

It can be understood that the decisions discussed here are possibly based on the policy reason that we need at least these incremental innovations. However, it is time to reconsider whether this policy may lead to innovative companies concentrating their research on these fields rather than on drug discovery which is entirely new, and therefore preventing the development of innovative medications in the future.

4. Conclusion

The determination of nonobviousness is a rather complicated and difficult task. In addition, the test for nonobviousness depends more on the difference between the facts of the cases than the test for novelty. Regarding the nonobviousness of enantiomer patents in particular, it was argued that the decisions of the Federal Circuit on this issue have been mixed although they may not be regarded as necessarily inconsistent with each other, considering different evidentiary records to determine the existence of a motivation for the person skilled in the art to separate enantiomers with a reasonable expectation of success, the teaching in the prior art, the existence of superior properties of isolated enantiomers, and so on.^{231, 232} As Eisenberg said, it is not easy to find a meaningful guideline for the question of obviousness²³³ in this regard. In line with these issues, the particularity of the pharmaceutical industry in terms of low predictability and the level of skill of a person skilled in the art also need to be considered.

C. Impact of Lowering the Bar for the Patentability of Selection Inventions

Based on the enablement issue in anticipation, novelty at least is not a tough hurdle for a selected species from a disclosed broad Markush type claim or an enantiomer from a disclosed mixture of two enantiomers. This may increase the number of newly granted selection patents. The possible impact of patentability of selection inventions after grant is discussed below.

231 See Rebecca S. Eisenberg, *Pharma's Nonobvious Problem*, 12 Lewis & Clark L. Rev. 375, 424-427 (2008).

232 See also Rochelle Cooper Dreyfuss, *Nonobviousness: A Comment on Three Learned Papers*, 12 Lewis & Clark L. Rev. 431, 441 (2008) (noting that the Federal Circuit's view on nonobviousness of enantiomer patents seems to be remarkably flexible).

233 Eisenberg, *supra* note 231, at 427.

1. Easier Extension of Exclusive Right: “Evergreening” or “Life-Cycle Management”

This impact is increased if a selection invention is filed by the patentee of the basic patent, which is frequent because the basic patent holder has more and better knowledge and experience regarding the substance. This is because after exploiting his exclusive right and keeping third parties from using the basic patent, the exclusivity would be prolonged based on the grant of selection patents. This issue is even more important in relation to enantiomer patents because the grant of such patents would result in the issuance of a supplementary protection certificate which provides further market exclusivity²³⁴ in addition to the patent monopoly. This phenomenon in the pharmaceutical field is called an “evergreening” strategy (normally by generic companies) or a “life-cycle management” strategy (generally by innovative companies), which is used by innovative companies to prolong the market exclusivity of their products to the extent the law allows.²³⁵

With regard to this issue, Floyd J stated in the *Olanzapine* decision that the basic patent prevented a third party from bringing olanzapine to the market²³⁶ until the expiry of the basic patent. Lord Neuberger in the same case stated that it was unfair and inappropriate that Lilly should be able, in effect, to re-monopolise olanzapine in 1990 given that they had already done so in 1978 with the grant of its basic patent. Therefore, the impact of lowered bar for patentability of selection inventions would provide a much easier *de facto* extension of the exclusive right to the compound, given that the selection invention is held by the basic patent holder.

2. More Limitations to Exploiting Selection Patents

a) *Scope of a Selection Invention over a Basic Patent*

Before discussing the matter of exploitation of selection patents, the scope of selection patents and basic patents in force is clarified herein. The decisive factor for defining the scope of a patent is not what was invented, but what was claimed and granted.²³⁷ In other words, the scope of a patent is determined by the claim lan-

234 Escitalopram, Federal Court of the Justice, *supra* note 27, paras 66-77.

235 Michael Enzo Furrow, *Pharmaceutical Patent Life-Cycle Management After KSR v. Teleflex*, 63 Food & Drug L.J. 275, 276-277 (2008).

236 See Dr Reddy’s Lab, Patent Court, *supra* note 86.

237 Oberster Gerichtshof [OGH] [Supreme Court] Apr. 22, 1986, docket No. 4 Ob 319/86, IIC 80 (1989) (Austria)(holding that the deciding factor is not what was invented, but what was claimed and granted).