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 exclusivity[234] 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 market[236] 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* note86.
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).

guage,[238] regardless of what was really invented. This notion is especially important for selection inventions. Even though the inventor of a basic invention did not perceive the later improvement invention as his invention at the filing date, the later selection invention might be found to infringe the claim of a basic patent whose language is broad enough to cover the later invention.[239]

In his article, Lemley categorized and addressed three kinds of improvement inventions[240] based on the level of social contribution, namely, a minor improvement, a significant improvement, and a radical improvement.[241] According to Lemley, a minor improvement cannot be patented but is covered by the basic patent. A significant improvement could be patented but still falls within the scope of the basic patent, and therefore the basic patentee cannot capture the value of the improvement patent but can prevent the significant improver from using his basic invention, because an improvement patent is covered by the basic patent's claim. A radical improvement, of course, can be patented; while it literally infringes the basic patent claim, it may be protected under the 'reverse doctrine of equivalents', which will be discussed later.[242] In this regard, a decision of the German Federal Court of Justice holds that an embodiment which is the subject matter of a younger patent does not exclude infringement of an older patent which may, for instance, cover the younger patent's embodiment in general terms.[243] Considering that improvement/dependent patents infringe the basic patent in any way at least literally,[244] it seems worthwhile to discuss strategies for not discouraging improvement inventions while at the same time securing the reward of basic inventions.

Let us return to the *Olanzapine* case, as an example. After *Olanzapine*, less selection patents should be rejected at least on the ground of anticipation, i.e. for the basic patent disclosing the selected species.[245] *Under this setting, the more selection*

238 *See e.g.,* EPC Art. 69.

239 *See* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law* 75 Tex. L. Rev. 989, 991, 1000-1009 (1996-1997).

240 Improvement patent generally refers to a patent that is issued on an application filed later in time than a prior application and tends to build up the previously disclosed or patented invention . Thus, it does not have the same meaning as 'selection invention', however, it would be helpful to use this term to find the relationship between the selection invention and basic invention. The same goes to the 'dependent patents'.

241 Lemley *supra* note 256, at 1007-1013.

242 *Id*.

243 Hans-Rainer Jaenischen, *The Grant of a Compulsory License for Recombinant γ-IFN in Germany*, 11 Biotech. L. Rep. 369, 375 (1992); See also Bundesgerichtshof [BGH] [Federal Court of Justice] Jul.12, 1990, GRUR, 436 1991 (Ger.); *See also* Merges *supra* note 297, at 873-878.

244 *See also* Irina Haracoglou, Competition Law and Patents: a follow-on innovation perspective in the biopharmaceutical industry 60 (2008) (noting that it is broadly referred to as the "dependent patent", as it cannot be worked without infringing the earlier issued patent).

245 *See generally supra* III.B.

patents are granted, the more issues with respect to the exploitation of selection inventions arise, especially when the basic patent holder denies granting of a license. Where can we find remedies for these problems?

b) Possible Solutions

Improvement patents held by the patentee of the basic patent do not pose a problem in this respect, except for the "evergreening" issue.[246] Therefore, only those patents which are held by a third party who cannot exploit its invention without licensing the basic patent will be discussed.

(1) Reverse Doctrine of Equivalence

"The reverse doctrine of equivalence" is a doctrine that exists only in the US. This doctrine can only be applied where an improvement patent literally infringes the scope of a basic patent. If the degree of its improvement is sufficiently radical it can be found non-infringing even though it may literally and clearly infringe the scope of the basic patent.[247] This doctrine was named so because it is the opposite concept of the doctrine of equivalence, where something can be found infringing despite the fact that it is not literally covered by the claim.[248] Although the first reverse doctrine case cited is a case from 1898[249] and the U.S. Federal Circuit recognized its potential significance for the biotechnology industry,[250] this doctrine has rarely been applied in practice.[251] This is because a sufficient level of radicalness is not certain and there is concern that it might reduce the basic patentees' incentives in the first place. Accordingly, this doctrine is better used restrictively .[252]

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246 *See generally supra IV.C.1.*
247 *Id.,* at 1011.
248 *See* Robert Merges, *Intellectual Property Rights and Bargaining Breakdown: The Case of Blocking Patents* 62 Tenn. L. Rev. 75, 91 (1994-1995).
249 Westinghouse v. Boyden Power Brake Co., 170 U.S. 537 (1898).
250 *See* Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991) (holding Genentech's recombinant version of the Factor VIII:C does not infringe Scripps' version of Factor VIII:C, which is isolated from the human blood, based on Genentech's version's far most commercial significance).
251 *See* Merges, *supra* note 248, at 75, 91, and 93-94.
252 *See* Merges, *supra* note 297, at 867-868.

(2) Patent Act Consideration – Compulsory License

A compulsory license as an exceptional measure, i.e., a license authorised by a governmental body to a third party, for using the patent without the patentee's consent, for various reasons,[253] can be granted either on a significant improvement or on a radical improvement.[254] Art. 31(1) of the Agreement on Trade-Related Aspects of Intellectual Property Rights [hereinafter "TRIPs Agreement"[255]] provides several grounds for the granting of a compulsory license, which is determined by the member states, but is not binding. For example, the Japanese,[256] German,[257] and Korean[258] Patent Acts have provisions for compulsory licenses for reasons of public interest and for dependent patents. The UK Patents Act[259] and the Swiss Patent Act[260] provide a compulsory license provision for a dependent patent. In Europe, the authorities may be more willing to grant compulsory licenses. However, relatively few such licenses have actually been granted.[261] Since these provisions are rarely used, a German case concerning gamma-interferon will be reviewed to explore the possibility of granting a compulsory license for a dependent patent.

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253 Jerome H. Reichman et al., *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Frame-work under TRIPS, and an Overview of the Practice in Canada and the USA*1-2, (June 2003), available at http:// www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf.; *See also* Haracoglou, *supra* note 244, at 50.

254 This is according to Lemley's definition. The more general term would be a 'dependent patent'.

255 Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994).

256 Tokkyohō [Japanese Patent Act] Art. 93, para. 1 (Japan) (Award granting non-exclusive license for public interest) and Art. 92, para. 1 (Award granting non-exclusive license to work own patented invention).

257 Patentgesetz [German Patent Act, hereinafter GPA] Art 24(1) and 24(2) (Ger.); *translated* in World Intellectual Property Organization, Patent Law, http://www.wipo.int/clea/docs_new/pdf/en/de/de081en.pdf
Art. 24(1) : "A non-exclusive authorization to commercially exploit an invention shall be granted by the Patent Court in individual cases in accordance with the following provisions (compulsory license) if
1. the applicant for a license has unsuccessfully endeavored during a reasonable period of time to obtain from the patentee consent to exploit the invention under reasonable conditions usual in trade; and
2. *public interest* commands the grant of a compulsory license."
Art. 24(2): *see infra* note 268 and accompanied text.

258 Teukheo boeb [Korean Patent Act] Art 107, para. 1, no. 3 (S. Kor) (Award for the Grant of a Non-exclusive License and Art 138, para. 1 (Trial for Granting a Non-exclusive License).

259 Patents Act of 1977, §§ 48, 48A(1)(b)(i), (4), (c) (2004)(U.K.); For the U.S. Practice, *See generally also* David A. Balto & Andrew W. Wolman, *Intellectual Property and Antitrust: General Principles* 43 IDEA 395, 409-410, (2003) (addressing general trend in the United States with regards to compulsory licensing of which is not in the favor).

260 Switzerland Patent Act Art. 36; *See also supra* note 244, at 60.

261 Jerome H. Reichman, *Intellectual Property in the Twenty-first Century: Will the Developing Countries Lead or Follow?* 46 Hous L. Rev. 1115, 1139, (2009).

Since the introduction of the compulsory licensing provision into the German Patent Act in 1911, 12 applications for compulsory licenses have been filed before the German Federal Patent Court.[262] From these, only one compulsory license has been granted under section 24(1) of a GPA, on June 7, 1991.[263] This grant allowed the German company Bioferon to produce, to offer, and to market 'Polyferon' containing recombinant human gamma-Interferon *for a new medical indication* (chronic polyarthritis, which was widespread in Germany) which was developed by Bioferon itself. It was interpreted that the German Federal Patent Court stimulated the development of new medical uses of known products and enhanced the medical care through granting compulsory licenses.[264] It was further interpreted that the acknowledgeable necessary public interest under GPA § 24(1) could be i) a drug at issue showing characteristics which were not shown by an already marketed drug or ii) a drug avoiding undesired side effects of a marketed drug.[265] However, the German Federal Court of Justice revoked this license in December 5, 1995,[266] mainly based on lack of sufficient 'public interest" to justify granting a compulsory license.[267]

In the *Olanzapine* case, if the two patentees were different, one might have had recourse to GPA § 24(2),[268] which corresponds to Article 31(1) TRIPs Agreement and allows the grant of a compulsory license for a dependent patent, which cannot be exploited without using another invention protected by a previous patent and belonging to a different owner.[269] Section 24(2) of the GPA provides for compulsory licensing for dependent patents as follows:

> "If the applicant for a license is unable to exploit an invention for which he holds protection under a patent of later date without infringing a patent of earlier date, he shall be entitled within the framework of subsection (1) to request the grant of a compulsory license with respect to the owner of the patent of earlier date *if his own invention comprises*, in comparison with that under the patent of earlier date, *an important technical advance of considerable commercial significance*. The patentee may require the applicant for a license to grant him a counter license under reasonable conditions for the exploitation of the patented invention of later date."

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262 Astrid Buhrow et al., *Grenzen Ausschließlicher Rechte Geistigen Eigentums durch Kartellrecht (Q187) [Limitations on Exclusive Intellectual Property Rights by Competition Law (Q187)],* Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil. [GRUR Int.], 407, 409 (2005) (Ger.).

263 Bundespatentgericht (BPatG) [Federal Patent Court] Jun. 7, 1991, GRUR Int., 98 (1994) (Ger.).

264 *See* Jaenischen, *supra* note 243, at 375.

265 *Id.*

266 Bundesgerichtshof [BGH] [Federal Court of Justice] Dec. 5, 1995, GRUR, 190, 1996 (Ger.).

267 *See* Kimberly M. Thomas, *Protecting Academic and Non-Profit Research: Creating a Compulsory Licensing Provision in the Absence of an Experimental Use Exception*, 23 Santa Clara Computer & High Tech. L. J. 347, 364-365 (2007).

268 *See supra* note257, Section 24(2).

269 *See* IPR Helpdesk, *Some Basic Issues Surrounding Improvements Made to Patented Invention and to Dependent Patents,* available at *http://www.ipr-helpdesk.org/.*

This provision provides the opportunity to obtain a compulsory license under the condition that the improvement patent contains an important technical advance of considerable economic significance, in comparison with those of the basic patent, and plays a role in preventing the huddling of innovation by blocking patents[270] and in improving the technological development.

In the U.S., it was suggested that the U.S. courts should grant compulsory licenses as a remedy for antitrust violations and/or that compulsory license provisions should be incorporated into the U.S. Patent Act.[271] The more preferable solution would be enacting (or implementing) compulsory licensing provisions, for the public's interest[272] and for the dependent patent.[273]

(3) Competition Law Consideration – the Orange Book Standard Decision

One may try to find remedies against the blocking effect of basic patents in the competition law area, namely, by way of claiming a so-called "compulsory license objection" or "Euro-defence"[274] against the action for patent infringement. In this regard, the German Federal Court of Justice recently pronounced its decision on the *Orange Book Standard* case (KZR 39/06).[275]

The patent at issue was a patent on a standard known as the "Orange Book Standard" related to the manufacture of writable CDs. The Court provided some guidelines for this defence in that the defendant had to act like a "true licensee", by i) determining a reasonable license fee objectively (presumably based on common practice in the relevant industry or market intelligence); ii) regularly rendering accounts; iii) paying or depositing (e.g. into an escrow account) the hypothetical license fees.

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270 Joseph Straus, *Patent Application: Obstacle for Innovation and Abuse of Dominant Position under Article 102 TFEU?* J. Eur. & Compet. Prac., 1, 12-13 (forthcoming 2010) doi: 10.1093/jeclap/lpq011.

271 *See* Jackson, *supra* note 2, at 119, 142-143.

272 *See* Thomas, *supra* note 267, at 365.

273 *See also* Jerome H. Reichman, *Harmonization without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty* 57 Duke L. J. 85, 116 (2007) (addressing when necessary, compulsory licenses to unblock dependent patents and enable improvers to reach the market could also be enacted, a solution that remains fully consistent with the TRIPs Agreement.).

274 *See* Thomas Hays, *An application of the European Rules on Trademark Exhaustion to Extra-market Goods* 91 Trademark Rep. 675, 679 (2001) (addressing the "Euro Defense" as follows: "Euro Defense" is a legal tactic akin to alleging "unclean hands". A defendant asserts that, while it may have infringed upon an intellectual property right under other circumstances, enforcement of that right would be a violation of the EC's competition laws, particularly of EC Treaty Articles 81 and 82 (now EFTU Articles 101 and 102)).

275 Bundesgerichtshof [BGH] [Federal Court of Justice] May 6, 2009, [GRUR], 694, 2009 (Ger.).

However, before an analogy to the situation of dependent patents can be drawn, to solve the above problem, a number of open questions should be answered by the Federal Court of Justice, like what is a reasonable amount of royalty, whether the defendant still can raise a non-infringement argument, and others.

c) Conclusion

The holdings in the *Olanzapine* and *Escitalopram* cases have heightened the level of disclosure in the prior art necessary to anticipate selection inventions. In addition to the discussion about the justification for allowing more selection patents, the limited exploitation thereof is another issue, once they are granted. In other words, the change in the patentability requirements could possibly just bring more but almost useless patents in so far as the basic patent is in force. This is even more so because a most adequate solution, the compulsory license, has hardly been used.

However, this issue may not be a real problem in jurisdictions whose laws allow the grant of compulsory licenses for dependent patents and try to use this legal instrument to a greater extent and as necessary.

D. Different view in other jurisdictions

1. Selection Inventions in Korea

Recently the Korean Supreme Court rendered its decisions on the patentability of enantiomer patents on the world's top blockbusters, namely Plavix and Lipitor.

a) Clopidogrel Decision[276]

Sanofi-Aventis' Korean Patent No. 103094 on dextro-rotatory[277] enantiomer of clopidogrel was challenged over the earlier patent claiming clopidogrel as racemate.[278]

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276 Supreme Court Decision [S. Ct.],(hereinafter 'Sanofi-Aventis') 2008Hu736, 2008Hu743, Oct. 15, 2009 (S. Kor.).

277 "Dextro-rotatory" and "levo-rotatory" is another way of indicating the chirality of each enantiomer. However, there is no fixed relation to the (R)- or (S)- enantiomer. For example, an *(R)* isomer can be either dextro-rotatory or levo-rotatory.

278 The prior patent disclosed especially ".. is an asymmetric carbon atom. In fact, this formula represents both the dextro-rotatory molecule claimed as well as its levo-rotatory enantiomer.".