

novelty had failed in both courts below, it was not renewed before the House of Lords.<sup>105</sup>

#### 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.<sup>106</sup> 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*<sup>107</sup>

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.<sup>108</sup>

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”

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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.

applying the so-called “problem-solution approach<sup>109</sup>” which started from its fundamental step to identify the ‘closest prior art’. While disagreeing with the Federal Patent Court’s assumption that a person skilled in the art would have chosen Chakrabarti first, the Court stated that there was no such higher ranking of the “closest prior art”; and only from a retrospective view it became clear what prior publication came closest to the invention and how an inventor could have approached the problem, in order to arrive at the solution according to the invention.<sup>110</sup> It seems that the court is concerned about the risk of hindsight if as a starting point for the determination of an inventive step, one selects the closest prior art. The Court also stated that the selection of the starting point therefore required the justification that generally lay in the efforts of a person skilled in the art to find a better solution for a specific purpose than the known state of the art makes available.<sup>111</sup> While elaborating the structure and activity relationship of the disclosed compounds, the Court held that since ‘Chakrabarti’ taught away or provided information which was out of the scope to make skilled person be interesting or promising to reach the olanzapine, it was not obvious.<sup>112</sup>

The Court also stated that obviousness could only be confirmed if an ordinary person skilled in the art *could* not only have had obtained the invention by combining e.g. two citations, but also, that a suggestion/motivation (“hint”) to do that combination would be necessary to come to the conclusion of obviousness. The Court confirmed its position, as already expressed earlier, that this “hint”, however, would not have to be in the to be combined citations of prior art themselves, but also could be found in the general mindset and knowledge of the ordinary person skilled in the art. Insofar, the Court’s position is, and always has been, in line what KSR vs. Teleflex in U.S. has taught, different from the EPO’s position according to which the “hint” has to be in the citations themselves.

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109 Guidelines for Examination in EPO C-IV. 11.5 “*Problem-and-solution approach*” (stating that in order to assess inventive step in an objective and predictable manner, the so-called “problem-and-solution approach” should be applied. Thus deviation from this approach should be exceptional. In the problem-and-solution approach, there are three main stages: (i) determining the “closest prior art”, (ii) establishing the “objective technical problem” to be solved, and (iii) considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.).

110 Olanzapine, Federal Court of Justice, *supra* note 57, at 601.

111 *Id.*, at 601-602.

112 Bundesgerichtshof [BGH] [Federal Court of Justice] (hereinafter ‘Olanzapine, BGH’) Dec. 16, 2008, BeckRS 05422, paras 52-57, 2009 (Ger.).

## b) *Enantiomer Invention – Escitalopram Decision*

The Federal Patent Court held that it was obvious to resort to the method of chiral chromatography to separate the enantiomers.

The Federal Court of Justice agreed that a person skilled in the art had reason at the date of priority to attempt to produce or isolate the citalopram's enantiomers since it was known that one enantiomer can have a better effect and other might have the opposite or side effect.<sup>113</sup> However, based on the fact that there was no obvious way to obtain the escitalopram at the date of priority; that it was not certain which way would provide industrially useful scale production; that there was not enough motivation to choose the method; that there was uncertain expectation of success; and that there were many failures to separate it, the Court held that the invention is not obvious.<sup>114</sup>

## 2. From the U.S. Perspective

Nonobviousness has been a much more difficult requirement to meet than the novelty requirement,<sup>115</sup> and in the U.S., after the KSR decision, it has been hotly discussed whether this Supreme Court decision has changed the law of obviousness.<sup>116</sup>

### a) *Markush Claim – Olanzapine Decision*

The U.S. Federal Circuit held that several prior art references, in fact, *taught away* from exploring the compounds which did not possess an electron-withdrawing group in one benzene ring, where olanzapine exactly has a hydrogen atom.<sup>117</sup> On the one hand, he recognized the *structural similarity* with a compound which has an ethyl group ('ethyl-olanzapine') instead of a methyl group of olanzapine; on the other hand, Judge Rader addressed that patentability for a chemical compound did not depend only on structural similarity, but also accounted for the unexpected

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113 Escitalopram, Federal Court of Justice, *supra* note 24, at paras 37-38; *But see also Id.*, paras 39-41 (noting that there was no overwhelming need to separate the enantiomer.).

114 *Id.*, paras at 42-65.

115 See e.g., Miles J. Sweet, *The Patentability of Chiral Drugs Post-KSR: The More Things Change, the More They Stay the Same*, 24 Berkeley Tech. L.J. 129, 136 (2009).

116 See e.g., Jonathan M. Spenner, *Obvious-to Try Obviousness of Chemical Enantiomers in View of Pre-and Post-KSR Analysis*, 90 J. Pat. & Trademark Off. Soc'y, 477, 478-479 (2008).

117 Eli Lilly, *supra* note 73, at para 40.