the single embodiment of the prior art reference (earlier patent) could have enabled a narrower claim scope in the earlier patent, covering at least the embodiment itself.

In the *Olanzapine* case, the issue went further, as is discussed in this paper.[172] That is, in case the earlier patent did not enable the later claimed invention because there was no single embodiment to do so in the earlier patent even with consideration of the common knowledge of a person skilled in the art, one may say that the whole claim of the earlier patent can not have been fully enabled. The implication of this will be discussed in detail in section IV.A.3.b).

There are several differences of enablement[173] between the patent-defeating context and the patent-obtaining context. Among them, the difference in the scope of enablement has several implications, and thus the impact of this requirement is further discussed below.

3. Implications of Enablement Requirement in Anticipation

The enablement requirement held by the *Olanzapine* decision and confirmed by the *Escitalopram* decision, brought us not only some clear guidelines to the novelty test, but also several impacts on the law of patentability on selection inventions. These impacts are further discussed.

a) The Test of Anticipation: Precedent Test of Obviousness?

As the German Federal Court of Justice said, novelty examination is a separate test to determine patentability[174] and is not a 'first step of examining obviousness'. However, by way of lowering the bar for novelty, the Courts seem not to sufficiently differentiate the test of novelty from that of obviousness.

In particular, the *Escitalopram* court made significant efforts to evaluate the difficulty of the resolution of citalopram *in order to assess novelty,* after admitting that it was apparent that a racemate of a chemical compound like citalopram had equal amounts of two enantiomers. In the end, the Court found that this did not lead to Escitalopram being anticipated. This could be interpreted as novelty being dependent on the difficulty of obtaining a claimed compound, based on the common

172 *See generally supra* III.A.1.
173 *See also* Mueller *supra* note 167 (asserting that different standards of enablement should be applied in each context.).
174 Olanzapine, the Federal Court of Justice, *supra* note 57, at 599.

knowledge of a person skilled in the art. The level of enablement of the prior art reference is determined in order to assess novelty.

Since the enablement requirement is considered when assessing novelty,[175] the determination of novelty has became more relative and, to some extent, similar to the test of obviousness. In the U.S., *prima facie* obviousness established based on the prior art disclosure of racemates and *de facto* disclosure of the enantiomer itself was rebutted based on no reasonable expectation of success and the difficulty of separation.[176] It may be difficult to differentiate between a skilled person not being able to obtain the claimed invention within the context of anticipation from there being no expectation of success to separate within the context of nonobviousness. This in turn tells us that the courts possibly do not clearly distinguish between the novelty and the nonobviousness requirements, which is contrary to what the German Federal Court of Justice has postulated.[177] It seems at least that the same test is repeated in both steps, or that both steps are determined by a single test for the assessment of patentability. Can it therefore be said that the test for novelty is placed in the broader context of the test for "inventive step"[178]?

b) A Possible Ground for Challenging the Basic Patent

Again, as the German Federal Court of Justice held, a prior art reference does not directly and unambiguously reveal an invention unless the publication makes it easily possible for the person skilled in the art to obtain it. Since the prior art reference in the *Olanzapine* case did not enable the claimed invention, it did not anticipate the invention (i.e. the single compound, olanzapine).[179] At this point, it is necessary to recall the definition of a selection invention. Since a selection invention (e.g. a compound) is an invention selected from the broader concept of an earlier invention (e.g. a Markush type claim), the scope of this invention, by definition, should fall into the scope of the earlier patent,[180] which is the case in the *Olanzapine* decision. Thus, both the selection patent claiming olanzapine and the earlier patent claiming the broader scope of invention cover the compound, olanzapine. This leads to the conclusion that the fact the earlier patent document cannot enable the selection invention in the anticipatory context would inevitably mean that the earlier patent application did not enable its own claimed invention at least

175 *See Infra* IV.A.2.
176 *See* Sweet, *supra* note 115, at 142; *See also* Forest Lab *supra* note 79, at 1268; *See also infra* IV.B.1.c).
177 Olanzapine, the Federal Court of Justice, *supra* note 57, at 599.
178 *See e.g.,* Tilmann *supra* note147, at 158-159.
179 *See supra* III.B.1.
180 *See e.g.*, Agranat et al., *supra* note 3.

in part (e.g. covering that compound). In other words, when the earlier patent fails to enable the later selection invention, in the patent-defeating enablement context, it fails to enable its own claims in part, in the patent-supporting enablement context. Given that the selection invention has been patented over the basic prior patent, the prior patent would be invalid at least with respect to a part of its claim scope, for insufficiency of its disclosure.[181] The selection invention then is not a dependent invention any more, and the owner of the selection invention does not need to license the basic patent. Other relevant issues will be further discussed in the next section.

c) Other Implications of the Rules for Disclosure in the Olanzapine Case

In the *Olanzapine* decision, the rules for 'disclosure' were explained in relation to anticipation. Further areas where the rules for disclosure play a role are: i) validity of priority claiming (priority application(s) v. application claiming the priority); ii) sufficiency of the disclosure (content of the application v. claim scope); iii) support for amendments (content of the application v. amended claim); and iv) limitation or validity of patent (content of the application v. patent).[182]

Let's have a look at these "concept of disclosure" issues while applying the *Olanzapine* case. Take a patent application, which has one independent Markush type claim theoretically covering several thousands of compounds and several dependent claims, and discloses 10 embodiments. For example, under the examination of sufficiency of disclosure, an examiner may object to other claims except those claiming 10 embodiments on the basis that they are not 'directly and unambiguously' disclosed, unless those claims are so obvious to the person skilled in the art, in the overall context of the document, that they are easily evident to him when reading the document attentively. In turn, when the applicant would try to overcome

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181 *See e.g.,* Dr Reddy's Lab, Court of Appeal, *supra* note 91, at para 116 (Lord Neuberger partly noted that if there had been a challenge to the validity of the 235 patent on appropriate grounds (e.g. under section 72(1)(c) of the UK Patent Act: ground for the revocation: the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art), it would have been revoked); *But see* Examination Guidelines for Patent and Utility Model in Japan (June 2010) 1.5.3. (3)(2) (hereinafter "Japanese Examination Guidelines") (noting that to acknowledge that the chemical substance is not disclosed in the prior art disclosing the chemical formula, does not mean "that the claim violates the enablement requirement under Art. 36(4) of Japanese Patent Act where the publication is a patent application claiming the chemical substance as one of alternatives of a Markush-type formula".).

182 *See e.g.* Tilmann *supra* note147, at 159; *See also e.g.,*Wolfgang Bublak et. al., *Offenbarungsgehalt der Vorveröffentlichung einer chemischen Strukturformel (Disclosure in the Prior Publication of a Chemical Structural Formula)*, GRUR 382, 389 (2009).

this rejection ground through the amendment of claims,[183] he may only obtain his exclusivity for the claims directed to 10 individual embodiments out of at most 100 times compounds in the extreme, because of the same reason as above. Assume that there were only 3 individual embodiments in the priority application – it is a very typical case in which the applicant prepares more embodiments during a 12 month period -, can even 10 individual embodiments enjoy the claiming of priority?

It would be interesting to see whether the Federal Court of Justice will uniformly apply this concept of disclosure in terms of novelty to other areas of disclosure, and if not, to what extent it would do so.

4. Conclusion

It is acknowledged that determination of the patentability of selection inventions is a more difficult issue,[184] and is considered case by case, specifically different from other inventions.[185]

The *Olanzapine* and the *Escitalopram* decisions lowered the bar for patentability, especially for the novelty requirement with respect to selection inventions. On the one hand, it is understood that society wants to motivate companies to research these areas, and thus more selection inventions become available. However, on the other hand, it is hard to find a justification for the fact that selection inventions are treated differently from basic inventions.

Floyd J said in the *Olanzapine* decision that the above discussed extension of the exclusivity term could not alter the principles to be applied when deciding whether the patent's teaching was novel or non-obvious over the basic patent.[186] In his opinion, this situation should not be treated differently from when the basic patent is owned by a party other than the patentee, or when the prior part is not a patent document.[187] It may be difficult to understand why the same reasoning should not be applied to the treatment of selection inventions and basic inventions. The possible impact of this enablement requirement, i.e. a possible extension of exclusivity, will be considered in further depth in IV.C.

183 *See e.g.,* Heiko Sendrowski, *"Olanzapine" – eine Offenbarung? (Olanzapine – a disclosure?)* GRUR 797, 801 (2009).
184 Chisum, *supra* note 106, at § 3.02[2][b].
185 *See also* MPEP *supra* note 157, § 2131.03 (When the prior art discloses a range which touches, overlaps or is within the claimed range, but no specific examples falling within the claimed range are disclosed, a case by case determination must be made as to anticipation).
186 *See* Dr Reddy's Lab, Patent Court*, supra* note 86.
187 *Id.*