision for the current law. The Court held further that a not explicitly disclosed individual compound could only be considered to have been disclosed *if a person skilled in the art "reads it along"* in the sense of the *Elektrische Steckverbindung* decision, for example because it was familiar to him as the usual implementation of the stated general formula, and therefore occurred to him as also having been meant when he read the general formula.[64] Otherwise, the disclosure of the individual compound was necessary to destroy novelty.[65]

61 *Id*.
62 *Id.*
63 *Id.*, at 600.
64 *Id.*
65 *Id.*

### b) *Enantiomer Invention – Escitalopram Decision*

#### *(1) Federal Patent Court Decision*[66]

The Federal Patent Court stated that the patent was invalid for lack of novelty. A chemical compound having one chiral atom was no longer novel where claimed in the form of an enantiomer, if specific indication of the enantiomer in a prior publication had been given, and if the skilled person was able to produce the compound on the basis of this indication and his general knowledge.[67] The court found that the person skilled in the art would easily have been able to separate the Escitalopram from the racemic mixture disclosed in the prior art patent specification in a way which was commonly used before the priority date of the *Escitalopram* patent.[68]

#### *(2) Federal Court of Justice Decision*

While admitting that the person skilled in the art on the basis of his general knowledge had been able to recognize that citalopram having a chiral carbon had two different structures, the Federal Court of Justice stated that this fact does not lead to a disclosure which is detrimental to novelty.[69] Citing the *Olanzapine* decision, the Court said that, in order to *'make them* [the individual enantiomers] *available' to the skilled person for the purpose of novelty examination,* further information was as a rule required, in particular with regard to their *individualisation*.[70] The Court concluded that since the prior document did not directly and unambiguously disclose the individual enantiomers to the person skilled in the art and since he had to find a way to resolve the racemate, the prior patent was not detrimental to novelty.[71]

66 Bundespatentgericht (BPatG) [Federal Patent Court] Apr. 24, 2007, Beck-Rechtsprechung [BeckRS], 14624, (2007) (Ger.).
67 *Id.,* at para II, especially II b).
68 *Id.*
69 Escitalopram, Federal Court of Justice, *supra* note 27, at para 30.
70 *Id.,* para 33.
71 *Id.*, para 35.

## 2. From the U.S. Perspective

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

### *a) Markush Claim – Olanzapine Decision[73]*

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".[74] The defendants argued that 'Chakrabarti' anticipated the patent in view of *In re* Petering[75] and *In re* Schaumann.[76] 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".[77] 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[78]

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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.