amount of prior arts over time. Fourthly, the novelty requirement is treated more strictly in the pharmaceutical field than in other technical fields, since novelty is judged based on whether the idea of the invention is new, not on whether the product has been accessible to the public.[160] Put differently, the mere earlier disclosure of an idea, not the accessibility of a product can keep the invention from being patented, thereby possibly disincentivizing pharmaceutical companies to launch a product, wherein the launch can take longer than in other industries. Lastly but most importantly, the novelty requirement including the level of enablement depends on the jurisdiction and on the developmental status of law. Therefore, the assessment of novelty seems to be rather relative. In the next section, the last mentioned aspect of novelty, i.e. the enablement requirement is further discussed.

### 2. Enablement as a Requirement for Anticipation

What is the relationship between anticipation and enablement? An enabling disclosure is required for anticipation of the invention in main jurisdictions. The German Federal Court of Justice held in the *Olanzapine* decision that the concept of disclosure was exclusively what a person skilled in the art directly and unambiguously derives from the prior art as the content of teaching, thereby enabling him to specifically carry out the invention.[161] Under US practice, too, in order to anticipate the claimed invention, a prior art disclosure must enable it either explicitly or inherently, such that the skilled artisan could practice the invention without undue experimentation.[162] Tilmann interpreted this requirement in accordance with the narrow purpose of the novelty requirement, namely, to avoid double-patenting.[163] He said that it was correct to require that the information in a prior art document discloses 'directly and unambiguously' the subject matter of a claim to avoid double-patenting, and also noted that this came close to the wordings of EPC Arts. 83 and 84.[164] Enablement has played a key role in the context of anticipation; however, it has rarely been discussed.[165]

The main differences between enablement as a requirement for anticipation and enablement as a requirement for sufficiency of disclosure can be summarised as

160 Roin, *supra* note 8, at 517-518.
161 *Id.,* at 599-600.
162 *See* Kieff, *supra* note 152; *see also* Smithkline Beecham Corporation v. Apotex Corp., 403 F.3d 1328, 1342 (Fed. Cir. 2005); *see* also *In re* Brown, 329 F.2d 1006 (C.C.P.A. 1964).
163 See Tilmann, *supra* note 147, at 152.
164 *Id.*
165 *See* Seymore, *supra* note 148, at 6; *see also, e.g.,* Chester v. Miller, 906 F.2d 1574, 1576 n. 2 (Fed. Cir. 1990) (noting that for being prior art under section 102(b), the reference must place the anticipating subject matter at issue into the possession of the public through an enabling disclosure).

follows: The first distinction hinges on whether the requirement is introduced by legislative or by judicial bodies. The enablement requirement (sufficiency of disclosure) for obtaining a patent is clearly stated in the statutes, e.g. EPC Art 83 or 35 U.S.C. § 112.[166] However, the enablement requirement for anticipation is specified neither in EPC Art 54, nor 35 U.S.C. § 102, nor anywhere else in the patent statutes. This requirement for anticipation was established by the courts.[167]

The second difference depends on whether the utility of the invention is to be enabled as well. The Federal Circuit in *Novo. Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp*.[168] confirmed that the standard for enablement of a prior art reference for purposes of anticipation under § 102 differed from the enablement standard under 35 U.S.C. § 112, namely, the specification should enable a person skilled in the art to 'use' the invention to meet the requirement under § 112, but the specification did not need to do so to meet the requirement under § 102.[169]

The third difference is whether the scope of the invention has to be enabled when the prior art reference is a patent (application) itself. In order to meet the enablement requirement for the 'patent-obtaining purpose' under EPC Art 83 or 35 U.S.C. § 112, the specification must enable the whole scope of the claimed invention, but to meet it for 'patent-defeating purpose', it would be enough to enable the scope of the invention at issue.[170] Thus, the description of a single embodiment for a broad claim in an earlier patent (application) can enable the invention for anticipation purposes, but the same embodiment alone may not be enough to provide a sufficient description for the earlier patent (application) itself.[171] However, even in this case,

166 EPC Art. 83 (2007) (stating that the European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art); 35 U.S.C. § 112 ¶1 (2006) (stating that the specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same).

167 Janice M. Mueller et al., *Enabling Patent Law's Inherent Anticipation Doctrine*, 45 Hous. L. Rev. 1101, 1137-38 (2008); *see also In re* LeGrice, 301 F.2d 929, 939 (C.C.P.A. 1962) (holding that anticipation under § 102(b) "requires that the description of the invention in the printed publication must be an 'enabling' description").

168 Novo. Nordisk Pharms., Inc. v. Bio-Tech. Gen. Corp., 424 F.3d 1347, 1359 (Fed. Cir. 2005) (citing Rasmusson v. SmithKline Beecham Corp., 413 F.3d 1318, 1325 (Fed.Cir.2005).

169 *Id.* (citing *In re* Hafner, 410 F.2d 1403, 1405 (C.C.P.A.1969)); *see also* in re Schoenwald, 964 F.2d 1122, 1124 (citing *In re* Donohue, 632 F.2d 123, 126 (C.C.P.A. 1980) ("proof of utility is not a prerequisite to availability of a prior art reference under 35 U.S.C. § 102(b)"); *see also Bristol-Myers Squibb, supra* note152, at 1379 (holding that anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art.). This can be viewed differently in different jurisdictions.

170 Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1562 (Fed. Cir. 1991); *see also* Kieff et al., *supra* note 152, at 207-211.

171 *In re* Lukach, 442 F.2d 967, 969 (C.C.P.A. 1971) (noting the difference of the enablement requirement for the patent obtaining purposes from that for the patent defeating purposes).

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.