

Abstract

Selection inventions can be defined as inventions that have a specific concept selected from a prior broader or larger generic concept of invention, and that have superior or advantageous properties to the broader concept which have not been disclosed in the prior art. Considering innovations are mostly derived from existing technologies, selection inventions are typical examples. As recognized from the *IG Rule* in the U.K. jurisprudence which does not clearly distinguish novelty from obviousness, however, the novelty of selection inventions has been debated from the very beginning of their history. The importance of selection inventions, especially in the pharmaceutical industry is higher than previously, since this industry has seen R&D expenditure soar and the dearth of new medical entities over the last decade. According to the recent report of the European Commission on a pharmaceutical sector inquiry, this trend seems to be proven to some extent.

Selections in *Olanzapine* and *Escitalopram* cases, were directed to a species selection from a broad Markush type disclosure or an enantiomer selection from a racemate containing two enantiomers, respectively. Novelty of selection inventions was the core issue in the courts, since the prior art reference did disclose either the genus of a claimed compound as a broad Markush type claim covering species (*Olanzapine*) or a racemic mixture of two enantiomers (*Escitalopram*), but both did not enable the person skilled in the art. Overall, the courts held that the disclosure of a broad genus or a racemate itself is not sufficient to anticipate a claimed invention, and should provide “direct and unambiguous” disclosure or “individualized description” of claimed compound. For this purpose, the claimed compound should be enabled in the prior art reference. In *Olanzapine*, both the highest courts in Germany and U.K. parted from their old case law, namely, *Fluoran* regarding the novelty over genus disclosure and its *IG Rule* on special requirements on patentability of selection inventions. The assessment of disclosure in prior art references was heavily based on the difficulty of preparing the claimed compound.

The next issue before the courts was, of course, the obviousness requirement. Obviousness could be assumed based on the structural similarity of compounds, but this assumption was reverted in all courts again. It was interesting to see that the German Federal Court of Justice did not agree with the EPO’s so called ‘problem-solution approach’ while alerting hindsight bias. But, not surprisingly various elements for determining obviousness were assessed in courts, like insufficient motivation to reach the claimed compound, teach-away, hindsight issues, unex-

pected results and the like. In *Escitalopram*, the previous failures to obtain the claimed compound, i.e., the difficulty of preparation played an important role in determining nonobviousness over the prior art reference.

The novelty requirement has a fundamental function in the patent system, since it is required to prevent from re-monopolizing something that already exists in the public domain. Thus the change in novelty assessment can have a significant impact on patent law. Determining novelty involves several relative elements, and among those, the enablement requirement within the context of anticipation raises the following issues. Firstly, since the difficulty of obtaining a claimed invention is assessed in the novelty test, the same step can be taken again when determining obviousness. Secondly, given that a prior art reference is a basic patent, since both a basic and its selection patent cover the same compound (selected species), this failure of enablement in the context of patent-defeating purposes may also mean the failure thereof in the context of patent-obtaining purpose. Thirdly, this disclosure issue may impact other concepts of disclosures in patent law, such as validity of priority claims, support of amendment over the original disclosure, limitation or validity of patents, and so on.

Since the level of obviousness is judged by a person skilled in the art, the perception of this hypothetical person plays a key role in determining obviousness. It was suggested in this paper that the courts might define a person skilled in the pharmaceutical art differently from they have done. Regarding the obviousness of enantiomers, one may easily compare the difficulty to obtain one compound out of two to that out of millions. It is, of course, not easy to find a meaningful guideline for the question of obviousness.

The scope of selection patents falls within the scope of basic patents. In case both patents belong to the same patentee, this may possibly be an “evergreening” situation. If the patent holder of a selection invention is different, the freedom to exploit the later patentee’s exclusive right would be limited (so-called “blocking effect”) until the basic patent expires. This is even more so because a satisfactory solution, the compulsory license, has hardly been used. Thus, one may also wonder how much the increased number of selection inventions would be helpful to society.

Lastly, this paper would like to pose i) whether this lowered bar for the patentability of selection inventions would provide more incentives for companies to focus on second-generation inventions rather than first-generation inventions, thereby making less new medical entities available in the future; and ii) whether society is ready to avail of selection inventions by providing proper legal schemes which may allow patentees of selection inventions to make those inventions more available.