IV. Discussion

Patents claiming basic inventions like new medical entities are generally very broad, and thus are difficult to be circumvented. During the term of a basic patent, it is not possible to launch a product in the market that relies on dependent patents, unless the dependent patent holder infringes or licenses-in the basic patent. However, even after expiration of the patent, it is still not easy to freely bring a product to the market, especially in the pharmaceutical fields. This is because innovative companies try to extend their exclusivities in the market and to recoup their investments through seeking patents for selected or improved inventions, based on their basic and fundamental patents. Furthermore, the same activities could be conducted by third parties, either competitors of innovative companies or generic companies. Therefore, the existence and number of selection patents has an impact on the freedom of generic companies.

As the European Commission reported in its pharmaceutical sector inquiry, 80~90% of pending claims or granted patents during the period of 2000 to 2007 were categorized as selection inventions.[143] Patentability requirements for selection inventions may play an important role in the pharmaceutical market. The higher or stricter the patentability requirements for selection inventions, the lower is the likelihood that patents are granted for them, and the easier the market entries of generics. In this section, the implications of laws of patentability on selection inventions will be discussed.

A. Anticipation

1. Relativity[144] of Novelty

The novelty requirement for inventions is not controversial.[145] It is 'a separate examination' step for patentability, as the German Federal Court of Justice stated

143 *See supra* notes 21-23 and accompanying texts.

144 One may distinguish "relative novelty" from "absolute novelty" in terms of degree of disclosure. The former may mean that a particular prior disclosure or use of the invention is not regarded as prior art which takes away the novelty of the invention. The latter may mean that the invention must not have been previously disclosed anywhere in the world in any way before the filing date. *See also* Lewis Anten, *What's new with novelty – Section 102 of S. 643*, 54 J. Pat. Off. Soc'y 75, 75-76 (1972). The latter may also be understood as

in its *Olanzapine* decision,[146] and has a different purpose and function from obviousness.[147] The Federal Court of Justice noted its purpose of avoiding double patenting, and it is acknowledged that novelty as a basic patentability requirement is mandated to ascertain that no exclusive right is given to an invention that is already in the public domain.[148]

If every element of a claimed invention is identically disclosed, either explicitly or inherently,[149] in a single prior art document, the document deprives the invention of novelty,[150,151] The document 'anticipates' the claimed invention when it enables the whole claimed invention on top of disclosing each and every element of the invention.[152] In case the prior art fails to disclose one or more elements of the

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the novelty requirement under EPC Art. 54 and Art. 55. *See also* Patents and Technological Progress in a Globalized World 4-5 (Wolrad Prinz zu Waldeck und Pyrmont et al. eds., 2009) (indicating that all disclosures of the invention are considered as prior art without any restriction with respect to time, place, or manner.). However, "relativity" of novelty in this paper is different from these concepts, and will be discussed in this section.

145 *See* John F. Duffy, *Rethinking the Prospect Theory of Patents,* 71 U. Chi. L. Rev. 439, 502-503 (2004).

146 Olanzapine, the Federal Court of Justice, *supra* note 57, at 599.

147 *See also* Winfried Tilmann, *Validity of Selective Product Claims – Venice Conferences III and V, Lundbeck and Olanzapine,* IIC 149, 151-152 (2010); *See also* Diastereomers/BAYER, Feb. 09, 1982, 8 O.J.E.P.O. 296, 301 (1982) (holding that the purpose of Art. 54(1) EPC is to prevent the state of the art being patented again.).

148 Sean B. Seymore, *Rethinking Novelty in Patent Law*, 60 Duke L. J. 1, 2 (forthcoming 2011); *See also* Tilmann *supra* note147*,* at 151-152 ("According to the outdated view, the purpose of novelty requirement was interpreted as 'avoiding double patenting', however, the prior art must not necessarily be a patent document, it is well acknowledged that the purpose is to avoid patenting an information which already has been given to the public by a first disclosure.").

149 *See* Schering corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1377 (Fed. Cir. 2003) "A prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference." (citing Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed.Cir.1991).

150 EPC Art. 54; 35. U.S.C. § 102(a) and (b); *See* Lindemann Maschinenfabrik GmbH v. Am. Hoist & Derrick Co., 730 F.2d 1452, 1458 (Fed. Cir. 1984) (holding that the trier of fact must identify the elements of the claims, determine their meaning in light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference); *See also* Glaxo Inc. v. Novopharm Ltd., 52 F.3d 1043, 1047 (Fed. Cir. 1995) (holding that a prior art reference must disclose each and every feature of the claimed invention, either explicitly or inherently.

151 *See also* Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347-49 (Fed. Cir. 1999) (holding that anticipation requires that the four corners of a single prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation).

152 *Id.*, at 1347-1349; *See also* F. Scott Kieff et al., Principle of Patent Law 525 (4th ed. 2008); *See also* Elan Pharms., Inc. v. Mayo Found., 346 F.3d 1051, 1054 (Fed. Cir. 2003) (holding a reference is enabled when its disclosures are sufficient to allow one of skill in the art to make and use the claimed invention, quoting Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1374 (Fed. Cir. 2001)).

claimed invention or to enable the claimed invention, an obviousness rejection may still be raised with respect to the prior art.

At first glance, the assessment of novelty seems to be relatively straightforward and simple.[153] The only test for novelty would be to compare the claimed invention and the entire knowledge of the prior art, and to determine that the claimed invention is novel when there is a difference from what is already known, regardless of the degree or extent of the difference.[154] However, it is not as easy as it sounds. Firstly, the determination of novelty involves many factors. It is, in fact, dominated by standards which need judgement based on various elements, just as other patentability determinations.[155] For example, in order to decide inherent anticipation – "it is inherently disclosed only if it is the natural result flowing from the explicit disclosure of the prior art" –, it should be judged what is regarded as a "natural result".[156] To determine whether the invention is either explicitly or inherently anticipated in an enabling manner, we should judge the level of ordinary skill of "the person of ordinary skill in the art" and the degree of experiments which would be regarded as "undue".[157] Secondly, the complexity of determining novelty varies according to technology. It is more straightforward in relatively predictable fields like electrical or mechanical engineering; however, it is more difficult for chemical, biotechnological, or pharmaceutical inventions which lie in unpredictable fields.[158] Thirdly, it also depends on the developmental status of inventions. The novelty requirement is easier to achieve for fundamental inventions (e.g. basic patents) than for improvement inventions[159]considering the increasing

153 *See e.g.*, F Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B. C. L. Rev., 55, 86-87 (2003).

154 *See* François Dessemontet, The Legal Protection of Know-how in the United States of America 194 (H.W. Clarke trans., 2d ed. 1976).

155 John F. Duffy, *Rules and Standards on the Forefront of Patentability,* 51 Wm. & Mary L. Rev. 609, 638-639 (2009).

156 *Id.*, at 638; *See also Schering*, *supra* note 149, at 1379 (holding an invention to be inherently disclosed only "if it is the natural result flowing from the explicit disclosure of the prior art.".).

157 Id.; *see also* Advanced Display Sys., Inc. v. Kent State Univ., 212 F.3d 1272, 1282 (Fed. Cir. 2000) (holding that anticipation requires describing every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation); exemplary multifactors to determine "undue" experiments are given in U.S. Patent & Trademark Office, Manual of Patent Examining Procedure, § 2164.01 (8th ed. 8th rev. 2010) [hereinafter MPEP] (citing *In re* Wands, 858 F.2d 731, 737 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.).

158 Seymore, *supra* note 148, at 9-10, 14-16.

159 *See also* Theon van Dijk, *Patent Height and Competition in Product Improvements,* 44 J. Indus. Econom. 151, 152-153 (1996).

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).