

## VI. PROPOSALS

In the literature on economics, particular emphasis has been placed on the best way to design optimal patent policies.<sup>1305</sup> Much debate about the patent system has focused on the trade-off between the dynamic benefits of innovation and the static costs of monopoly power given to the innovators as rewards.<sup>1306</sup> The status costs are generally measured by “deadweight loss”, which is the value of inventions that would be under-used, because a patentee would charge a monopoly price. Consequently, only those buyers willing and financially able to pay the monopoly price could use the inventions.<sup>1307</sup> However, overprotecting intellectual property is as harmful as underprotecting it,<sup>1308</sup> as Kozinski J noted:

“Creativity is impossible without a rich public domain. Nothing today, likely nothing since we tamed fire, is genuinely new: Culture, like science and technology, grows by accretion, each new creator building on the works of those who came before. Overprotection stifles the very creative forces it's supposed to nurture.”<sup>1309</sup>

There has also been a tension between providing strong patent rights to encourage break-through innovations, thereby possibly discouraging the de-

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1305 *Luski/Wettstein*, 1 *Probl. Perspect. Manage.* 31, 31 (2004).

1306 *Gilbert/Shapiro*, 21 *RAND J. Econ.* 106, 106 (1990); *Arrow*, 1962; *Kamien/Schwartz*, 1982, 195 (noting according to the increase of the reward for innovation, total expected expenditure of participants is raised collectively and increase the expected appearance of the innovation); *Svatos*, 13 *Soc. Philos. Policy* 113, 119 (1996); *Scherer/Ross*, 1990, 624; *O'Donoghue*, 29 *RAND J. Econ.* 654, 658 (1998).

1307 See e.g.: *Friebel et al.*, 2006, 23.

1308 *White v. Samsung Electronics America, Inc.*, 989 F.2d 1512, 1513 (9th Cir. 1993).

1309 *White v. Samsung Electronics America, Inc.*, 989 F.2d 1512, 1513 (9th Cir. 1993) (Kozinski, J. dissenting); see also *Gordon*, 102 *Yale L. J.* 1533, 1556-57 (1993); *Matutes/Regibeau/Rockett*, 27 *RAND J. Econ.* 60, 78-80 (1996) (arguing that it should be expected that the patentee would effectively be granted exclusive rights to the applications of a basic discovery and also could acquire protection on applications which they had not yet worked out.).

velopment of subsequent improvements.<sup>1310</sup> And balancing between two inventors has also been an important issue,<sup>1311</sup> as noted by Lord Mansfield in 1785.<sup>1312</sup>

This tension exists because we live in active investment climates in which companies invest to improve each other's products/innovations in various ways. However, it is not easy to balance the rights of all concerned. For example, if we do not provide broad enough protection to the first innovations, we will hamper the incentive to create in the first place. However, if we provide complete exclusivity to the first generation innovations, we will stifle R&D by second generation inventors.<sup>1313</sup> However, as discussed so far, more weight should be given to the basic inventions in the pharmaceutical industry, which can bring more NMEs to the public. As instruments to this end, many scholars have considered the trade-off among patent breadth, length, and patentability requirements, and so on.<sup>1314</sup> This chapter will present the arguments on each instrument by scholars, which will be followed by the practical proposals on the instruments for pharmaceutical inventions.

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1310 *Jaffe/Lerner*, 2004, 50; *Scotchmer*, 5 J. Econ. Perspect. 29-41 (1991); *Friebel et al.*, 2006, 27; *Heller/Eisenberg*, 280 Science 698 (1998); *Merges/Nelson*, 90 Colum. L. Rev. 839, 916 (1990); *Merges/Nelson*, 25 J. Econ. Behav. Organ. 1, 20-23 (1994); cf. *Bessen/Maskin*, 40 RAND J. Econ. 611 (2009) (arguing even patent would inhibit the innovation in complementary and sequential innovation).

1311 *Lemley*, 75 Tex. L. Rev. 989, 989-990 (1997).

1312 *Sayre v. Moore*, 1 East 361 n.(b), 102 Eng. Rep. 139, 140 n.(b) (K.B.1785), cited in *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 480 n. 33 (1984). (on a copyright case against improved navigational chart noting "we must take care to guard against two extremes equally prejudicial; the one, that men of ability, who have employed their time for the service of the community, may not be deprived of their just merits, and the reward of their ingenuity and labour; the other, that the world may not be deprived of improvements, nor the progress of the arts be retarded.").

1313 *Lemley*, 75 Tex. L. Rev. 989, 990 (1997); *Merges/Nelson*, 90 Colum. L. Rev. 839, 871-79 (1990); see also *Sony Corp. of Am. v. Universal City Studios, Inc.*, 464 U.S. 417, 480 n. 33 (1984) in the copyright context, *supra* 1312 .

1314 See e.g., *Friebel et al.*, 2006, 21-23.

## A. Introduction

In the art of pharmaceutical sciences, the first issue between the two problems in this dissertation, the dearth of NMEs and the drastic increase of second generation inventions, has generally been of interest. While it has not been easy to overcome or even suggest overcoming the dearth of NMEs, some scholars have suggested that the key would be to increase substantially the number and quality of innovative, cost-effective new medicines, without incurring unsustainable R&D costs.<sup>1315</sup> To do so, many scholars have proposed transiting from “me-too” or “me-slightly better” drugs to highly innovative medicines and re-focusing resources such as money and talent on discovery research.<sup>1316</sup> One chief officer of a pharmaceutical company that has been facing revenue loss announced that the company needed to rely much more on new medicines.<sup>1317</sup> The U.S. government has also attempted to overcome the crisis created by a lack of new medications by implementing the so-called “wild card patent term extension” but this proposal was finally rejected.<sup>1318</sup> How, then, can the patent regime help to bring more new basic medicines to the public?

Providing general patent policy recommendations is difficult, since the framework is dynamic and complicated in nature, and the strategic behaviour of many firms is involved. However, in general, as profit opportunities have expanded, firms have competed to exploit them by increasing R&D investment.<sup>1319</sup> Patents create incentives and chances to explore the known or unknown possibilities that may exist within the scope of the patent.<sup>1320</sup> Prospect theory is in the same vein. According to Kitch’s prospect theory, the broad prospect of intellectual property can allocate better resources and

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1315 *Paul, et al.*, 9 Nat. Rev. Drug Discov. 203, 203 (2010) (noting “our parametric analyses further reveal where the greatest improvements in productivity must occur.”).

1316 *Paul, et al.*, 9 Nat. Rev. Drug Discov. 203, 213 (2010).

The recommendations from the scientific point of view were much more improvements in understanding of human (disease) biology, and fostering scientific creativity and being opportunistic for serendipitous scientific and medical findings.

1317 *Armstrong*, Bloomberg, April 12, 2012.

1318 Project Bioshield II Act of 2005. S. 975, 109th Congress (2005–2006); *See supra* 978 and accompanying texts.

1319 *Scherer*, 20 Health Affair. 216, 220 (2001).

1320 *Domeij*, 2000, 90.

activities to innovations once they are made.<sup>1321</sup> This theory recognizes that many patents appear at the beginning of the process that starts with conception and ends with innovation.<sup>1322</sup> Namely, this theory envisages inventions as something made by a single firm as only the first step in a long and expensive process of innovation.<sup>1323</sup> There is always pressure to file a patent application as early as possible, since competition is fierce. Moreover, the patent system only requires something that works and not the end product that is finished and commercially available.<sup>1324</sup> Even though this theory attracts criticism, such as limitation to the scope of patents<sup>1325</sup> and dense thickets of intersecting, overlapping, and cross-blocking patents, the benefits of this theory fit the pharmaceutical industry best.<sup>1326</sup> One thing is clear: Without patent protection, the threat of competition hampers investment in R&D.<sup>1327</sup>

In addition, the evidence that companies terminate many projects on commercial grounds suggests that many more drug candidates may be developed if the markets can be made more economically attractive.<sup>1328</sup> In the following sections, the way to help to increase the new medications and decrease the second generation inventions in the pharmaceutical industry will be analyzed and recommendations will be made. Before that the discussion will focus on the main issues, and the nature and value of selection inventions will be analysed.

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1321 *Kitch*, 20 J. Law Econ. 265, 276-280 (1977) (based on Schumpeterian tradition that there is not sufficient incentive to innovate in market place and prospect of realizing monopoly profits would provide with the incentive for innovation); *See also Kamien/Schwartz*, 1982, 189-90 (noting monopolist would make an efficient allocation of fixed level of resources); *Burk/Lemley*, 54 Case W. Res. L. Rev. 691, 726-727 (2003).

1322 *Kitch*, 20 J. Law Econ. 265, 283 (1977).

1323 *Burk/Lemley*, 89 Va. L. Rev. 1575, 1615 (2003).

1324 *Kitch*, 20 J. Law Econ. 265, 270-71 (1977).

1325 *Merges*, 76 Cal. L. R. 803, 840-42 (1988).

1326 *Burk/Lemley*, 54 Case W. Res. L. Rev. 691, 726-728 (2003).

1327 *Machlup*, 1958, 36-37.

1328 *Cockburn*, 2006, 26.

B. Nature of selection inventions

1. Different natures of selection inventions

The definition of each selection invention was provided in chapter 2. Here, the nature and value of species selection invention will be further explained in comparison with other selection inventions.

a) Species selection invention

The value of a species selection invention exists in the choice of one compound out of a range of candidates (sometimes millions). A similar situation exists in the invention of a DNA sequence. Apart from the issue of whether a DNA sequence is a patentable subject matter,<sup>1329</sup> the existence thereof in nature, or of a DNA library, including the multitude of DNA sequences, does not automatically render the sequence non-novel, unless the sequence concerned had recognisably been made available.<sup>1330</sup> Like the genus claim, a DNA library of many gene fragments, does not enable a person skilled in the art to *locate* the gene in question.

In *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, Bryson J used his leaf analogy to argue that a gene simply isolated from the body cannot be patentable subject matter just as a naturally grown

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1329 There are some jurisdictions, where the patentable subject matter is mattered on the DNA sequence invention. See e.g., *Association for Molecular Pathology et al. v. Myriad Genetics Inc. et al.* 133 S.Ct. 2107, 2109 (2013) ("A naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but cDNA is patent eligible because it is not naturally occurring.").

1330 *Biogen/Alpha interferons*, T301/87, OJ EPO 1990, 335, 351.

leaf cannot be patentable simply because it was snapped from the tree.<sup>1331</sup> To this dissent, the majority argued as follows:

“With respect, no one could contemplate that snapping a leaf from a tree would be worthy of a patent, whereas isolating genes to provide useful diagnostic tools and medicines is surely what the patent laws are intended to encourage and protect. Snapping a leaf from a tree is a physical separation, easily done by anyone. Creating a new chemical entity is the work of human transformation, requiring skill, knowledge, and effort.”<sup>1332</sup>

The majority’s opinion seems to differentiate a DNA sequence from a leaf based on the difficulty of isolation and the usefulness of genes. It could have been relatively difficult to isolate a DNA at the time of this invention. However, the separation was already very well known and was not difficult to a person skilled in the art, once he knew the sequence of the DNA. The majority values more highly and differentiates the usefulness of the DNA invention from a leaf, thus arguing that the DNA invention must have been encouraged and protected. In this sense, it would be fair to say that, if a snapped leaf from the whole forest were useful, say to cure breast cancer, which the Myriad’s DNA invention tried to diagnose, no one would argue that a patent should not be granted on the leaf. Consequently, the majority appears to distinguish the inventions according to their value and thereby tries to grant a patent to encourage and protect the invention.

The extreme undue burden that would have been necessary to enable a person skilled in the art to locate and to make practical use either of the genetic sequence or of the species compound and the particular beneficial use thereof rendered this type of selection invention novel and/or patentable.

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1331 *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1352 (Fed. Cir. 2012) (“[E]xtracting a gene is akin to snapping a leaf from a tree. Like a gene, a leaf has a natural starting and stopping point. It buds during spring from the same place that it breaks off and falls during autumn. Yet prematurely plucking the leaf would not turn it into a human-made invention. That would remain true if there were minor differences between the plucked leaf and the fallen autumn leaf, unless those differences imparted “markedly different characteristics” to the plucked leaf.”), *aff’d in part, rev’d in part, Association for Molecular Pathology et al. v. Myriad Genetics Inc. et al.* 133 S.Ct. 2107 (2013).

1332 *Association for Molecular Pathology v. U.S. Patent and Trademark Office*, 689 F.3d 1303, 1332 (Fed. Cir. 2012), *aff’d in part, rev’d in part, Association for Molecular Pathology et al. v. Myriad Genetics Inc. et al.* 133 S.Ct. 2107 (2013).

b) Other selection inventions

The other selection inventions discussed, i.e. optical isomers, crystalline forms, or metabolites are selected from a much smaller group. The size of a group from which an enantiomer is chosen depends on the number of chiral carbon atoms in the molecule, and the optical isomers can be selected out of two options. Crystalline forms are selected out of a couple of forms,<sup>1333</sup> unless they are a newly synthesized form. Metabolites are also screened out of a couple of substances, which are acquired after analyzing and profiling the sample of the subject who received the parent drug. Thus, the nature of other selection inventions seems to relate more to the difficulty of separation/isolation from the previous mixtures.

2. Selection inventions from the era of penicillin to the 21th century

a) Early medications and the novelty requirement

Lack of novelty was already the major hurdle that early medications had to overcome to secure patents. One very early case was *aspirin* (acetyl salicylic acid). Patents on it were filed in Germany,<sup>1334</sup> the United States, and the United Kingdom.<sup>1335</sup> However, only the patent<sup>1336</sup> filed in the United States in 1898 managed to survive after an infringement suit in 1909.<sup>1337</sup> Considering that the compound is simple and was already available on the market, the results are not surprising. The cases of early antimicrobial drugs were not much different from that of aspirin. Neither *sulphanilamide*, whose appearance in 1935 foreshadowed the technological change in the drug industry, nor *penicillin*, which was the first antibiotic, was patented.<sup>1338</sup> The for-

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1333 However, the novelty requirement seems to be higher than other selection inventions.

1334 *Dutfield*, 2009, 18 (noting the German application was granted but rejected later because only processes were patentable and the compound was not new).

1335 *Dutfield*, 2009, 18 (noting the British application was filed in 1898 but invalidated in 1905 in an infringement case based on the lack of novelty).

1336 U.S. Patent No. 644,077 (February 27, 1900, under the title of “acetyl salicylic acid”).

1337 *Kuehmsted v. Farbenfabriken of Elberfeld Co.*, 179 F. 701 (7th Cir. 1910).

1338 *Temin*, 10 Bell J. Econ. 429, 435 (1979).

mer was a previously known substance, and the latter was a known natural substance.<sup>1339</sup>

b) “Made available to the public” for the first time

The infringement cases of two patents<sup>1340</sup> on adrenaline<sup>1341</sup> in 1911 appear to be the first to require a court to consider the patentability of a “purified form” of natural products extracted from living organisms.<sup>1342</sup> The decision delivered by the renowned Hand J held that the novelty of such extracts was not destroyed by the fact that it was merely an extracted product without change. Consequently, he upheld the patentability thereof.<sup>1343</sup> More importantly, he further noted,

“Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically.”<sup>1344</sup>

*Streptomycin* was the second antibiotic that came to the market after penicillin and the first to be effective against tuberculosis. In 1948, *Streptomycin* was covered by two patents. One was granted to the Rutgers Research and Endowment Foundation and was related to methods of extraction and production.<sup>1345</sup> The other one was granted to Merck and covered complex salts

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1339 *Temin*, 10 Bell J. Econ. 429, 435 (1979); for the penicillin, *see also Dutfield*, 2009, 141 (noting “penicillin was not patented, as aspirin should probably not have been on account of its already being known about”); *American Cyanamid Co. v. F.T.C.*, 363 F.2d 757, 760 (6th Cir. 1966).

1340 U.S. Patent No. 730,176 (June 2, 1903, under the title of “Glandular extract product”); U.S. Patent No. 753,177 (February 23, 1904, under the title of “Glandular extract compound”).

1341 This is a hormone produced by adrenal glands and which increases heart rate, constricts blood vessels, dilates air passages and participates in the fight-or-flight response of the sympathetic nervous system.

1342 *Dutfield*, 2009, 108-09.

1343 *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.N.Y., 1911); reversed in part in *Parke-Davis & Co v. H K Mulford & Co*, 196 F. 496 (2nd Cir. 1912) (reversed to the extent that the claim didn’t have the limitation such as “of product of the suprarenal glands.”).

1344 *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.N.Y., 1911).

1345 U.S. Patent No. 2,449,866 (September 21, 1948, under the title of “streptomycin and the process of preparation”).

of streptomycin containing inorganic salts.<sup>1346</sup> Even though streptomycin was also a natural product, the patent claimed to the satisfaction of the examiner that “for the first time streptomycin is available in the form which not only has valuable therapeutic properties but also can be produced, distributed, and administered in a practicable way.”<sup>1347</sup> Patents were also granted in 1951 on the invention of *Vitamin B<sub>12</sub>*, which was indeed the extraction of a pure substance<sup>1348</sup> and in 1955 on the composition containing VtB<sub>12</sub> and the process to prepare it.<sup>1349</sup> The validity of these patents was attacked. The Appeals Court upheld the validity of the first patent entirely based on the Court’s determination that the invention provided the world with a medication for the first time that could successfully treat pernicious anemia without having the unfavourable reaction from the earlier liver extracts, and that the isolated form had not existed in nature.<sup>1350</sup> *In the United States*, therefore, at least a naturally occurring substance either in the composition or in less purified form does not anticipate the claims directed to the pure material.<sup>1351</sup> The patents on the substances isolated or purified from the mixture were granted because they made the medication available to the public for the first time.

*In Germany*, precedents were established in the *Reichspatentamt*<sup>1352</sup> in the 1920s and 1930s by granting patents on hormones, and were used to consolidate the notion that purified biological products could generally be

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1346 U.S. Patent No. 2,446,102 (July 27, 1948, under the title of “complex salts of streptomycin and process for preparing same”); *Temin*, 10 Bell J. Econ. 429, 436 (1979) (noting “the chemical modifications made to streptomycin to enable it to be purified created a new product and both this new product and the process by which it was made were patentable.”).

1347 *Dutfield*, 2009, 23 (citing the words of the U.S. patent No. 2,449,886).

1348 U.S. Patent No. 2,563,794 (August 7, 1951, under the title of “Vitamin B<sub>12</sub>”).

1349 U.S. Patent No. 2,703,302 (March 1, 1955, under the title of “Vitamin B<sub>12</sub>-active composition and process of preparing same”).

1350 *Merck & Co. v. Chase Chemical Co.*, 273 F.Supp. 68, 84 (D.N.J. 1967) (noting “the patentees of the ‘794 patent have given to the world, for the first time, a medicine that can be used successfully in treating all patients suffering with pernicious anemia, a medicine that is subject to accurate standardization, and avoids the unfavorable reactions of the earlier liver extracts. It did not exist in nature in the form in which the patentees produced it, and nothing in the prior art either suggested or anticipated it.”).

1351 *In re Kratz*, 592 F.2d 1169, 1174 (C.C.P.A. 1979); *In re Bergstrom*, 427 F.2d 1394, 1401-02 (C.C.P.A. 1970).

1352 German Imperial Patent Office.

come proprietary.<sup>1353</sup> However, until recent years the important difference from the American practice was that, as in most of continental Europe,<sup>1354</sup> only process patents to manufacture a drug could be granted in Germany.<sup>1355</sup>

### 3. Analysis and conclusion

The nature of selection inventions is different. Namely, their nature is to locate and characterise one out of numerous, sometimes millions, of candidates. The nature of the rest of the selection inventions exist in their isolation or the separation from the mixture. As discussed, isolated or separated chemical compounds were patented. However, these decisions<sup>1356</sup> were decided a century ago when the pharmaceutical industry was arguably not yet a research-based industry but a manufacturing industry.<sup>1357</sup> The knowledge of the average skilled person in the pharmaceutical art has dramatically increased yearly ever since.<sup>1358</sup> Furthermore, patents were granted to isolated compounds, based mainly on the fact that the compounds *were available for the first time* in the form that could cure the disease therapeutically and commercially.

One may doubt whether subsequent selection inventions have also made something available to the public for the first time. Even if they have, however, the public already had the older versions, which usually were covered by the basic patent. One may also doubt whether it is proper to apply the

1353 *Gaudillière*, 24 *Hist. Technol.* 107, 125 (2008).

1354 For example, the U.K. has interesting history of development, i.e. it prohibited claims to the chemical substance in 1919 and removed this prohibition in 1949. In addition, the Section 4 (7) of UK 1949 Patents Act had stated that a claim to a new substance shall be construed to as not extending to the substance when found in nature.

1355 For example, product patents on pharmaceuticals and chemicals had been granted in Germany from 1968, in Japan from 1976, in Switzerland from 1977, and in Italy from 1978 and in Spain and in Portugal from 1992; *See e.g., ter Meer*, 57 *J. Pat. Off. Soc'y* 763, 763 (1975) (noting “there have been changes in the German patent law, particularly in the chemical field, in large measure due to the change of the Patent Law in 1967 which abolished the prohibition against the claiming of chemical products, *per se.*”); *Nastelski*, IIC 1972, 267, 267.

1356 *See supra* 1340 -1353 and accompanying texts.

1357 *Dutfield*, 2009, 59-60.

1358 *Hansen/Hirsch*, 1997, 51.

patentability requirement of a century ago to the inventions in the present highly developed technological era. One may also doubt whether the absolute product protection afforded by a patent is appropriate for second generation inventions. Usually, the patentability of these inventions was acknowledged because of the difficulty of separation. If the technical contribution to the art were the method of separation of something out of the mixture that already existed and provided the therapeutic contribution to the public, the protection of the method to manufacture the substance would be enough. Some scholars argue that the various second generation patents do not have that much value, because they function only to protect the fundamental innovations, and these scholars even argue that these kinds of activities are obviously be wasteful from a societal point of view.<sup>1359</sup> This is different from species selection inventions that make a new medicine available to the public. More importantly, the difference between species selection invention and the rest is that the former would be the NMEs that could open an entirely new field of second generation inventions and the latter would be IMDs.

Considering the different values of selection inventions and the needs of the society, the proper ways for the patent law to help bring more NMEs to the public will now be discussed.

### C. Proposals on the breadth of patents

#### 1. Arguments on the breadth of patents

Although it should not be taken for granted that better protection necessarily leads to more innovation,<sup>1360</sup> the allowable breadth of the claims is decisive for the consequences of the patent system,<sup>1361</sup> and is one of the key means to incentivize innovation.<sup>1362</sup> Thus, many arguments have been brought forward regarding the proper scope of the patent to send messages to the industry to help to foster more useful innovations.

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1359 *Hopenhayn/Mitchell*, 32 RAND J. Econ. 152, 163 (2001).

1360 *Levin et al.*, 1987 Brookings Paper on Econ. Activity, 783, 787 (1987).

1361 *Lerner*, 25 RAND J. Econ. 319 (1994).

1362 *Scotchmer*, 5 J. Econ. Perspect. 29, 30 (1991).

## a) Arguments for a broader patent scope

Many arguments have been brought forward regarding the broader scope of patents. The scope of protection conferred by patents can be broadened to increase rewards for basic inventions.<sup>1363</sup> Many scholars claim that a broader scope in patents would increase the power of the patentee to *exclude competition*, which would lead to more innovations for various reasons here adduced. For example, Kitch argues that broad patent rights were mandatory, basically because enhanced breadth would provide incentives to develop technology by allowing the inventors to appropriate the full benefits of the development.<sup>1364</sup> Harrelson contends that broader and stronger exclusivity must be given, because the underprotection of patent rights would decrease the quantity and quality of new products beneficial to society in the long run.<sup>1365</sup> Along with Klemperer, Gilbert and Shapiro argue that broadening the scope of patents increases the per-period profit for the innovator, because a broader patent protection would allow the innovator to charge a high premium or would prevent competitors from selling close substitutes, respectively.<sup>1366</sup> Green and Scotchmer argue that the broader scope of the patents in sequential innovations would determine the division of profit between them rather than the level of per-period profit.<sup>1367</sup>

Eisenberg and Strandburg also contend that based on a reduction of the strength of patent monopolies, the use of patented invention would increase, however, to put existing technologies into use – i.e., the *investment* itself – would be undermined.<sup>1368</sup> Scotchmer further argues that the patentee of the

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1363 *Avorn*, 309 *Science* 669, 669 (2005).

1364 *Kitch*, 20 *J. Law Econ.* 265 (1977).

1365 *Harrelson*, 7 *Wid. L. Symp. J.* 175, 187-88 (2001).

1366 *Gilbert/Shapiro*, 21 *RAND J. Econ.* 106, (1990) (defining breadth as anything increasing the flow rate of innovator's profits uniformly during the period of protection); *Klemperer*, 21 *RAND J. Econ.* 113 (1990) (defining breadth as a quality advantage conferred on the patentee); cf. *Green/Scotchmer*, 26 *RAND J. Econ.* 20 (1995) (arguing that broader patents in the sequential innovations would determine not the level of per-period profit, but the division of profit between them.).

1367 *Green/Scotchmer*, 26 *RAND J. Econ.* 20 (1995) (defining scope protecting innovator from quality improvements).

1368 See e.g., *Eisenberg*, 56 *U. Chi. L. Rev.* 1017, 1036-44 (1989); *Strandburg*, 1 *UC Irvine L.R.*, 265, 276 (2011).

original invention will collect a larger share of the profit if second generation products are not patentable.<sup>1369</sup>

Other arguments arising from the nature of intellectual assets provide further support for broader scope of rights. Namely, the broader upstream patents would be *helpful for SMEs*. Lerner argues that this is so, because increasing the patent's scope increases the value of the firm, as the result of which broader patents help to attract capital investment.<sup>1370</sup> In addition, based on Lerner and Merges' report that the allocation of control rights to the smaller parties at the time of licensing increases with its financial health,<sup>1371</sup> one can argue that the broader patent scope can be useful if it confers bargaining power either directly or by facilitating financing that enhances SMEs' bargaining power.

Grady and Alexander also maintain that granting broader patent rights to a nascent invention, which is in early development and can signal many various improvements, would avoid the possibility of races to patent the improvements, but would likely induce a rush to patent the original concepts.<sup>1372</sup> Scotchmer and Chang urge that broad patent protection could provide a necessary spur to further innovation, because it would motivate R&D investment in the initial basic technologies, the stand-alone values of which are less than their subsequent innovations.<sup>1373</sup> O'Donoghue and Friebel *et al.*, claim that to induce a large target innovation, larger rewards for larger innovations or some protection against future innovations must be

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1369 *Scotchmer*, 27 RAND J. Econ. 322 (1996); *Chang*, 26 RAND J. Econ. 34, 48-49 (1995) (arguing that broadest protection should be provided not only to those that are very valuable relative to possible improvements, but also those that have very little value relative to the improvements (=which has relatively low stand-alone value)).

1370 *Lerner*, 25 RAND J. Econ. 319, 325-28 (1994) (by noting that the increase in patent scope leads to increase in the firm's valuation).

1371 *Lerner/Merges*, 1997, 27-28.

1372 *Grady/Alexander*, 78 Va. L. Rev. 305, 318 (1992).

1373 *Scotchmer*, 5 J. Econ. Perspect. 29, 31 (1991); *Chang*, 26 RAND J. Econ. 34, 48-49 (1995) (further argued that broadest protection should be provided not only to those that are very valuable relative to possible improvements, but also those which has relatively low stand-alone value because it may also be a breakthrough innovation in the sense that it might generate great spillovers in the form of improvements.).

provided by the patent system.<sup>1374</sup> According to O'Donoghue *et al.*, without some leading breadth of patents, the effectiveness of the patent system to promote innovation will be seriously impeded.<sup>1375</sup>

For the *biopharmaceutical field*, Mazzoleni and Nelson believe that granting patents in the biotechnology field, in which there is a long way to go to reach practical applications, has helped spur research specialist firms.<sup>1376</sup> In addition, they contend that a patent holder with a monopoly on the basic innovation will develop the basic innovation and some of the improvements as well,<sup>1377</sup> not only because the original inventors would earn the entire profit from the improvements,<sup>1378</sup> but also because they have more and better (or perhaps the most and best) knowledge of and experience with the basic substances in this sector.<sup>1379</sup> Burk and Lemley distinguish the pharmaceutical industry from other industries, such as the software and most semiconductor industries, in which inventions were characterized by more incremental improvements.<sup>1380</sup> While insisting that those incremental improvements would not be entitled to the broader scope of the protection, they claim that inventions in the pharmaceutical industry should be entitled to it, because innovations in this industry were likely to take the form of discrete new inventions that usually open up an entire field of inquiry.<sup>1381</sup>

#### b) Arguments against a broader patent scope

To the contrary, Merges and Nelson argue that allowing and enforcing broader patent rights would tend to hinder technical progress, harass the

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1374 O'Donoghue, 1996, 49-50; See also Friebel *et al.*, 2006, 26 (noting that some protection against future innovations should be provided to the basic inventions, for early inventors to fully consider the value of his contribution to future R&D or to allow them to compete with future inventors).

1375 O'Donoghue/Scotchmer/Thisse, 7 J. Econ. Manage. Strat. 1, 3 (1998).

1376 Mazzoleni/Nelson, 27 Res. Policy, 273, 282 (1998).

1377 Merges/Nelson, 90 Colum. L. Rev. 839, 873 (1990).

1378 Scotchmer, 5 J. Econ. Perspect. 29, 32-33 (1991) ("under broad patent protection, the incentive for the first innovator to develop a second generation product will be stronger than for an outside firm (provided the first innovator has expertise to develop the new product, and thinks of it), since the first innovator will earn the entire incremental profit.").

1379 Landes/Posner, 2003, 330.

1380 Burk/Lemley, 89 Va. L. Rev. 1575, 1657 (2003).

1381 Burk/Lemley, 89 Va. L. Rev. 1575, 1657 (2003).

competitors out of the field, and cut down diversity and creativity of the development.<sup>1382</sup> Following this, Nelson with Mazzoleni repeat that stronger patent protection might hinder both technological and economic progress in the field of industries, such as semiconductors, computers, telecommunication, and so forth, because it would induce more litigation and increase costs, and it would hinder the entry of new players.<sup>1383</sup>

Barnett even argues that imperfect patent protection would generate as much incentive to develop as those generated by broader patent protections, because it would encourage upstream researchers, who work on research that is relatively far removed from a commercial end product, to collaborate with downstream firms to appropriate at least some of the spillover applications of the patented research.<sup>1384</sup> Landes and Posner are concerned that broad protection might result in an excessive return of the inventor's fixed costs of invention.<sup>1385</sup>

For the biopharmaceutical field, Rai also maintains that patents on early-stage, nascent biopharmaceutical inventions should not be given broad protection because the protection on those inventions is different from the protection on the end-product drugs, and most cumulative innovation in the industry occurs before a drug is produced.<sup>1386</sup> Heller and Eisenberg claim that strengthening IPR would impede and discourage research rather than promote it; the so-called "anticommon problem."<sup>1387</sup> The "anticommon" is characterized by fragmented property rights. Only by aggregating these rights is it possible to make effective use of the property.<sup>1388</sup> To aggregate the fragmented property rights, high search and negotiation costs are necessary to locate and bargain with the many right holders.<sup>1389</sup>

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1382 *Merges/Nelson*, 25 J. Econ. Behav. Organ. 1, 20-23 (1994) (however, noting that a strong patent may be essential if the inventor of a new chemical product is to profit from the invention); *Merges/Nelson*, 90 Colum. L. Rev. 839, 843-44 (1990) (noting "[w]ithout extensively reducing the pioneer's incentives, the law should attempt at the margin to favor a competitive environment for improvements, rather than an environment dominated by the pioneer firm").

1383 *Mazzoleni/Nelson*, 27 Res. Policy, 273, 280-83 (1998) (noting also broad and strong patent rights would benefit some industries, though they didn't give separate examples.).

1384 *Barnett*, 37 San Diego L. Rev. 987, 1031-32 (2000).

1385 *Landes/Posner*, 2003, 323.

1386 *Rai*, 16 Berkeley Tech. L. J. 813, 818, 836-38 (2001).

1387 *Heller/Eisenberg*, 280 Science 698, 700 (1998).

1388 *Heller*, 111 Harv. L. Rev. 621, 670-72 (1998).

1389 *Burk/Lemley*, 89 Va. L. Rev. 1575, 1611 (2003).

c) Arguments on patent scope with consideration of other relevant factors

*Value dependent*

While stressing the heterogeneity of innovations, Hopenhayn and Mitchell contend that the courts could give a broader scope of protection to fundamental breakthroughs.<sup>1390</sup> Merges and Nelson seem to admit the argument to grant a broad set of claims for breakthrough innovations. They note that, “since the inventor may have enabled a broad new range of applications, courts reason, it is unfair to limit her to the precise embodiment through which she discovered the broader principle claimed.”<sup>1391</sup>

*Situation dependent*

Patent breadth has an impact on the difficulty and cost of inventing around the patent and, thereby, on the entrance of competitive products onto the market. Taking Bell’s invention of the telephone as an example, Grady and Alexander explain as follows: If we were to grant a very narrow protection on it, an incremental improvement would not infringe Bell’s patent, and a second generation improver could enjoy not only the revenue derived from the improved portion but also the entire revenue from Bell’s basic telephone invention. This kind of system would punish the first innovator and reward only the second, and revenue dissipation at the level of second generation invention would get worse.<sup>1392</sup> On the other hand, with a broad protection, Bell would control all opportunities for developing new communication devices, thereby reducing revenue dissipation at the improvement stage. However, granting such a large reward to Bell, who introduced a nascent and generally crude device to society, would lead to revenue dissipation at the pioneer level of innovation.<sup>1393</sup> Finally, they contend that the courts might reconcile these effects by adjusting patent scope on a case-by-case basis. For example, when the improvement-stage revenue dissipation is serious, it will

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1390 *Hopenhayn/Mitchell*, 32 RAND J. Econ. 152, 162-64 (2001) (arguing so in a special setting where the patent authorities can offer a menu of patent types with different lengths and breadths).

1391 *Merges/Nelson*, 90 Colum. L. Rev. 839, 848 (1990); *Hoffman*, 89 Cornell L. Rev. 993, 1041-42 (2004).

1392 *Grady/Alexander*, 78 Va. L. Rev. 305, 307-308 (1992).

1393 *Grady/Alexander*, 78 Va. L. Rev. 305, 307-308, 316-321 (1992).

give broad protection to the original patents, thereby effectively eliminating the possibility of revenue-dissipating rushes to the modifications.<sup>1394</sup>

Landes and Posner point out that the patent system makes no effort to match the degree of patent protection to the variables, such as fixed cost or R&D, ease of inventing around, or the degree of patent protection to create adequate incentives to invest.<sup>1395</sup> Posner insists that the cost of inventing must be compared to the cost of copying in order to determine the optimal patent protection for an inventor, while comparing the software industry where the cost of invention is relatively low with the pharmaceutical industry, where it is very high.<sup>1396</sup>

There is also an interesting suggestion that the patent breadth should be determined by the cost of R&D and the type of invention.<sup>1397</sup> Specifically, when the R&D cost is low, protection of the product should be narrow and protection of the process should be broader. When the R&D cost is high, protection of the product should be high, and the protection of the process innovation should be narrow. However, this argument seems intended to protect process invention more efficiently.<sup>1398</sup>

## 2. Interim conclusion

Granting broad protection to basic inventions would provide basic inventors with maximum incentives, but could discourage improvements, because the probability of infringing the original patent by an improvement inventor would be higher.<sup>1399</sup> As shown in the previous chapter, many arguments have been advanced for and against a broader scope of patents. Among the argu-

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1394 *Grady/Alexander*, 78 Va. L. Rev. 305, 318 (1992); *cf. Matutes/Regibeau/Rockett*, 27 RAND J. Econ. 60, 79 (1996).

1395 *Landes/Posner*, 2003, 300.

1396 *Posner*, Sep, 30, 2012.

1397 *Eswaran/Gallini*, 27 RAND J. Econ. 722 (1996).

1398 *Eswaran/Gallini*, 27 RAND J. Econ. 722 (1996).

1399 *Jaffe/Lerner*, 2004, 48-51; *Scotchmer*, 5 J. Econ. Perspect. 29, 30-35 (1991); *Levin et al.*, 1987 Brookings Paper on Econ. Activity, 783, 788 (1987) (noting strong protection of individual achievement may retard the advance of technology, since technological development is often an interactive and cumulative process); *cf. Gilbert/Shapiro*, 21 RAND J. Econ. 106 (1990) (discussing breadth of patent protection in the context of single innovation with hardly focusing on cumulative innovation).

ments against a broader scope of patents, Nelson with Mazzoleni repeat that stronger patent protection might hinder progress, however, they insist that this could happen in certain fields of industry, such as semiconductor, computer, telecommunication,<sup>1400</sup> but not in the field of biopharmaceutical industry. Barnett could have argued so, because he does not address the downstream inventors' incentives.<sup>1401</sup> In other words, even though upstream inventors may try to collaborate with downstream inventors, the downstream inventors will be less willing to collaborate with the upstream inventors, since they have more and better room to research because of the narrower scope of patents on the upstream inventions. Landes' and Posner's concern does not apply to pharmaceuticals, because the fixed costs of pharmaceutical inventions, if they are NMEs, are among the highest in any industries, and because these costs must embrace all of the failures that enabled the product to reach the market.<sup>1402</sup>

There are also specific arguments for the narrow scope of protection for the biopharmaceutical patents. However, Rai's hierarchy given to cumulative inventions is one level higher than the one on which this dissertation focuses; i.e. the early stage invention in the scope of this dissertation is the end-product drug, and the later stage inventions are improvements on that drug. A word about the "anticommon problem" is necessary. The problem with the anticommon theory is not necessarily the scope of the patent but rather the number of rights held by different owners.<sup>1403</sup> Furthermore, Rader Chief J argued in his blistering dissent that this problem just did not happen because of little commercial value of experiments and the increased need for cooperation.<sup>1404</sup> Moreover, there was no empirical research substantiating these alleged concerns.<sup>1405</sup> Finally, since in the field of the pharmaceutical art usually one, not many, basic invention is required to exploit second generation inventions, the IPRs in this art are not that fragmented.

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1400 *Mazzoleni/Nelson*, 27 Res. Policy, 273, 280-83 (1998) (noting also broad and strong patent rights would benefit some industries, though they didn't give separate examples.).

1401 *Rai*, 16 Berkeley Tech. L. J. 813, 829-30 (2001).

1402 See subsection III.A.1.c).

1403 *Burk/Lemley*, 89 Va. L. Rev. 1575, 1613 (2003).

1404 *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348, 1375 (Fed. Cir. 2012) (Rader Chief J. dissenting).

1405 *Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348, 1375 (Fed. Cir. 2012) (Rader Chief J. dissenting); See also e.g., *Caulfield*, 84 Chi.-Kent L. Rev. 133, 137 (2009).

The question ultimately returns to what kind of invention we need, and the answer for this industry was already given in chapter III.B, i.e. encouraging more breakthrough innovations. Thus, as many scholars have insisted, to obtain more basic inventions in the pharmaceutical field of technology, it would be advisable to provide them with a broader scope of protection. This broader scope of a patent's power to exclude others in turn "forces other firms, if they want to compete in the broad product field, to work on alternatives that may be very different from what is already presented."<sup>1406</sup> Thus, on the one hand, broad patent protection might reduce patent racing as pointed out by Kitch's critics; on the other hand, it could shift the race to the earlier period of invention, i.e. the race for the broad patent.<sup>1407</sup>

Since a breakthrough invention would have less prior arts in the new field that it has just opened, it would have a broad scope of protection. However, how can we practically grant the broad scope of patent in the field of pharmaceutical inventions? The doctrine of equivalents can be applied to accomplish this goal. In practice, however, it can hardly be applied to the pharmaceutical art. The way that the doctrine of equivalents is applied in Germany provides an example.<sup>1408</sup> In brief, the alleged embodiment would not be found to infringe the patent under the literal infringement, because the alleged embodiment is "modified." At this point, the unpredictability of pharmaceutical art is an important factor.<sup>1409</sup> Because of this lack of predictability in the activity, pharmacokinetics and efficacy of compounds, which leads one atom modification of a known compound to be ineffective or promisingly effective, the second condition<sup>1410</sup> would be very difficult to meet, i.e. the person skilled in the art would not be able to find the modified element as having the same effect. Thus, equivalent protection for this industry is neither easily nor properly applied.<sup>1411</sup> Infringement under this doctrine could still be found if the patent is claiming a process invention<sup>1412</sup> or if there is a relationship between prodrugs and metabolites, such

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1406 *Mazzoleni/Nelson*, 27 Res. Policy, 273, 275 (1998).

1407 *Landes/Posner*, 2003, 324.

1408 See *supra* 1071 -1073 and accompanying texts.

1409 See subsection III.A.1.c)(1).

1410 "Whether a person skilled in the art by means of his specialist knowledge is able to identify the modified means as having the same effect."

1411 *Hansen/Hirsch*, 1997, 326.

1412 See e.g., *BGH/Metronidazol*, GRUR 1975, 425 (holding the infringement of a process patent by equivalent means, in the case where the infringing embodiment differed from the wording of the claim).

as in the hetacillin case in the United Kingdom.<sup>1413</sup> Therefore, granting a broader scope of patent claims for selection inventions is not a proper tool for the promotion of pioneering innovations.

Although granting a broad scope of patent does not help to promote basic invention in this art, the already broad scope of genus patent could be a problem because of the overlapping scope of patents with species selection inventions. In the next section, the solutions that can minimize this problem will be discussed.

### 3. Solutions to the overlapping scope with species selection invention

While a patent on the basic invention, such as an NME, is still in force, second generation patents will be subservient to the earlier patent. A patent in this situation can be called a “blocking patent,”<sup>1414</sup> i.e. each patentee may block the other from using second generation patents without a license.<sup>1415</sup> The absolute product protection and the broad claim, such as the Markush type claim, make this blocking effect possible. Suggested solutions to this problem include licensing, the doctrine of reverse equivalents, and a compulsory license.<sup>1416</sup>

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1413 *Hansen/Hirsch*, 1997, 343.

1414 It is important to distinguish the concept of “blocking patents” in this thesis from that described in the Pharma Sector Inquiry. DG Competition defined the “blocking patents” as follows: “[Another originator company] filed several “paper” patent applications related to [our company’s molecule]. The only objective was to impede [our company] from developing [our company’s molecule], as far as (i) no research laboratory data and/or work exists related to this paper patent applications, and (ii) [the other company] has no right on [our compound] compound, protected by patents owned by [our company] A letter [...] was received by [our company] from [the other company], [...] stating that [the other company] is not ready to achieve any settlement at all regarding the blocking patents.” See *DG Competition*, 2009, 391.

1415 *Jackson*, 9 J. Tech. L. & Pol’y, 117, 119 (2004); *Merges/Duffy*, 2011, 398.

1416 *Merges/Nelson*, 90 Colum. L. Rev. 839, 904 (1990); *O’Donoghue*, 29 RAND J. Econ. 654, 658 (1998). (noting strength of leading breadth could be determined by the interpretation of “use of technology”, the doctrine of equivalents, and the doctrine of reverse equivalents.); *Merges*, 62 Tenn. L. Rev. 75 (1994).

a) Voluntary licensing agreements

Licensing is certainly one way to solve this problem. The second generation inventor will try to secure a license from the controlling patentee. Licensing is also advantageous to the basic patentee, because transactions that involve patents are important in monetizing the value of the patent. The basic patentee knows that his patent's value is constantly declining because of its limited term and the threat of new competing technologies, especially considering the limited ways to extract value from an asset that awards only a right to exclude, not a right to use.<sup>1417</sup>

Licensing agreements can occur at two stages: *ex ante* or *ex post*. The difference is whether the second inventor has already incurred the R&D cost for the second generation invention at the time of the license negotiation. Both inventors can negotiate at *ex ante* license before second generation inventors invest any R&D costs. Green and Scotchmer argue that *ex ante* licensing is proper with the wide patent breadth of a basic patent.<sup>1418</sup> Conversely, in *ex-post* licensing, where the second inventor can bargain only after he has incurred the cost and finished the R&D project, firms may underinvest in the second generation inventions, since they know that they will have less bargaining power, because they have incurred costs.<sup>1419</sup> However, these second generation inventions in the pharmaceutical art usually follow the success of a product covered by the basic patent, i.e., either the basic patentee or the secondary inventor will try to pursue these kinds of inventions. Consequently, the order between licensing and the investment does not make a significant difference. *Ex ante* licensing is especially difficult and is typically excluded from consideration.<sup>1420</sup>

Licensing agreements also occur in mutual directions. Cross-licensing between two patentees can be a solution in the situation where the patents block each other and the most efficient invention is to be employed.<sup>1421</sup> Along with Scotchmer, Chou and Haller suggest that the basic patentee

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1417 Kieff, 2008, 16.

1418 Green/Scotchmer, 26 RAND J. Econ. 20 (1995); see also Gallini/Scotchmer, 2002, 72.

1419 Friebel et al., 2006, 27.

1420 Denicolò, 31 RAND J. Econ. 488, 488 (2000); Heller/Eisenberg, 280 Science 698, 699-700 (1998).

1421 Landes/Posner, 2003, 317; Merges/Nelson, 90 Colum. L. Rev. 839, 865-66 (1990).

might be able to extract more of the profit facilitated by the basic innovation by offering a licensing contract that the subsequent inventor can accept;<sup>1422</sup> and the improvers can use their inventions without being concerned about infringement.

However, problems have arisen regarding licensing agreements.<sup>1423</sup> Firstly, because licensing lessens competition, raises antitrust concerns, and may retard innovation.<sup>1424</sup> Secondly, *ex ante* licensing will prevent innovations from appearing in the patent race.<sup>1425</sup> Thirdly, *ex post* licensing can create incentives for inefficient entry by imitators, who seek to “invent around” the original patent.<sup>1426</sup> Fourthly, if the transaction cost is high, it might limit the use of contracts.<sup>1427</sup> Lastly, but importantly, obtaining licenses may not be always possible, because the patentees may prefer to have exclusivity either to avoid competition or sometimes even to attempt to dominate the industry, if they are able.<sup>1428</sup> Since patents matter more in the pharmaceutical industry, companies in these fields might be even less willing to participate in patent pools that would undermine their exclusivity.<sup>1429</sup> In the same manner, they might not be willing to license out to their competitors.

#### b) Non-voluntary licenses

If the second generation patentee fails to acquire a license, he could try to ask the competent authorities to grant a license against the basic patentee’s

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1422 *Chou/Haller*, 1995; *Scotchmer*, 27 RAND J. Econ. 322 (1996); *Chang*, 26 RAND J. Econ. 34, 43-48 (1995); *Green/Scotchmer*, 26 RAND J. Econ. 20 (1995) (also arguing it can be achieved by broadening the first inventor’s patent protection); *Matutes/Regibeau/Rockett*, 27 RAND J. Econ. 60, 77-78 (1996).

1423 *Merges/Nelson*, 90 Colum. L. Rev. 839, 874 (1990) (noting general problems in licensing, e.g. steep transaction costs).

1424 *Chang*, 26 RAND J. Econ. 34, 49 (1995) (arguing the lax antitrust scrutiny of collusion despite reducing the dead weight loss, both because such collusion would be unnecessary and because collusion between holders of competing patents would be desirable only in limited circumstances).

1425 *Gallini/Scotchmer*, 2002, 68.

1426 *Chang*, 26 RAND J. Econ. 34 (1995).

1427 *Mazzoleni/Nelson*, 27 Res. Policy, 273, 279-80 (1998).

1428 *Svatos*, 13 Soc. Philos. Policy 113, 120 (1996).

1429 *Heller/Eisenberg*, 280 Science 698, 700 (1998); Patent pools may be more needed for industries with a strong need of standardization to achieve compatibility amongst various devices.

will, if it is available in his jurisdiction. Under this title, the area of non-voluntary licensing agreement will be explored to try to find solutions.

### (1) Compulsory licenses

As Ann noted, compulsory licenses would be the only exception to the general rule, i.e. patents should do no more than reward and promote innovative activity and encourage the disclosure of the results of their innovative activities.<sup>1430</sup> This exceptional measure of a license authorized by a governmental body to a third party for working the patent without the patentee's consent can be granted for various reasons.<sup>1431</sup> The three most prevalent circumstances under which compulsory licensing provisions are applied are when a dependent patent is blocked, when a patent is not worked, and when an invention is related to food or medicine.<sup>1432</sup> In addition, compulsory licensing can be applied as a remedy in antitrust or misuse situations.<sup>1433</sup> The most relevant ground for this dissertation is that a compulsory license can be granted on dependent patents.<sup>1434</sup> Among the selected jurisdictions, the patent acts of Germany,<sup>1435</sup> the United Kingdom,<sup>1436</sup> and Korea<sup>1437</sup> provide provisions for compulsory licensing of dependent patents. The United States Patent Act does not include an explicit authority for a court to order a compulsory license.<sup>1438</sup> Even in the selected jurisdictions, relatively few such compulsory licenses have actually been granted.<sup>1439</sup> 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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1430 *Ann*, 2009, 361.

1431 *Reichman/Hasenzahl*, 2003, 12-15; *See also Haracoglou*, 2008, 50; TRIPS Agreement, Art. 31 (1) (providing the grounds for the grant of compulsory license, determined by the member states, but not binding).

1432 *See in general, Julian-Arnold*, 33 *IDEA* 349 (1993).

1433 *See in general, Julian-Arnold*, 33 *IDEA* 349 (1993).

1434 This is because the older form of medication is available in the public, thus the reason for the medicine would be hardly applied.

1435 GPA Art. 24(2).

1436 U.K. Patents Act of 1977, §§ 48, 48A(1)(b)(i), (4).

1437 Korean Patent Act Art. 138, para. 1.

1438 *Reichman*, 46 *Hous L. Rev.* 1115, 1139 (2009).

1439 *Reichman*, 46 *Hous L. Rev.* 1115, 1139 (2009).

From 1961 to 2003, twelve applications for compulsory license were filed with the BPatG, only one of which was granted.<sup>1440</sup> This grant allowed the German company Bioferon to produce, to offer, and to market “Polyferon” containing recombinant human gamma-interferon for the new medical indication - chronic polyarthritis, which was widespread in Germany. Bioferon had developed Polyferon. This decision was interpreted in a way that the BPatG desired to stimulate the development of new medical uses of known products and enhanced medical care by granting compulsory licenses.<sup>1441</sup> It was further interpreted that the acknowledged necessary “public interest” under § 24(1) German Patent Act (“GPA”)<sup>1442</sup> 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.<sup>1443</sup> However, BGH revoked this license, mainly based on the lack of sufficient “public interest” to justify granting a compulsory license.<sup>1444</sup> On this decision, *Thomas* comments that “a German court will not grant a compulsory license in order to redress the private interest conflict between the parties, but if exploitation of the invention is in the public interest, then a German court may consider granting a compulsory license.”<sup>1445</sup> However, it appears that the BGH decided the way it did because the basis of the original decision was § 24(1), not § 24(2) GPA.

Considering that the product was for a new medical indication, one may wonder if the conclusion would have been different had a compulsory license under the GPA § 24(2) argued before the same court. Namely, in a case like *Olanzapine*, if the two patentees had been different, would the second patentee have had recourse to § 24(2) GPA to allow the grant of a compulsory license for a dependent patent, which cannot be exploited without using another invention protected by a previous patent? § 24(2) GPA clearly provides the opportunity to obtain a compulsory license under the condition that the

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1440 *Buhrow/Nordemann*, GRUR Int 2005, 407, 409.

1441 *Jaenichen*, 11 Biotechnol. Law Rep. 369, 375 (1992).

1442 GPA § 24(1): A non-exclusive authorization to commercially use an invention shall be granted by the Patent Court in individual cases in accordance with the following provisions (compulsory license) if 1. the person seeking a license has unsuccessfully endeavored during a reasonable period of time to obtain from the patentee consent to use the invention under reasonable conditions usual in trade; and 2. public interest commands the grant of a compulsory license.

1443 *Jaenichen*, 11 Biotechnol. Law Rep. 369, 375 (1992).

1444 *BGH/Polyferon*, GRUR, 190, 1996.

1445 *Thomas*, 23 Santa Clara Computer & High Tech. L. J. 347, 364-65 (2007).

improvement patent contain an important technical advance of considerable economic significance, in comparison with those of the basic patent.<sup>1446</sup> As Straus commented, § 24(2) GPA would play a role in preventing hindrance of the innovation by blocking patents<sup>1447</sup> as well as in improving technological development. Moreover, one can consider this impact in regard to the SPC system in Europe. The SPC not only grants the same rights as conferred by the basic patents, but the granted SPC is also subject to the same limitations and the same obligations.<sup>1448</sup> If the compulsory licenses for the SPC could also be issued as the British Patents Court once held,<sup>1449</sup> when the basic patent acquired the SPC, the blocking effect would not be prolonged. Therefore, even though the difficulty in setting the right royalty rate is fully understandable, the preferable solution would be to enact or implement compulsory licensing provisions for the dependent patent.<sup>1450</sup>

## (2) Case law relevant to compulsory licenses

*In the United States: eBay Inc. v. MercExchange, L.L.C.*

An injunction is an effective way of enforcing a patentee's right.<sup>1451</sup> Before the *eBay* case, injunctive relief was regularly granted in an infringement case. In *eBay v. MercExchange*, however, the U.S. Supreme Court unanimously rejected the claim that as a "general rule a permanent injunction will

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1446 GPA Sec. 24(2) ("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.").

1447 Straus, 1 J.E.C.L. & Pract. , 189 (2010).

1448 Council Regulation 469/2009, Art. 5.

1449 *Research Corp's Supplementary Protection Certificate* [1994] R.P.C. 667, 674.

1450 See also Reichman/Dreyfuss, 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.); for the public interest, see Thomas, 23 Santa Clara Computer & High Tech. L. J. 347, 365 (2007).

1451 cf. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006).

issue once infringement and validity have been adjudged"<sup>1452</sup> and formalized the notion that a court should consider the public impact before granting an injunction to stop infringement. Even though the Supreme Court did not mention a compulsory license as a remedy to the denial of an injunction, many lower courts have granted such relief, i.e. "ongoing royalties" after the denial of a permanent injunction.<sup>1453</sup>

In the *eBay* case, the Supreme Court held that the plaintiff claiming injunctive relief must demonstrate (i) that he had suffered an irreparable injury, (ii) that remedies available at law were inadequate to compensate for that injury, (iii) that considering the balance of hardships between the plaintiff and the defendant, a remedy in equity was warranted, and (iv) that the public interest would not be disserved by a permanent injunction.<sup>1454</sup> This sort of a compulsory license is not a necessary remedy, and, indeed, on remand in the *eBay* case, the District Court did not impose a compulsory license.<sup>1455</sup> Instead, the Court warned that there could be a "real potential for enhanced damages" for the possible post-trial infringement.<sup>1456</sup>

Damage awards for infringements and injunctive relief to prevent infringement through judicial orders to shut down the infringers' production or sales are fundamentally different remedies.<sup>1457</sup> The potentially continued infringement is serious. Without the threat of an injunction, the patentee would be forced to negotiate with the infringing party about granting a license. The risk of incurring treble damages under American law is a strong inducement to the allegedly infringing party to negotiate in good faith. Of course, a myriad of various factors should be considered before granting this kind of remedy. However, this could resolve the mutual blocking problem.

#### *In Germany: Orange Book Standard case*

The blocking effect of basic patents in the competition law area may be attacked by claiming a so-called "compulsory license objection" or the "Eu-

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1452 *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394-395 (2006).

1453 See e.g., *z4 Technologies, Inc. v. Microsoft Corp.*, 434 F.Supp.2d 437 (E.D.Tex. 2006); *Finisar Corp. v. DirecTV Group, Inc.*, 2006 WL 2709206 (E.D.Tex. 2006), reversed in part with different ground, *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323 (Fed. Cir. 2008); *Merges/Duffy*, 2011, 952-53.

1454 *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006).

1455 *MercExchange, L.L.C. v. eBay, Inc.*, 500 F.Supp.2d 556, 585 (E.D.Va.,2007).

1456 *MercExchange, L.L.C. v. eBay, Inc.*, 500 F.Supp.2d 556, 581 n.23 (E.D.Va.,2007).

1457 *Ann*, 2009, 362.

ro-defense”<sup>1458</sup> against a suit for patent infringement. If an attack succeeds, the plaintiff will not receive the benefit of an injunction and cannot claim it. The BGH held its decision on the *Orange Book Standard* case, in this regard.<sup>1459</sup>

At issue was a patent on the “Orange Book Standard” and was related to the manufacture of writable CDs. The primary issue was whether the patentee had abused a dominant position contrary to Art. 102 TFEU<sup>1460</sup> by refusing to grant a license. The Court provided significant prerequisites for this compulsory license defense. The defendant had to act like a “true licensee,” which required that i) the party seeking a license should have made to the patentee an unconditional offer which the patentee cannot refuse and remains bound by said offer, ii) if the alleged infringer has already used the subject matter of the patent before the patentee has accepted the offer, the alleged infringer must pay or guarantee the payment of the license fees resulting from the contract,<sup>1461</sup> and he can do so by rendering accounts about the extent of his acts of use and by complying with the payment obligation, such as depositing the license fees.<sup>1462</sup> The dominance of an essential patent is similar to the dominance of the basic patent over second generation inventions. However, it would be better to wait some time before applying this defense in dependent patent cases. Many questions remain to be answered by the Court, including what is a reasonable amount of royalty, about which the

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1458 See *Hays*, 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)).

1459 *BGH/Orange Book-Standard*, GRUR 2009, 694.

1460 Article 102 of TFEU: “Any abuse by one or more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States.” Such abuse may, in particular, consist in: (a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions; (b) limiting production, markets or technical development to the prejudice of consumers; (c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; (d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.”

1461 *BGH/Orange Book-Standard*, GRUR 2009, 694, 696.

1462 *BGH/Orange Book-Standard*, GRUR 2009, 694, 697.

patent holder and the alleged infringer are likely to disagree, whether a running royalty, which was apparently featured by the BGH, is proper, whether the defendant can still raise a non-infringement argument, and others. Unlike the *eBay* case in the United States, however, the German court appears to grant the injunction if the infringement is confirmed and the existence of market dominance or the abuse thereof is denied.<sup>1463</sup>

c) Reverse doctrine of equivalents

A judicially devised counterpart to the doctrine of equivalents is the “reverse doctrine of equivalents.” As some scholars have argued, improvers could escape liability under this doctrine.<sup>1464</sup> The source of this doctrine is the following statement in the *Graver Tank* case.<sup>1465</sup>

“The wholesome realism of this doctrine is not always applied in favor of a patentee but is sometimes used against him. Thus, where a device is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way, but nevertheless falls within the literal words of the claim, the doctrine of equivalents may be used to restrict the claim and defeat the patentee's action for infringement.”<sup>1466</sup>

This doctrine can be a good remedy in the situation where a dependent patentee and a dominant patentee are unable to reach a license agreement, and the introduction of the invention to the market can be facilitated. Once a patentee establishes literal infringement, the alleged infringer can try to establish noninfringement under the reverse doctrine of equivalents.<sup>1467</sup> As *Merges* argues, this doctrine can be used to influence reluctant patent holders

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1463 *BGH/Orange Book-Standard*, GRUR 2009, 694, 697 (holding “Just as the proposed licensee cannot be denied the possibility to defend himself first of all against the accusation of infringement, the consequence being that the action has to be dismissed in its entirety if the accusation of infringement turns out to be unjustified, the patent holder cannot be prohibited from first of all asserting the claim for injunctive relief based on the patent, the consequence being that this claim must be adjudged if the infringement is confirmed and if the court negates a dominant position on the market or an abuse of the same.”).

1464 *Lemley*, 75 Tex. L. Rev. 989, 1010-13 (1997); *Merges/Nelson*, 90 Colum. L. Rev. 839, 911 (1990); *Merges*, 62 Tenn. L. Rev. 75, 91-99 (1994).

1465 *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 608-09 (1950).

1466 *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 608-09 (1950).

1467 *SRI Intern. v. Matsushita Elec. Corp. of America*, 775 F.2d 1107, 1023-24 (Fed. Cir. 1985).

who considered using “holdup rights” against improvers,<sup>1468</sup> and it can be valuable, since it can help to maintain a balance in infringement cases by mitigating the impact of literal infringement.<sup>1469</sup> Lemley also insists that this doctrine will serve as a crucial release valve that will prevent the patentees from stifling improvements.<sup>1470</sup>

Most importantly, the doctrine will be applied in the cases where there is a “considerable added value” in the contested embodiment.<sup>1471</sup> According to Lemley, the radical improver is the inventor of an improvement sufficiently different to constitute a departure from all that came before it.<sup>1472</sup> Landes and Posner also note that, “if the contribution made by the improvement greatly exceeds the contribution made by the original patented invention, the improver is allowed to practice his invention without being deemed an infringer, even though he is making use of the prior invention without a license from the patentee.”<sup>1473</sup> This is permitted because the degree of the blocking problem is dependent on the situations. The problem will be more significant if the contribution of the prior inventor is of very little value compared to the improvement; the problem will be less significant if the contribution of prior invention is of the same or greater value than the selection patent.<sup>1474</sup>

The application of this doctrine should be limited,<sup>1475</sup> and, indeed, courts have rarely applied it.<sup>1476</sup> One of the biggest concerns is that both patents should be evaluated to confirm the additional contribution by a species selection invention. However, considering that a species selection invention can be developed into another NME, the species selection inventions could be at least as valuable as the genus patent if a medicine covered by the basic patent was developed; it could be even more valuable if no medicine covered by the basic patent was developed. Thus, this doctrine is more likely to be

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1468 *Merges*, 62 Tenn. L. Rev. 75 (1994).

1469 *Merges*, 73 J. Pat. & Trademark Off. Soc'y 878, 880 (1991).

1470 *Lemley*, 75 Tex. L. Rev. 989, 1010-13 (1997).

1471 *Domeij*, 2000, 129.

1472 *Lemley*, 75 Tex. L. Rev. 989, 1010 (1997).

1473 *Landes/Posner*, 2003, 317.

1474 *Merges/Nelson*, 90 Colum. L. Rev. 839, 865-66 (1990).

1475 *Domeij*, 2000, 129 (noting like the uncertainty caused by the doctrine of equivalence, there is uncertainty to interpret the claims and the case is exceptional).

1476 *Durham*, 1999, 148-419.

applied for species selection inventions,<sup>1477</sup> because there is less concern about assessing the values of both patents. Moreover, since this assessment would be made not before the patent office but before a court, which would have a greater opportunity to consider evidence as the patent lives, one may not need to worry too much about the difficulty in applying this doctrine. Therefore, it would be advisable for courts to apply this doctrine when a broader prior genus patent holds up the sale of a new medication or at least to try applying it actively to encourage manufacturers to invest their resources in the products that are literally covered by the broader earlier patent.

#### d) Conclusion

There have been many proposals by scholars<sup>1478</sup> about voluntary license agreements. Since the pharmaceutical companies usually do not want to undermine their exclusivities by licensing, apart from the license agreements with academia or SMEs, voluntary license agreements do not seem to be of practical use. Among the judicially acknowledged compulsory licenses, the *eBay* case appears to be the most applicable to dependent patents. Most properly, either an implementation of the statutory compulsory license or an improved use of the reverse doctrine of equivalence would be desirable to solve the problem created by using the dominant patent to block the exploitation of a dependent patent. The same approach could be applied to the situation in which the basic patent blocks the use of inventions on dosage forms, combinations of active ingredients, or especially new medical uses.

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1477 This situation is different from the doctrine of equivalents can scarcely be applied for the chemical selection inventions; or also different from other selection inventions would be still difficult to be applied this doctrine because of their comparably low value.

1478 See *supra* 1418 -1422 and accompanying texts.

## D. Proposals on the length of patents

## 1. Arguments on the length of patents

The breadth and length of a patent are often contrasted, but they are substitutes.<sup>1479</sup> The limited patent term is one of the devices employed to minimize the social cost of patent exclusivity.<sup>1480</sup> Empirical research has shown that the economic benefit of having patents often vanishes before they expire.<sup>1481</sup> It is also reported that the *de facto* term is chosen by the patentee in return for renewal fees.<sup>1482</sup> Indeed, reportedly no more than 50% of patents are maintained longer than 10 years across technologies and countries.<sup>1483</sup> The effective economic life of a patent ends at the moment when any non-infringing but competitive improvements emerge in the market.<sup>1484</sup> Again, there are substantial inter-industry variations. Unlike in industries in which the life cycle of a product is very short and its turnover is frequent, such as electronics, the lifetime of a patent is more relevant in the pharmaceutical industry.<sup>1485</sup> The value of patent protection in this industry is clearly demonstrated by the market erosion that occurs when generic versions are introduced after a patent expires.

In contrast to the breadth of patents, their duration is not hotly debated, probably because many patent systems set a statutory 20-year patent term. While disagreeing with the uniform patent life, Cornelli and Schankerman assert that “differentiated patent lives can be welfare improving because of an ‘incentive effect’: allowing firms with high R&D capabilities to choose longer patent lives gives these firms an incentive to invest more R&D re-

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1479 Landes/Posner, 2003, 331.

1480 Landes/Posner, 2003, 302.

1481 Hunt, 1999, 2; See for instance, Mansfield/Schwartz/Wagner, 91 Econ. J. 907 (1981).

1482 Scotchmer, 30 RAND J. Econ. 181 (1999); Cornelli/Schankerman, 30 RAND J. Econ. 197 (1999).

1483 Scotchmer, 30 RAND J. Econ. 181, 182 (1999); Cornelli/Schankerman, 30 RAND J. Econ. 197, 197 (1999); O'Donoghue/Scotchmer/Thisse, 7 J. Econ. Manage. Strat. 1, 2 (1998).

1484 Scotchmer/Green, 21 RAND J. Econ. 131 (1990) (noting “the effective life of the patent is the time until it is superseded by a superior technology.”); Friebe et al., 2006, 30; O'Donoghue/Scotchmer/Thisse, 7 J. Econ. Manage. Strat. 1 (1998) (defining “effective patent life as a life which is “the expected time until a patented product is replaced in the market”).

1485 Levin et al., 1987 Brookings Paper on Econ. Activity, 783, 816 (1987).

sources.”<sup>1486</sup> While arguing that the patents used for good inventions live much longer than the existing statutory maximum term, they contend that it might be optimal to grant a zero patent life for inventions with low value, and an infinite life for inventions with high value.<sup>1487</sup> Under the circumstances of cumulative inventions, Green and Scotchmer argue that a longer duration of a patent should be attributed, especially to the first inventor, if a sequence of innovations was provided by different inventors rather than by the concentrated effort of one company. They reason that it is difficult to divide profit between the first and second inventors and that the incentive to undertake basic research will inevitably be too weak.<sup>1488</sup> Other scholars discuss this issue in consideration of other factors. Gilbert and Shapiro argue that the optimal patent life should be infinite, while the patent breadth should be narrow.<sup>1489</sup> Alternatively, as O'Donoghue *et al.*, maintain, although the statutory life of a patent and its effective economic life differ, both can coincide when the breadth of the patent is so broad as to cover every subsequent innovation in a product that infringes the basic patent.<sup>1490</sup>

As Nordhaus shows, however, a longer patent life brings a more inventive input to society, but it also prolongs the deadweight loss of such inventions.<sup>1491</sup> Thus, the optimal life of a patent should be finite and should end at the point at which the increased number of inventions and the length of the monopoly are in balance.<sup>1492</sup> The determination of this point remains unsolved.

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1486 *Cornelli/Schankerman*, 30 RAND J. Econ. 197, 197 (1999).

1487 *Cornelli/Schankerman*, 30 RAND J. Econ. 197, 198, 209 (1999).

1488 *Green/Scotchmer*, 26 RAND J. Econ. 20, 20-21 (1995).

1489 *Gilbert/Shapiro*, 21 RAND J. Econ. 106, 111-112 (1990) (But also mentioning that “overly-long patent would retard subsequent innovation by establishing monopoly rights to an entire line of research”).

1490 *O'Donoghue/Scotchmer/Thisse*, 7 J. Econ. Manage. Strat. 1,2 (1998).

1491 *Nordhaus*, 1969, 70-75.

1492 *Nordhaus*, 1969, 76-86.

## 2. Proposals on the length of patents

### a) Proposal on the length of basic patents

#### (1) Introduction

Since the pharmaceutical industry is very susceptible to the terms of patents, the patent term can be certainly and efficiently applied to basic pharmaceutical patents to incentivise the drug companies to invest more in the R&D targeting NMEs. The current term of a patent, however, does not serve this purpose well.

The uniform patent term starts to run from the patent filing date, but the effective patent term runs from the date when the product reaches the market. The latter date varies highly from industry to industry and from product to product. Generally, the longer it takes to bring a drug to market, the greater the investment that must be made will be, and the better the protection provided to the product will need to be in order to justify incurring the R&D cost. This is quite the reverse of what it should be. First, without consideration of a patent term extension, the drugs containing NMEs that take longer than ten years to get to market could enjoy fewer than ten years of exclusivity. In contrast, second generation inventions or even dosage regimes, such as “once a day prior to sleep” can theoretically enjoy at least 17 years of exclusivity if the patent examination is completed within three years.<sup>1493</sup> Therefore, there have been significant deadweight losses by second generation patents, and the uniform patent term has not provided enough incentives for basic innovations. In this sense, the patent system seems to provide *de facto* reverse-discriminatory protection to basic inventions, because it takes so long time to get each invention to market.

Even if the patent term extension, which aims to compensate the reduced exclusivity period because of the long R&D<sup>1494</sup> is considered, the situation is not significantly improved. As the preamble to the Council Regulation 469/2009 clearly states, the purpose of this system is to encourage research, especially long and costly research on medicinal products.<sup>1495</sup> In the United States, one-half of the time during which the drug is evaluated as an inves-

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1493 Of course, it is not possible to note that this kind of invention does not deserve the 17 years' exclusivity.

1494 See e.g., Rai, Ill. L. Rev. 173, 182-83 (2001).

1495 Council Regulation 469/2009, Preamble (3).

tigational new drug, plus the time during which the drug is pending approval at FDA, would be compensated.<sup>1496</sup> In Europe, neither the date of the patent grant nor the duration of clinical trials is relevant to the duration of the SPC, because only the date of first marketing approval in the community matters.<sup>1497</sup> The medication that gains first marketing approval between five and ten years from the patent filing date, is most likely covered by second generation inventions, and could enjoy fifteen years of maximum effective patent life. However, those medications that are launched ten years after the filing date can never enjoy the maximum effective life<sup>1498</sup> (see Figure 9). In Korea, the situation is comparably better, since the whole period necessary for the clinical trial and the regulatory approval can be extended. However, the extension period still has a five year cap, as do the systems in other jurisdictions. The basic reason for this is probably that the patent term extension system was not originally meant to compensate for the loss of exclusivity because of the long R&D period, but was instead meant to offset the accelerated generic entry into the market. Some scholars point out that the effective patent terms for inventions having unduly long R&D periods might not be effective enough to convince manufacturers to invest in such inventions, which can cause society to lose these innovations.<sup>1499</sup>

## (2) Proposed term of basic patents

How can this problem be remediated? Ideally, the system must award each invention in accordance with the extent that it contributes to society or in an amount that will compensate the cost and time of R&D. However, calculating the amount of such an award would be very difficult and, even if possible, would incur significant administrative costs.<sup>1500</sup> Considering the discrepancies discussed above and the shortage of basic medications, therefore, it would be advisable to include a provision on the patent term of the basic invention as follows:

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1496 35 U.S.C. § 156.

1497 Council Regulation 1768/92, Article 13.

1498 See subsection V.C.3..

1499 *White*, 38 J. Pat. Off. Soc'y 839, 853 (1956).

1500 In addition, there could be an invention which comes just out of the brilliance of inventor, even though it does hardly apply to the pharmaceutical inventions.

“The term of a patent, which covers a product containing an active ingredient that has not been subject to the marketing approval process related to the first commercial marketing of the active ingredient, shall be the later of either i) 15 years after the marketing approval date or ii) 20 years after the patent filing date.”

### (3) The basis of the proposal

According to the proposal, an NME that gains marketing approval from the regulatory authority would enjoy fifteen years of effective term,<sup>1501</sup> but, if it fails to gain marketing approval, it would still enjoy the conventional patent term. The fifteen year effective term is based on the maximum effective patent term with SPC protection,<sup>1502</sup> and considers the regulatory exclusivity available in Europe, which is eight to ten years for the new medical entities,<sup>1503</sup> and which is longer than the one in the United States. The second option, which is to set the patent term at 20 years after the patent filing date, was added in consideration of the decision in *Canada – Term of Patent Protection*. In this dispute, the Panel, and afterwards the Appellate Body of the WTO, reviewed Canada’s patent term calculation based on seventeen years after the grant of the patent. They found a violation of Art. 33 TRIPS, because this calculation failed to provide a patent term of at least twenty years from the patent application filing date, regardless of the fact that the calculation would often lead to a longer term.<sup>1504</sup> Since the TRIPS Agreement sets out the minimum standards of protection to be provided by each member,<sup>1505</sup> further protection could be provided.

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1501 *Domeij*, 2000, 283.

1502 In fact, considering the R&D for the chronic diseases, Alzheimer’s disease, or cancers, it would be much advisable to provide longer protection, however, it was found very difficult to propose something without any further basis.

1503 Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.

1504 *WTO-Panel Report*, Canada-Term of Patent Protection, WT/DS170/R (May 5, 2000); *WTO-Appellate Body Report*, Canada-Term of Patent Protection, WT/DS170/AB/R (Sep 18, 2000).

1505 TRIPS Art. 1(1) “Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, *implement in their law more extensive protection than is required by this Agreement*, provided that such protection does not contravene the provisions of this Agreement.” [Emphasis added].

TRIPS compliance must be considered further. Canada challenged the same issue before the WTO-Panel contending that the SPC regulation was incompatible with the obligation of the non-discrimination principle based on the field of technology (Art. 27(1)),<sup>1506</sup> since it is available only for pharmaceuticals and for agricultural chemical products.<sup>1507</sup> However, this request was not pursued by Canada. In the same manner as this SPC regulation, the German Patent Act<sup>1508</sup> and the British Patents Act,<sup>1509</sup> the American Patent Act<sup>1510</sup> and the Korean Patent Act contain provisions that benefit only the pharmaceutical and agrochemical industries.

Many scholars have discussed the scope of this non-discrimination principle according to Art. 27(1) TRIPS and argued that Art. 27(1) did not require a single level of protection for all technologies and that it must be distinguished from “differentiation” for legitimate reasons.<sup>1511</sup> This principle was also considered by the WTO Panel in *Canada-Patent Protection of Pharmaceutical Products*.<sup>1512</sup> The Panel noted that “[t]he ordinary meaning of the word ‘discriminate’ is potentially broader than these more specific definitions.” It certainly extends beyond the concept of differential treat-

- 1506 TRIPS Art. 27(1): “inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, *patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*” (Emphasis added).
- 1507 Request for Consultations by Canada, *European Communities - Patent Protection for Pharmaceutical and Agricultural Chemical Product*, December 7, 1998, WT/DS153/1. This dispute was indeed initiated by Canada as a kind of a counter-claim against the dispute initiated by the EC on the provisions of Canadian Patent Act (*Canada-Patent Protection of Pharmaceutical Product*, March 17, 2000, WT/DS114/R), however, it have not been pursued by Canada.
- 1508 GPA Sec. 49a.
- 1509 U.K. Patents Act, Sec. 128B and Schedule 4A.
- 1510 35 U.S.C. § 156; *see also* 35 U.S.C. § 103(b) (2000).
- 1511 *Correa*, 3 Tul. J. Tech. & Intell. Prop. 1, 7 (2001) (noting “differential treatment does not necessarily mean discriminatory treatment, because different technologies might require different treatment.”); *Dinwoodie/Dreyfuss*, 13 Mich. Telecomm. Tech. L. Rev. 445, 452 (2007) (“We suggest that those defending an exclusion as compliant with Article 27 should be permitted to rebut a showing of disparate treatment by demonstrating a legitimate purpose.”); *Berger*, 17 Conn. J. Int’l L. 157, 200 (2002).
- 1512 *WTO-Panel Report*, Canada - Patent Protection of Pharmaceutical Products, WT/DS114/R (Mar 17, 2000).

ment. It is a normative term, pejorative in connotation, referring to results of the unjustified imposition of differentially disadvantageous treatment.<sup>1513</sup> This could be interpreted as allowing members to treat different fields of patent protection differently if they do so for a legitimate regulatory purpose.<sup>1514</sup> The panel further noted that “Article 27 does not prohibit bona fide exceptions to deal with problems that exist only in certain product areas.”<sup>1515</sup> This further suggests that the members may adopt different rules if the differences are adopted for bona fide purposes and if such measures are consistent with other provisions of TRIPS.<sup>1516</sup> Thus, this proposed provision should be interpreted as not violating the TRIPS Agreement. Even if it does, since the existing industry-specific provisions have encountered little challenge, the threat of such an attack would likely be limited.<sup>1517</sup>

#### (4) Expected effects

The guaranteed effective patent term proposed by the proffered provision could motivate the pharmaceutical industry to incur the investment of the R&D of new medical entities with less concern about the period to recover the R&D costs. Furthermore, ample litigation and invalidity actions have already occurred with regard to the validity of patent term extensions. By adapting this provision, the unnecessary waste of resources through litigation would be substantially reduced. Additionally, the manufacturers could invest the saved resources in R&D as long as the patentee is confident about the patentability of the ultimate invention. This optimized effective patent term would also provide the SMEs with more bargaining power and would help them to attract funding. In the end, and most importantly, this could increase the number of NMEs and ultimately the health of society.

One may argue that this proposal may delay access to medicine. However, it is undeniable that medicine must first be available before access can be taken into consideration.

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1513 *WTO-Panel Report, Canada - Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar 17, 2000), para 7.94.

1514 *Gervais*, 2012, 2.369.

1515 *WTO-Panel Report, Canada - Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar 17, 2000), para 7.92.

1516 *Gervais*, 2012, 2.369.

1517 *Roin*, 87 Tex. L. Rev. 503, 558 (2009).

b) Proposal on the patent term extension of second generation patents

As Landes and Posner worry, protection might realize a return vastly in excess of the inventor's fixed cost of innovation. This would be especially true if the inventor could effectively extend his patent term by obtaining improvement patents.<sup>1518</sup> In fact, a patentee could enjoy the patent term of a selection invention plus its SPC in addition to those of the basic patent. These proliferating patent rights and SPCs on second generation patents have signalled the manufacturers to invest more in second generation inventions.

Following the same logic that supports protecting basic inventions, it would be proper to provide a shorter protection period to the second generation patents. However, since the TRIPS Agreement sets out the minimum standards of protection that should be provided by each member,<sup>1519</sup> it would be absurd to do so.

However, the patent term extension on second generation patents could be limited in two ways. Firstly, it could be reduced through the heightened patentability requirements, which will be discussed in the next chapter, and the reduced number of second generation patents that would result. Secondly, until the effect of heightened patentability requirements is established, grants of patent term extensions could be restricted. As long as a biologically active moiety is the same, the patent term extension would be granted to the first substance applied, as in the *Doxorubicin-sulfate* case in Germany. This could further be applied to granting a patent term extension to salts or esters.

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1518 *Landes/Posner*, 2003, 323.

1519 *See* TRIPS Art. 1(1).

E. Proposals on the patentability requirements

Patents should be granted to the extent necessary to encourage the innovation that otherwise would not reach the public,<sup>1520</sup> and that are socially desirable.<sup>1521</sup> These can be controlled through the patentability requirements.

1. Introduction: Technology specific patentability standards

The Imperial Supreme Court of Germany has held that the question of whether an invention exists cannot be answered differently for an invention in the field of the chemical industry than for an invention in the field of the mechanical industry.<sup>1522</sup> As some scholars note, the law must be the same for all patents and types of inventions.<sup>1523</sup> Certainly, in the past, the inventions were more homogeneous than they are today, and it made more sense to have a unified set of rules for inventions.<sup>1524</sup> Some scholars also advocate for a uniform patent system, because of the difficulty of implementing differential treatment.<sup>1525</sup> Jaffe and Lerner argue for a uniform system, because as soon as patentees in a particular category receive the better treatments, there would be an inevitable tendency for people to position themselves to

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1520 *Lessig*, 11 St. John's J. Legal Comment. 635, 638 (1996) (noting “while we protect real property to protect the owner from harm, we protect intellectual property to provide the owner sufficient incentive to produce such property. ‘Sufficient incentive,’ however, is something less than ‘perfect control’.”); *Lemley*, 83 Tex. L. Rev. 1031, 1065 (2005) (noting “[g]ranting intellectual property rights imposes a complex set of economic costs, and it can be justified only to the extent those rights are necessary to provide incentives to create.”); *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, 1345-46 (7th Cir. 1983) (Posner, J. concurring in part and dissenting in part, especially noting “[t]he inherent problem was to develop some means of weeding out those inventions which would not be disclosed or devised but for the inducement of a patent.”); *Burk/Lemley*, 89 Va. L. Rev. 1575, 1598-99 (2003).

1521 *Roin*, 87 Tex. L. Rev. 503, 512 (2009).

1522 *Kongo-Rot*, Decision of the Reichsgericht (Imperial Supreme Court) of May 8, 1889, Patentblatt 1889, 209, 212.

1523 *Harmon/Homan/McMahon*, 2010, 14.

1524 *Allison/Lemley*, 82 B.U.L.Rev. 77 (2002). Considering this, one may doubt whether it is still appropriate to apply the same rules in today’s increasingly complex landscape of inventions.

1525 *Jaffe/Lerner*, 2004, 203-05.

get the most favourable treatment.<sup>1526</sup> At the same time, however, they acknowledge the differences between the technologies and the specificities of the pharmaceutical industry and further admit that it is vitally important to resolve the problems with patenting in different areas.<sup>1527</sup> Regarding these inter-industry differences, Wagner argues there need be no concern, because they are merely factual differences.<sup>1528</sup> However, “[o]ne-size-fits-all’ ultimately fits few”,<sup>1529</sup> and this approach has been repeatedly challenged.<sup>1530</sup>

We have a uniform patent system, which provides technology-neutral protection to all kinds of inventions.<sup>1531</sup> However, although technology-neutral in theory, patent law is technology-specific in application.<sup>1532</sup> For example, for software patents in the United States, a series of decisions has not only eliminated the enablement and best mode requirements, but has also found that a high-level functional description is sufficient to meet these requirements.<sup>1533</sup> In contrast, for patents in biotechnology, the courts have focused on the unpredictability of the arts, and emphasized proof of the

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1526 *Jaffe/Lerner*, 2004, 203-05.

1527 *Jaffe/Lerner*, 2004, 205 (“[...] the problems in business methods, software, and biotechnology derive from the unique properties of these technologies.”).

1528 *Wagner*, 50 *Adv. Genet.* 367 (2003).

1529 *Crews*, 49 *J. Copyright Soc’y U.S.A.* 549, 564 (2001).

1530 *Hilty*, 2009, 92.

1531 *Burk/Lemley*, 17 *Berkeley Tech. L.J.* 1155, 1156 (2002).

1532 *Burk/Lemley*, 89 *Va. L. Rev.* 1575, 1577 (2003); *Burk/Lemley*, 17 *Berkeley Tech. L.J.* 1155, 1156 (2002). (also noting the legal rules were the same, but the application of those to different industries were different from each other); cf. *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1323-27 (Fed. Cir. 2003) (noting but criticizing technology specific requirements between the biotechnology (*Reagents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566-69 (Fed. Cir. 1997)) and software invention (e.g.: *Northern Telecom, Inc. v. Datapoint Corp.*, 908 F.2d 931, 941-43 (Fed. Cir. 1990), *cert denied*, 498 U.S. 920 (1990)); *See also Klemperer*, 21 *RAND J. Econ.* 113, 127 (1990) (noting optimal patent policies vary across different classes of products).

1533 *Burk/Lemley*, 17 *Berkeley Tech. L.J.* 1155, 1162 (2002); e.g., *Fonar Corp. v. General Electric Co.*, 107 F.3d 1543, 1549 (Fed. Cir. 1997) (“[...] writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed.”); *see also Mahajan*, 67 *Fordham L. Rev.* 3297, 3317 (1999) (noting, for example, it was not mandatory to disclose the source code of the patented program).

structure of the invention.<sup>1534</sup> As is noticeable from the name itself, a person skilled in the art is very specific to the particular technology in which the inventions are involved. This imaginary person is involved in determining many doctrines in the patent law, such as non-obviousness, enablement disclosure, definiteness of patent claims, claim construction, doctrine of equivalents, and others. Thus, the assessments of these doctrines are already technology specific. A skilled person in the software industry is so skillful as to need little guidance from the prior art to implement a new idea in software. However, a skilled person in the biotechnology industry is apparently less skillful, and so needs much more information from the prior art to enable an invention. If one imagines that the same standard were applied in biopharmaceutical inventions and software inventions, it would be tantamount to requiring disclosure of the entire source code, symbol by symbol, including all source code permutations that would not alter the function of the software.<sup>1535</sup> Indeed, this concept of an imaginary person leaves the discretion to the courts or patent offices, and proper exploitation of this concept will allow the flexible tailoring of the law to the different fields of technology.

Some scholars suggest adopting technology specific patent rules to deal with the specific attributes of different technologies.<sup>1536</sup> As a representative characteristic, the field of biotechnology is considered less “predictable” than the fields of mechanics or electronics.<sup>1537</sup> The Federal Circuit perceived unpredictability in the pharmaceutical field that might distinguish pharmaceutical inventions from mechanical inventions in its assessment of obviousness.<sup>1538</sup> In the *Eli Lilly* case, the Federal Circuit heightened the written

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1534 See e.g., *Reagents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) (“A definition by function, [...] does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.[...] It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. [...] Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.”).

1535 *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1325 (Fed. Cir. 2003).

1536 See e.g., *Long*, 55 Fed. Law. 44, 49 (2008); *Meurer*, 8 Wash. U. J. L. & Pol’y 309 (2002) (arguing the scope of business method patents should be construed narrowly).

1537 See, e.g., *In re Vaeck*, 947 F.2d 488, 496 (Fed. Cir. 1991).

1538 *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1090 (Fed. Cir. 2008).

description requirement specifically for biotechnological inventions,<sup>1539</sup> which received heavy criticism from many scholars.<sup>1540</sup> Considering the heterogeneity of inventions and technologies and the developments thereof, the uniform application of patent requirements would not only be difficult, but also unfair. Instead, they contended that industries must be treated differently through the existing patent law provisions and doctrines.<sup>1541</sup> Based on these *de facto* technology specific patentability standards, the proposals on the patentability of pharmaceutical inventions including the way to implement this principle will be analyzed and provided.

## 2. Proposals on the novelty requirement

### a) Arguments on the novelty requirement

Many scholars argue that a more demanding patentability requirement would result in a higher level of innovations. Luski and Wettstein contend that lowering the novelty requirement would result in lowering the levels of R&D and innovation and that heightening the novelty requirement would prevent firms from pursuing sub-optimally small innovations and increase R&D expenditures and social welfare.<sup>1542</sup> Scotchmer and Green caution against a weak novelty requirement, which would induce firms to patent even incremental inventions.<sup>1543</sup> They further argue that, with a strong novelty requirement, the market would be more concentrated (e.g. possibly only competition between advanced innovation and the base-level technology) by softening post-innovation competition. Thus, the innovators would realize a better profit flow at the second stage, and a strong requirement would

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1539 *Reagents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559 (Fed. Cir. 1997).

1540 See *supra* 899 .

1541 *Burk/Lemley*, 89 Va. L. Rev. 1575, 1638-68 (2003); see also *Long*, 55 Fed. Law. 44, 49 (2008).

1542 *Luski/Wettstein*, 1 Probl. Perspect. Manage. 31, 40-42 (2004); See also *La Man-na*, 10 Int'l. J. Indus. Org. 81, 81-82 (1992) (noting that a high minimum patentability standard would be more optimal instrument than setting patent life, and would demand the patentees to develop his idea into a well-defined form with specifically beneficial properties to be granted as patents).

1543 *Scotchmer/Green*, 21 RAND J. Econ. 131 (1990).

induce more innovators to enter into the race.<sup>1544</sup> Van Dijk coins a new term, “patent height,” which is mainly determined by the stringency of the novelty requirements and defines the degree of protection against rival improvements.<sup>1545</sup> He explains that patent height could be deployed as a policy instrument to incentivize certain types of research, thus high protection would stimulate basic research.<sup>1546</sup>

Abramowicz and Duffy maintain that it could even be considered as a way of permitting patents to issue on products that are not technologically novel if they do not exist in the market place.<sup>1547</sup> Roin argues for relaxing the novelty requirement for basic inventions in the pharmaceutical art and proposes amending the novelty requirement to allow patenting drugs that have not yet been developed and are not otherwise covered by a valid patent or a pending patent application.<sup>1548</sup> At the same time, he recommends applying the traditional patentability standards to drugs that are derived from certain minor changes to existing drugs.<sup>1549</sup>

## b) Proposal on the novelty requirement of species selection invention

### (1) Meaning of something “made available to the public” in the pharmaceutical industry

Owing to the cumulative nature of technologies, some patents granted today can hinder the follow-on inventions,<sup>1550</sup> as long as they are still valid and can exclude others from exploiting their inventions. However, after patent term expiration, these inventions are available to the public, and the public must be free to use them. The U.S. Supreme Court held as follows:

“First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions, to stimulate further innovation and to permit the public

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1544 *Scotchmer/Green*, 21 RAND J. Econ. 131 (1990) (*cf.* In the same literature, they also argued the weak patentability would be attractive as well, since it would permit the technologies to be patented and this is also socially valuable.).

1545 *Van Dijk*, 44 J. Ind. Econ. 151, 152 (1996).

1546 *Van Dijk*, 44 J. Ind. Econ. 151, 165-66 (1996).

1547 *Abramowicz/Duffy*, 83 N.Y.U. L. Rev. 337, 398 (2008).

1548 *Roin*, 87 Tex. L. Rev. 503, 558, 567 (2009) (further distinguishing the one which did not need to go through the clinical trials from those which needed to do so.).

1549 *Roin*, 87 Tex. L. Rev. 503, 558, 567 (2009).

1550 *See* subsection II.A.

to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.”<sup>1551</sup>

In other words, the information already disclosed to the public must keep providing free access to them and cannot be subject of further patent protection.<sup>1552</sup> To accomplish this, those inventions that have been made available to the public constitute the prior art and claims to identical inventions would lack novelty. As Merges notes, “[t]he logic behind [the novelty requirement] is fairly straightforward, [since, if] information is already in the public domain when the ‘inventor’ seeks to patent it; society has no need to grant a patent to get this information.”<sup>1553</sup> In addition, denying an invention a patent because of the lack of novelty could mean that an idea has been available to the public. This is proper for such industries as mechanics, where, once the idea, like the structure of a wheel, is available, the public can easily exploit the idea and enjoy the product.

However, what is the meaning of an idea being available to the public in the pharmaceutical art? One may look at one genus invention claimed as a Markush type claim<sup>1554</sup> and consider what kind of invention the public can practice once the patent expires, or what kinds of ideas become public domain and remain for the free use of the public. A person skilled in the art may have a fairly good idea about the structures and expected potential therapeutic effects of millions of compounds, and he could work on them for future development. However, the public could hardly benefit from a new medication, unless someone has invested and succeeded in gaining market-

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1551 *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979); see also *Ann*, 2009, 361 (noted “[p]atents, as a rule, shall do no more than reward and promote innovative activity and encourage the disclosure of its results.”).

1552 *Eisenberg*, 53 Vand. L. Rev. 2081, 2088 (2000) (“Granting patents on technologies that are not new would impose the social costs of monopolies without the countervailing benefits of promoting development and introduction of welfare-enhancing inventions.”); *Merges*, 7 High Tech. L. J. 1, 12-13 (1992).

1553 *Merges*, 7 High Tech. L. J. 1, 12-13 (1992); see also Art. 54(2) EPC (“The state of the art shall be held to comprise *everything made available to the public* by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application.” [Emphasis added]); See also 35 U.S.C. 2011 Art. 102(a) (“A person shall be entitled to a patent unless—(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or *otherwise available to the public* before the effective filing date of the claimed invention.” [Emphasis added]).

1554 See e.g. *supra* 110 and accompanying texts.

ing approval for it as a drug.<sup>1555</sup> In this sense, the novelty requirement seems to treat the pharmaceutical field more strictly than it does other technical fields, since novelty is judged based on whether the idea of the invention is new, not on whether the product is or has been accessible to the public.<sup>1556</sup> Put differently, the mere earlier disclosure of an idea, not the accessibility of a product, can keep the invention from being patented, thereby possibly depriving the pharmaceutical companies of opportunities to invest in launching a product. The situation has been getting worse because of the over and immature disclosure problem,<sup>1557</sup> which has prevented more potential drugs from becoming patentable. The same would be true for any industry where the itinerary from the invention to the product is long and costly, and investment is unlikely to be decided upon without the patent protection.

## (2) A patent as a double-edged sword to NMEs

In contrast to what has been observed hitherto, a patent can be a double-edged sword to NMEs, because patent law better protects tangible products and processes than it does information. A medication is rich in information, which costs time and money.<sup>1558</sup> This could also be because the patent is not granted in exchange for subsequent investments,<sup>1559</sup> but for the creation and disclosure of inventions, which is secured through the novelty requirement. On the one hand, many pharmaceuticals could not have reached the public without a patent protecting them from the copycats; on the other hand, the prior arts which are mainly the prior patents, and the stricter novelty requirement in this industry have potentially prevented medicines from being further developed, because the basic idea was disclosed somewhere. This simply results in much reduced health gains as compared to those that could have been produced by the medications.

A more liberalized approach to the patentability requirements of species selection inventions, therefore, would provide more opportunities for com-

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1555 See also, *Straus*, 2009, 482.

1556 *Roin*, 87 Tex. L. Rev. 503, 517-518 (2009).

1557 See subsection III.B.2.c)(3).

1558 See subsection III.A.1.

1559 *Kitch*, 20 J. Law Econ. 265, 276 (1977) (“[...] the development of patented inventions generally requires significant investments that lead to unpatented information.”).

panies to conduct research. This approach would be in line with earlier cases in which courts have held to grant patents on the medications that were purified from a mixture of natural products, because the inventions made the medications available for the first time for any uses.<sup>1560</sup> How, then we can reach the goal? This will be reviewed in light of statutory examples, proposals, and the implications of the *Olanzapine* decisions.

(3) Statutory exceptions to the novelty requirement and considerations thereof

According to the UK Patents Act 1949, an invention was not deemed to have been anticipated solely because it was published in the United Kingdom either in a specification filed in pursuance of an application for a patent made there more than fifty years earlier or in a specification describing the invention for the purposes of an application for protection in any country outside the United Kingdom made more than 50 years earlier.<sup>1561</sup> This provision means that an inventor who unearths lost technology might make a significant contribution to scientific progress.<sup>1562</sup>

There are also a few existing exceptions in the form of industry specific provisions, such as Art. 54(4) and (5) EPC (special novelty provision for 1<sup>st</sup> and 2<sup>nd</sup> medical use) and 35 U.S.C. § 103(b) (special non-obviousness provision for biotechnological invention). The former provides statutory exceptions to novelty to the extent that, even if a substance is not new, it is still patentable for any medical method if the use for any medical method was not comprised in the state of the art. In addition, even if the substance was patented for one medical use, it is still patentable for a new use of the same substance. By now it should be easy to be noticed that the novelty exceptions provided by the EPC seem to have a similar basis to the decisions on the early medications, i.e. “made it available to the public for the first time as a medication.” In any case, it seems to be possible to make an exception in the patentability standards for drugs. However, there are further concerns. Firstly, dramatic alterations to the patentability standards would likely produce unexpected results given this industry’s creative litigation

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1560 See subsection VI.B.2.b); see e.g., *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.N.Y., 1911).

1561 UK Patents Act, 1949, Section 50(1).

1562 *Keeling*, 2003, 41.

tactics.<sup>1563</sup> Secondly, it would be difficult to implement specifically different treatment, and even if it could be done, it is doubtful whether the law can keep pace with the real progress in the development of technology. Thirdly, there is still concern about violating Art. 27(1) TRIPS.<sup>1564</sup>

Some scholars also argue against industry-specific patent legislation.<sup>1565</sup> Instead, they contend that industries must be treated differently through the existing patent law provisions and doctrines.<sup>1566</sup> As Long maintains, tailoring the application of different rules to the relevant circumstances can be done without the intervention of Congress.<sup>1567</sup> This would provide a degree of flexibility in the patent system for pharmaceutical inventions without involving legislative changes. Therefore, possible applications to pharmaceutical inventions will now be explored and suggested.

#### (4) Proposed novelty requirement for NMEs

Many scholars contend that a strong novelty requirement would bring more robust and advanced inventions and less incremental inventions. However, most of them do not seem to consider the specificities of the pharmaceutical art, such as the broad disclosure of the Markush type claim, the attrition rate of drug candidates, the easy and over-disclosure problem, and the unpredictability in this art. Roin, however, specifically discusses the problems in the industry and proposes increasing the amount of information necessary to make a drug not novel, such that a prior disclosure would not be adequate unless the disclosure were sufficient to support the invention as a drug (“his proposal”).<sup>1568</sup> He further contends that Congress would be justified in reforming patent law as above to ensure that such doctrines would no longer deter the development of socially valuable drugs.<sup>1569</sup> In the same article, however, he rejects his own proposal for the following reasons: that it could be a violation of the Constitution, namely, the two doctrines - (i) Congress can use the patent system only to “promote the progress of ... useful

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1563 *Roin*, 87 Tex. L. Rev. 503, 559 (2009).

1564 See *supra* 1506 -1517 and accompanying texts.

1565 *Burk/Lemley*, 89 Va. L. Rev. 1575, 1634-38 (2003).

1566 *Burk/Lemley*, 89 Va. L. Rev. 1575, 1638-68 (2003); see also *Long*, 55 Fed. Law. 44, 49 (2008).

1567 *Long*, 55 Fed. Law. 44, 49 (2008).

1568 *Roin*, 87 Tex. L. Rev. 503, 560 (2009).

1569 *Roin*, 87 Tex. L. Rev. 503, 560 (2009).

arts,”<sup>1570</sup> (ii) based on this Congress may not “authorize the issuance of patents whose effects are to remove existent knowledge from the public domain”,<sup>1571</sup> that it could be misused to evergreen the old drugs, that it could not solve the problems caused by the non-obviousness standard,<sup>1572</sup> and that it could violate Art. 27(1) TRIPS.<sup>1573</sup>

In light of this concern about overcoming non-obviousness hurdle, he gives up his proposal too early, if this was the reason for the rejection. Overcoming the novelty requirement is impossible as long as the invention is anticipated by the prior art. However, once it is different from the prior art, there are many grounds upon which to argue that the invention involves an inventive step. In addition, according to his proposal, the amount of prior art would be greatly reduced. Since non-obviousness is assessed over the prior art, this standard would not be that problematic. Instead, it is important to provide applicants with room to argue by relaxing the novelty requirement.

The real concern regarding his proposal arises from his intention to substantially reduce the prior art to only that which discloses the information which provides sufficient support for a drug. This would involve regarding something as novel that is not novel. This justifies his concern about the potential violation of the Constitution. In addition, as discussed, the amount of potential prior art would be substantially reduced. Since this provision could open the patent door too wide, which would increase the opportunity for double patenting. Further, as he mentions, this provision could be misused, since, as long as there is no prior art disclosing that the invention was available as a drug, the possibility of receiving a patent would be raised. In the end, the enforceability of these potentially overlapping patents would naturally create serious problems. Thus, while his apprehensions about the unpatentable drug are understandable, the proposal is somewhat at odds with patent law.

In fact, some of these problems appear to be solved by the *Olanzapine* decision within the realm of patent law, and it is therefore advisable to appreciate and apply it.

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1570 U.S. Const. Art. I, § 8, cl. 8.

1571 *Graham v. John Deere Co.*, 383 U.S. 1, 6 (1966).

1572 *Roin*, 87 Tex. L. Rev. 503, 559-60 (2009).

1573 *Roin*, 87 Tex. L. Rev. 503, 558 (2009). Regarding this concern, see subsection VI.D.2.a)(3).

## (5) Appreciation of the Olanzapine decision and its expected results

The *Olanzapine* decision<sup>1574</sup> may be the result of efforts to try to solve this problem. While giving up its earlier efforts to reconcile the discrepancy between the scope and the disclosure of the invention (See Figure 11), the BGH finally held that, unless the prior art disclosed the claimed invention clearly and unambiguously, the prior art does not deprive the novelty of the invention. Namely, contrary to its traditional position of denying selection inventions, the BGH increased the amount of information necessary to anticipate the later claimed invention. Therefore, this decision solved the problem sagely without changing the fundamental framework of the patent system.

Since the earlier disclosure of the genus claim is too broad, it is hardly possible to realize the full scope of invention. Thus, it would certainly be beneficial to provide an invention to find a narrower subgroup having particular properties which might have been difficult to find by trial and error.<sup>1575</sup> Even if the much relaxed novelty requirement in the *Olanzapine* decision raises some concerns,<sup>1576</sup> it enhances the possibility of resuscitating an invention in the lists of thousands of theoretically generated and published compounds.

Furthermore, a species invention does not create the situation in which a prior user unexpectedly identifies a new patent stopping him from continuing the work that he has long been undertaking. In *In re Cruciferous Sprouts Litigation*, the Federal Circuit reinforced the basic rule that a patentee must not have gained exclusive rights over something that was previously in the prior art.<sup>1577</sup> A species patent could prevent the genus patentee from working on the very species invention, but the species patent would not stop someone who has been working so far, because a species invention could have been patented, since no one appreciated the invention. On the contrary, a species patent could increase the possibility of making a new medication available to the public, which would allow society to benefit from further medications that would otherwise hardly have garnered investment and reached the market.<sup>1578</sup>

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1574 See e.g., *BGH/Olanzapine*, IIC 2009, 596.

1575 *Grubb/Thomsen*, 2010, 335.

1576 See subsection V.A.2.

1577 *In re Cruciferous Sprout Litigation*, 301 F.3d 1343, 1350 (Fed. Cir. 2002).

1578 See also, *Straus*, 2009, 483.

c) Discussion on the novelty requirement of other selection inventions

Novelty of selection inventions is mainly based on the identification, purification, or selection of the invention. As Lord Neuberger stated, the technical contribution of selection invention is to make a selected invention – in this case, an enantiomer - available for the first time.<sup>1579</sup> One may recall the earlier meaning of “make available to the public.” Patents were granted on the early medications that were products of extraction and purification from mainly natural sources when the nature of this industry was more a manufacturing industry than a research-based industry.<sup>1580</sup> These early medications were indeed made available to the public for the first time, as the result of which they could cure disorders for the first time. In a similar fashion, selection inventions, such as enantiomers, polymorphs, and metabolites, were also made available for the first time. However, the public already had access to the older ones, such as racemates, a group of polymorphs, or parent drugs.

Even though the level of contribution of other selection inventions is much lower, they were enabled for the first time. In addition, the anticipation has required both the specifically clear and unambiguous disclosure and enablement, and the prior art generally did not enable the selected ones. Therefore, it would be absurd to argue in favour of applying a different novelty requirement to other selection inventions.

### 3. Proposals on the inventive step requirement

The importance of the non-obviousness doctrine accords with the difficulty of the inquiry because this requirement attempts to measure technical accomplishment, which is a quality more abstract than novelty or utility.<sup>1581</sup> Thus, non-obviousness is described as a “nontriviality” requirement in patent law.<sup>1582</sup>

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1579 *Generics Ltd. v. Lundbeck* [2009] UKHL 12, para 83.

1580 *Dutfield*, 2009, 59-60.

1581 *Merges/Duffy*, 2011, 620.

1582 *Merges/Duffy*, 2011, 620.

a) Arguments on the inventive step requirement

(1) Arguments for a strict inventive step requirement

Many scholars contend that the demanding inventive step requirements would work better to promote R&D on advanced and major inventions. O'Donoghue shows that, when there are transaction costs, a patent system based on strict non-obviousness requirements is a better regime, which can stimulate R&D investment and increase dynamic social welfare.<sup>1583</sup> He explains that this is because, when an improvement is patentable only if it meets a stricter patentability requirement (or its size is large enough), inventors must pursue more ambitious projects, which will take longer to realize.<sup>1584</sup> In other words, a higher patentability requirement would stimulate R&D investment without significantly increasing market power and would provide forward protection by delaying the next patentable innovation and slowing down the market turnover.<sup>1585</sup> Similarly, Hunt argues that increasing the standard of non-obviousness would stimulate R&D investment or increase the average flow profit of patentable discoveries and the economically effective life of patents.<sup>1586</sup> Avorn contends that patent laws could take a more conservative view to determine whether a minor change of an existing molecule, such as one-atom changes or isomerisations, warrant patent exclusivity.<sup>1587</sup> Burk and Lemley also mention that lowering the obviousness threshold would make marginal inventions more likely be patented, but this would do nothing to encourage inventions that would have met the non-obviousness standard anyway.<sup>1588</sup> Merges similarly maintains that the strict non-obviousness requirement was to encourage companies to engage in “risky” R&D projects, where there is “relatively” high uncertainty of com-

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1583 O'Donoghue, 29 RAND J. Econ. 654, 664 (1998) (noting this is so because weaker patentability requirement might retard R&D because it provide less protection from future innovators); See also Hunt, 1999, 37-38.

1584 O'Donoghue, 29 RAND J. Econ. 654 (1998).

1585 O'Donoghue, 29 RAND J. Econ. 654, 673 (1998); Hunt, 1999.

1586 Hunt, 1999 11, 30-35 (also noting that lowered non-obviousness requirement would be less likely to raise R&D activity in industries that already innovate rapidly).

1587 Avorn, 309 Science 669, 669 (2005); See also, Angell, 2004, 240.

1588 Burk/Lemley, 89 Va. L. Rev. 1575, 1682 (2003).

mercial success.<sup>1589</sup> Scotchmer argues that a strong patentability requirement would weaken the incentives of subsequent inventors, and even that patents should not be granted on the applications and other second generation products.<sup>1590</sup>

(2) Arguments for a strict inventive step requirement together with broader protection

Some scholars recommend higher patentability requirements in the consideration of the broad scope of a basic patent. To protect basic inventions against future inventions, either the patent protection for second generation inventions could be denied or made harder through a high patentability requirement, or second generation inventions could infringe the patents of basic innovations by granting a broad patent scope of basic innovations.<sup>1591</sup> Both policies have a blocking effect on second generation inventions, since the second generation inventor would hesitate to invest or would not invest in them, either because the invention would be hard to obtain a patent for, or because the inventor would have less bargaining power. Denicolò and Zanchettin argue that granting a broader patent scope on the first invention would nevertheless be better, since, as long as the second innovation was patentable, it creates mutual blocking which might be solved through an *ex post* licensing agreement that would have a sharing effect.<sup>1592</sup>

However, a broader scope of patent would increase the market power and deadweight loss, thus, a higher patentability requirement would a better tool to achieve the goal with fewer side effects.

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1589 *Merges*, 88 Cal. L. Rev. 2187, 2225-2226 (2000) (noting “high-cost research justifies a less stringent standard of purely technical nonobviousness.”); *Merges*, 7 High Tech. L. J. 1, 3-4 (1992) (argued moderate lowering of patentability standards are required for the very high-cost research.).

1590 *Scotchmer*, 27 RAND J. Econ. 322, 323 (1996) (further arguing that the first innovators can collect more profit even by denying patents on second generation products than by granting some of them).

1591 *Friebe et al.*, 2006, 26; *Denicolò/Zanchettin*, 20 Int'l. J. Indus. Org. 801, 801-802 (2002); *Denicolò*, 31 RAND J. Econ. 488, 489 (2000); *Gallini/Scotchmer*, 2002, 66.

1592 *Denicolò/Zanchettin*, 20 Int'l. J. Indus. Org. 801, 825-826 (2002).

### (3) Arguments against a strict inventive step requirement

In contrast, some scholars warn that too high a hurdle on the patentability requirement would prevent desirable secondary innovations from occurring.<sup>1593</sup> Denicolò explains that this is because, when the second invention was seldom patentable, on the one hand only the first inventor would be willing to develop the second invention and fully internalize the benefit of the future innovation; on the other hand, the second innovation would be underinvested, because R&D competition would be eliminated.<sup>1594</sup> Lemley also notes that it would discourage improvements too strongly, thus freezing development at the first generation of products.<sup>1595</sup> As Friebel *et al.*, point out, demanding patentability requirements would weaken the second inventors' incentives only when (i) the prior art patents are still in force and (ii) where the inventions take place in more than two stages.<sup>1596</sup> Theoretically, this might result in so-called 'patent-thicket problems.'<sup>1597</sup>

### (4) Arguments for the relaxed inventive step requirement in risky and expensive R&D fields

Regardless of their basic positions, some scholars have justified a relaxed standard of non-obviousness in the field of technology, because its R&D is very risky and expensive.<sup>1598</sup> Merges especially urges that a moderate lowering of patentability standards, such as the non-obviousness requirement, would be required for the very high-cost research.<sup>1599</sup> Roin considers lowering the non-obviousness requirement to patent drugs that have not yet been

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1593 Denicolò, 31 RAND J. Econ. 488 (2000); Friebel *et al.*, 2006, 29.

1594 Denicolò, 31 RAND J. Econ. 488 (2000).

1595 Lemley, 75 Tex. L. Rev. 989, 990 (1997).

1596 Friebel *et al.*, 2006, 29.

1597 Friebel *et al.*, 2006, 29; Denicolò/Zanchettin, 20 Int'l. J. Indus. Org. 801, 803 (2002) (noting demanding patentability requirement would not have blocking effect on second generation inventions when the original innovator obtains the second generation innovation).

1598 Boyd, 12 Berkeley Tech. L. J. 311, 337-343 (1997); Merges, 7 High Tech. L. J. 1, 3-4 (1992); Merges, 88 Cal. L. Rev. 2187, 2225-2226 (2000).

1599 Merges, 7 High Tech. L. J. 1, 3-4 (1992); Merges, 88 Cal. L. Rev. 2187, 2225-2226 (2000) (noting "high-cost research justifies a less stringent standard of purely technical nonobviousness.").

developed.<sup>1600</sup> Boyd also asserts that a lowered standard of non-obviousness is required to permit the industry to overcome the risk aversion that is otherwise problematic.<sup>1601</sup>

Many scholars comment on the post-invention costs and the uncertainty of commercializing inventions in the assessment of non-obviousness, although these considerations are not relevant to the determination of obviousness.<sup>1602</sup> Benjamin and Rai argue that, where the economic expense or the risk of development of an invention is substantial, allowing a patent on even an obvious invention could be useful.<sup>1603</sup> Shavell also notes that, if an invention tends to fail the non-obviousness requirement, but its development cost is high and would clearly not be covered by the profits in the absence of patent protection, not awarding a patent on that invention would be a mistake under an economic analysis.<sup>1604</sup> Burk and Lemley also contend that, for patents to drive innovation and not merely invention, courts must consider the cost and uncertainty of post-invention testing and development.<sup>1605</sup> Abramowicz and Duffy argue that it makes sense to weaken the non-obviousness standards to encourage the commercialization of new products,<sup>1606</sup> or even to extend this theory to permit patents to issue on products that are technologically non-novel if they do not exist in the market place. Considering that these assertions were for inventions with high post-invention costs or uncertainty, the same can be argued for the basic patents on the pharmaceuticals which are the inventions themselves.

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1600 *Roin*, 87 Tex. L. Rev. 503, 558, 567 (2009) (further distinguishing the one which did not need to go through the clinical trials from those which needed to do so).

1601 *Boyd*, 12 Berkeley Tech. L. J. 311, 339 (1997).

1602 *Graham v. John Deere Co.*, 383 U.S. 1, 11 (1966) (providing outline of basic non-obviousness test).

1603 *Benjamin/Rai*, 95 Geo. L. J. 269, 278 (2007); *Kitch*, 20 J. Law Econ. 265, 265-67, 269 (1977) (advocating development as a significant consideration for granting patent rights).

1604 *Shavell*, 2004, 152-53, fn 31.

1605 *Burk/Lemley*, 89 Va. L. Rev. 1575, 1678 (2003); *see also Merges*, 7 High Tech. L. J. 1, 47, 33-34 (1992) (noting to consider the commercial uncertainty to assess non-obviousness).

1606 *Abramowicz/Duffy*, 83 N.Y.U. L. Rev. 337, 398 (2008).

b) Proposal on the inventive step of species selection inventions

There are further considerations on the expenditure of money on the creation of inventions to assess the inventive step. In the United States, several decisions noted that the expenditure of a large amount of money to make the invention tended to show that the invention was non-obvious.<sup>1607</sup> Commercial success has long been to be one of the secondary considerations in establishing an inventive step. Consideration of commercial success while judging obviousness helps to foster technological innovation.<sup>1608</sup> Post-invention costs are in the same vein as these considerations.

Expensive research alone, however, has not been regarded as an important indicator of patentability, and courts have considered this factor in a limited class of cases.<sup>1609</sup> Critics have also noted that commercial success is not a good indicator of patentability, because it is indirect and depends on a long chain of inferences that are weak,<sup>1610</sup> and because commercial success might instead indicate “sales promotion ability, manufacturing technique, ready access to markets, consumer appeal design factors, and advertising budget.”<sup>1611</sup> Simply put, the weak point of these arguments rests upon whether there is causal relationship between these factors and the technical value of the invention.

However, it would be still advisable to consider *post-invention costs* or *high-uncertainty in the course of development* as among the *secondary con-*

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1607 See for instance, *Panduit Corp. v. Dennison Mfg.*, 774 F.2d 1082, 1099 (Fed. Cir. 1985) (fact that patentee took a couple of years and spent millions of dollars is one of the evidence that the invention is non-obvious); *Edoco Technical Products, Inc. v. Peter Kiewit Sons' Co.*, 313 F. Supp. 1081, 1086 (C.D. Cal. 1970) (the fact that a long and expensive period of experimentation was required to solve the problem was an important evidence of non-obviousness); see also *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1379 (Fed. Cir. 2006), *reh'g denied* (Jan. 19, 2007) (the extensive time and money [the patentee] spent developing the racemate before redirecting its efforts toward the enantiomer was one of the indicators of non-obviousness); cf. *United States v. Ciba-Geigy Corp.*, 508 F. Supp. 1157, 1168 (D.C.N.J. 1979) (a costly research undertaken should be rewarded with a product patent).

1608 *Merges*, 76 Cal. L. R. 803, 837-388 (1988).

1609 *Merges*, 7 High Tech. L. J. 1, 55 (1992).

1610 *Kitch*, 1966 Sup. Ct. Rev. 293, 330-35 (1966) (also noting courts should even more cautious to hold the patents valid, since commercially successful patents can truly impose a monopoly tax on the market).

1611 *Kitch*, 1966 Sup. Ct. Rev. 293, 332 (1966); see also *Landes/Posner*, 2003, 305.

*siderations* for the following reasons. Firstly, the patent system aims to promote not only the invention but also the innovation. If high post-invention costs are incurred to bring an invention to the innovation or uncertainty in the same course, fewer innovations will be realized without patent protection. Commercial success has been used to transform the patentability doctrine partially into an instrument that rewards innovation rather than invention.<sup>1612</sup> Secondly, the benefit of the invention to the patients who are awaiting new medications must be considered. If an invention regarding a new drug failed to acquire a patent based on its relatively weak inventive step, the invention could hardly reach the market as a medicine. In the end, the loss of even one NME may be seen as a loss.

When considering post-invention costs or uncertainty, there appears to be a greater opportunity to argue that the basic invention establishes the inventive step which allows the patentee to secure a patent on it. Thus, the increased incentives could bring more NMEs to the public, which could in turn provide new opportunities to save or prolong life, or to improve the quality of life. On the other hand, the impact may not be so dramatic, since this factor can be considered only by the courts, not by the patent offices. The courts are in a better position to consider this factor basing their decisions on the evidence gathered in the period of time up to and during the litigation.

### c) Proposal on the inventive step of other selection inventions

#### (1) Introduction

Many scholars argue that a heightened inventive step requirement would result in better and advanced inventions, while too high a hurdle could stifle second generation inventions.<sup>1613</sup> Thus, a demanding inventive step requirement is to be recommended to encourage the manufacturers to work more on basic inventions. However, no proposal has been advanced to suggest how to raise the inventive step requirement, especially for the pharmaceutical art.

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1612 *Merges*, 76 Cal. L. R. 803, 876 (1988).

1613 See subsection VI.E.3.a).

(2) Proposed standard to assess the inventive step

*“Therapeutic contribution” as a secondary indicia*

The inventive step requirement prevents granting patents on inventions that are likely to reach the public without the inducement of the patent system and excludes such slight advances from the patent protection.<sup>1614</sup> Since patent exclusivity can be justified by this technical advance or contribution to the art, when there was no real technical advance in art, the objection of obviousness must be made.<sup>1615</sup> Therefore, the measurement of the technical contribution to the art is important in assessing the inventive step.

It is advisable to assess the level of “therapeutic contribution” of pharmaceutical inventions as a consideration of the technical contribution in this field. The value of a patent is calibrated by structural features; however, the value of a pharmaceutical patent is the therapeutic effect itself.<sup>1616</sup>

(3) Basis of the proposal

*Technical contribution of inventions*

The patentability requirement of computer-implemented inventions is defined in the EPO glossary as follows: “To be patentable, they must have technical character and solve a technical problem, be new and involve an *inventive technical contribution* to the prior art.”<sup>1617</sup> [Emphasis added]. However, it does not further define the inventive technical contribution to the prior art, which seems to refer to the inventive step of the computer-implemented invention. While distinguishing “inventive concept,” which was concerned with the “identification” of the core of the invention, the House of Lords held that “technical contribution” was concerned with the evaluation of its inventive concept, i.e. how far forward had it carried the

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1614 *Eisenberg*, 19 Berkeley Tech. L.J. 885 (2004).

1615 *Dr Reddy’s Laboratories Ltd v. Eli Lilly & Company Ltd*, [2009] EWCA Civ 1362, paras 40-52; *Agrevo/Triazoles*, T 939/92, OJ EPO 309, 319-20 (1996), point 2.4.2. (“it has for long been a generally accepted legal principle that the extent of the patent monopoly should correspond to and be justified by the technical contribution to the art [...]”).

1616 *Domeij*, 2000, 87.

1617 *EPO glossary*, available at: <http://www.epo.org/service-support/glossary.html>. (Last accessed on December 20, 2013).

state of the art.<sup>1618</sup> The European Examination Guidelines also note that, if an invention is shown to have considerable technical value, which provides a new and surprising technical advantage, this technical advantage is of great importance in assessing the inventive step.<sup>1619</sup> In turn, the test of inventive step is directly linked to the social practical value of the invention that is newly created by the inventor.<sup>1620</sup>

This technical contribution is also the basis for determining the breadth of a claimed invention, since the extent of exclusivity should not exceed the technical contribution to the art made by the invention as described in the specification.<sup>1621</sup> In other words, a patent should not be granted if the benefits do not exceed the costs.<sup>1622</sup> The provision of a product, such as other species inventions, is also one of the technical contributions to the art. According to the case laws, contributions of other species inventions lie more in the identification and purification of the claimed inventions. As Kitchin J properly pointed out, however, the inventive idea connected with an enantiomer is neither the discovery of the enantiomer nor its medicinal effect, only the process required to synthesize it.<sup>1623</sup> Although the exclusivity should not exceed the technical contribution to the art, instead of granting a patent on the process to manufacture the enantiomer, a further absolute compound protection is provided to these inventions. As a result, both old and new versions of the same drugs, i.e. enantiomer and racemate, polymorphs, metabolites and the parent drugs are concurrently available in a number of countries.<sup>1624</sup>

### *The genuine technical contribution of drug patents: Therapeutic contribution*

The genuine technical contribution of a drug invention to the pharmaceutical art should be the “therapeutic contribution.” This has been more often required in other regimes than the patent system. For example, some scholars

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1618 *Generics Ltd. v. Lundbeck* [2009] UKHL 12, para 30.

1619 EPO Examination Guidelines G-VII, 8.

1620 *Domeij*, 2000, 205.

1621 *Biogen Inc v. Medeva Plc* [1996] UKHL 18, point 80.

1622 *Mazzoleni/Nelson*, 27 Res. Policy, 273, 275 (1998).

1623 *Lundbeck v. Generics Ltd.* [2008] EWCA Civ 311, para 26; *Generics (UK) Ltd & Ors v. Lundbeck A/S* [2007] EWHC 1040 (Pat), paras 64-66.

1624 *Hutt/Valentová*, 50 Acta Facultatis Pharmaceuticae Universitatis Comenianae 7, 8 (2003).

propose the contribution of innovations, which is a therapeutic contribution in the case of a pharmaceutical innovation, as a ground for awarding a “prize,”<sup>1625</sup> which is a kind of a reward to the innovator as a lump sum payment and is an incentive to invest in the invention.<sup>1626</sup> The therapeutic contribution is also considered as an important factor in reimbursement schemes, such as controlling costs of the newer and costly drug, the therapeutic contribution of which may be small,<sup>1627</sup> in contrast to the innovative drugs which offer major therapeutic advances.<sup>1628</sup> The Korean Supreme Court has considered whether the claimed technical contribution of selected inventions also contribute to showing the *pharmaceutical effects (benefits)* over the basic inventions.<sup>1629</sup> It would be also highly advisable to require pharmaceutical inventions to prove their therapeutic contributions over the prior art. Such therapeutic contributions could also consist in the enhancement of absorption of a substance, prolongation of the duration of effects, mitigation of the side effect of main substance, and the like.

#### *Therapeutic contributions of other selection inventions*

One may need to consider the extent to which the other selection inventions contribute to the treatment as a medicine over their older versions. Higgins and Graham contend that even though those new products which are covered by improvement patents reach the market sooner, they are much less likely to provide improvement over previous products.<sup>1630</sup> Rai also insists that there are drugs that provide little or even no therapeutic advantage over existing drugs.<sup>1631</sup> These non-NMEs do little to increase the length of human life.<sup>1632</sup> Some new drugs covered by secondary fresh patents are frequently associated with higher potential monopoly costs, without providing measurable economic and/or clinical advantages.<sup>1633</sup> Many scholars doubt the clinical benefits of the enantiomer inventions over the racemates. Some sci-

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1625 *Arbex*, 2009, 3; *Abramowicz*, 2003, 91-118.

1626 *Rockett*, 2010, 355-56.

1627 *Schweitzer*, 2007, 126; *see also Rucker*, 1996, 73.

1628 *Schweitzer*, 2007, 146.

1629 *Korean Supreme Court/Lercanidipine*, 2010Hu2872, Jul. 14, 2011, para 2.; *Korean Supreme Court/Ibandronate*, 2010Hu3554, Sept. 8, 2011, para 2.

1630 *Higgins/Graham*, 326 *Science* 370, 370 (2009).

1631 *Rai*, III. L. Rev. 173, 205-06 (2001).

1632 *Lichtenberg*, 5 *Int. J. Health Care Fi.* 47, 70 (2005).

1633 *Zhang/Soumerai*, 26 *Health Affair.* 880, 884 (2007).

entists note “some new chemical entities<sup>1634</sup> might be minor modifications of older agents without offering measurable clinical benefits, such as esomeprazole (Nexium) versus omeprazole (Prilosec).”<sup>1635</sup> Other scientists also observe that the overall degree of clinical improvement that could be expected from the purified preparation of one isomer might be limited unless the total dose was correspondingly increased.<sup>1636</sup> They add that there is no published evidence to indicate any advantage of esomeprazole 40mg over omeprazole 40mg.<sup>1637</sup> Although the different physical properties of polymorphs could contribute the characteristics required to handle the substances, such as filterability or drying properties, it could hardly provide better therapeutic effects. The only action that could contribute to the clinical benefit of the metabolites would be to onset the therapeutic effects slightly earlier.

Regarding the two crystalline forms of atorvastatin, the BOA made it clear that although not every crystalline form provides improved filterability or drying characteristics, trying this carries a reasonable expectation of success.<sup>1638</sup> Therefore, the provision of crystalline forms that present nothing more than the obvious advantages of crystalline forms based on their improved physical and/or physicochemical properties would not be sufficient to find as an inventive. However, crystalline forms could be found non-obvious, if they provided unexpected pharmaceutical activity. Likewise, separation of enantiomer from the racemate or identification of a metabolite would provide virtually expected results.

#### (4) Expected effects

Consideration of the therapeutic contribution as one of the secondary indications would provide drugs with improved effects, could discourage inventors from working on the rather obvious modifications and variations of

1634 According to the criteria provided by this dissertation, Es-omeprazole is not a new chemical entity, but a second generation product.

1635 *Zhang/Soumerai*, 26 Health Affair. 880, 884 (2007).

1636 *Sachs/Shin/ Howden*, 23 (Suppl. 2) *Aliment Pharm. Ther.* 2, 7 (2006).

1637 *Sachs/Shin/ Howden*, 23 (Suppl. 2) *Aliment Pharm. Ther.* 2, 7 (2006) (For example, although esomeprazole 40 mg has been shown in some trials to be superior to omeprazole 20 mg, there is no published evidence to indicate any advantage of esomeprazole 40 mg over omeprazole 40 mg.).

1638 *Warner-Lambert/Atorvastatin polymorphs*, T 0777/08 (2011).

existing medications, and lead them to carry out research on more ambitious projects. Furthermore, since there is little monopoly situation in the pharmaceutical market,<sup>1639</sup> once an inventor acquired the patents on second generation inventions that show therapeutically advanced effects, these patents would provide them with more competitiveness in the market place as well.

In addition, the loss of these second generation inventions should not be of too much concern. Firstly, with some effort, work on second generation inventions can be performed without the help of a patent. Secondly, even if this leads to the loss of these inventions, since these kinds of inventions have followed successful basic inventions, the public would still have the “older” versions. In this regard, Roin notes that “this effect may be rather benign, such as when patent protection is denied to drugs that are so closely related to an older drug that they are unlikely to provide any additional therapeutic benefits.”<sup>1640</sup> Indeed, these criteria would not foreclose the patent grant on second generation inventions. For example, if it mitigates the toxic effect of the racemate, the choice of an enantiomer will be patentable. If the parent drug is too much of a burden to the patient’s metabolism and could be toxic, and a metabolite without this toxicity is found, this metabolite should be allowed patent protection. Therapeutic contribution could be further acknowledged when a new dosage form enables a certain group of patients to take the basic medication. Examples of such improvements are oral dosage forms when the original form was a parenteral drug, or combinations of active ingredients showing a synergistic effect, thereby allowing the dose of a drug to be lowered.

The adaptation of these secondary criteria could be expedited under the recent decision of Federal Circuit holding that evidence of secondary considerations must be considered as part of all of the evidence, not just when the decision maker remains in doubt after reviewing the art.<sup>1641</sup>

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1639 See subsection III.A.2.d).

1640 Roin, 87 Tex. L. Rev. 503, 537 (2009).

1641 *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Drilling USA, Inc.*, 699 F.3d 1340, 1349 (Fed. Cir. 2012).

#### 4. Discussions on the sufficiency requirement

##### a) Discrepancy between the scope of and the disclosure of a genus claim

In the *Fluoran* decision, the Court clarified that, even if the compound falls under a general formula in the prior art, nothing was said about the disclosure of the individual compound.<sup>1642</sup> In other words, the disclosure of a general chemical formula is not equivalent to the disclosure of all of the individual compounds that fall within the scope of the formula. However, all of these individual compounds literally infringe the claim that is characterised by the same general formula.<sup>1643</sup>

Similarly, the BOA noted that the question of the scope of the claims was distinct from the question of disclosure of these claims.<sup>1644</sup> According to the Board, there is a distinction between the extension of the concept and the intention of the concept, which extended from the individual examples and depended upon the person skilled in the art.<sup>1645</sup> (1) The maximum scope would be the full extent of the claim, (2) the next largest scope would be that which can be derived from the sum of individual examples by the person skilled in the art, and (3) the minimum scope would be the one indicated by the individual examples. It can be better understood by the following diagram.

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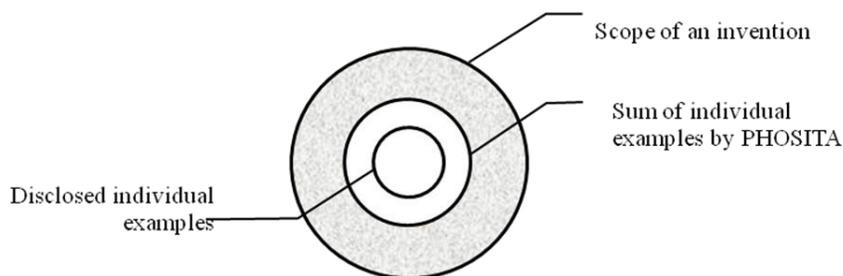
1642 *BGH/Fluoran*, GRUR 1988, 447, 449 (holding it was more essential whether the skilled person could have produced the compound).

1643 *Hansen/Hirsch*, 1997, 336.

1644 *Amazonen-Werke/Zustreicher*, T 378/94, 1996, point 3.1.1.

1645 *Amazonen-Werke/Zustreicher*, T 378/94, 1996, point 3.1.1. (“The scope of protection is related to the “extension” of the concept defined in the claim, ie the sum of all individual objects that show all the features of the concept. In comparison, the disclosure is associated with the “intention” of the concept, i.e. all the features that allow an intellectual summary of individual objects. [...] If a claim is concerned with general concepts, then it discloses only these general concepts and does not all of specific examples which come under these general concepts.”).

Figure 11: Discrepancy between the scope of and the disclosure of a genus claim<sup>1646</sup>



This discrepancy is hardly observed in other fields. The BGH's earlier approaches before its *Olanzapine* decision were that the disclosure was a simplified representation, as a result of which either the individual compounds in the compound selection<sup>1647</sup> or the intermediate values in the range selection (e.g., see Figure 6),<sup>1648</sup> which fall within the scope of disclosure, must be regarded as disclosed. Therefore, a patent on the selection could not be granted. Some scholars interpret the BGH's earlier general tendency not to grant the selection patents by broadening the content of disclosure of the generic formula as an effort to solve the discrepancy,<sup>1649</sup> i.e. to make the gray area in Figure 11 narrower by extending the area of middle circle to the outer circle. However, the end of this approach was declared through the novelty doctrine in the *Olanzapine* decision. Even if this approach may no longer be possible, one may still try to resolve the discrepancy by shrinking the biggest circle to reach the middle one, i.e. restricting the scope of the claim by applying the stricter disclosure requirement.

#### b) Stringent disclosure requirement of the basic invention

Patentability requirements, such as non-obviousness and enablement, rarely relate to the patent scope,<sup>1650</sup> but a stringent disclosure requirement would

1646 This figure is prepared by the author.

1647 *BGH/Fluoran*, GRUR 1988, 447.

1648 *BGH/Inkrustierungsinhibitoren (Incrustation inhibitors)*, GRUR 2000, 591, 593-94.

1649 *Hansen/Hirsch*, 1997, 336.

1650 *Chisum*, 15 AIPLA Q. J. 57, 58 (1987).

lead to patents with narrower scopes. Burk and Lemley argue that written description and enablement doctrines need to be recalibrated (reduced) to permit broader claiming of inventions.<sup>1651</sup> In contrast, Merges and Nelson maintain that more consistent and stricter interpretation of enablement and equivalents doctrines is necessary to achieve sounder policy.<sup>1652</sup>

The disclosure requirement is divided between the written description and the enablement. One may first consider applying a stricter enablement requirement. However, the enablement issue in respect of compounds is rarely raised. For example, olanzapine is a relatively simple chemical compound and is easily synthesized by the traditional method of manufacture. Thus, enablement was never drawn into question in this case. Next, in considering the written description, the specification must disclose the structure of the compounds and the claiming effects thereof that are commensurate with the scope of the claimed invention. As discussed in chapter III.B.2.c)(3), it is relatively easy to draw the structure, and there is a relatively fair relation between the structure and the technical effects. The unpredictability of inventions can play a role here, such that, if one can prove that some claimed compounds, for which a technical effect has not been demonstrated explicitly, do not show the predicted effects, part of the claim can be revoked. The examiners are hardly in a position to prove this and have to rely on third party observations in the course of the proceedings or during the opposition period after grant. However, once the scope of the basic invention becomes an issue, the selection patentee could test the compounds, invoke the lack of this requirement, and limit the scope of claims. One thing to note here is that the same scenario could not be realized in certain jurisdictions, such as the EPO, where violation of Art. 84 EPC, second sentence<sup>1653</sup> matters only during the original examination. Indeed, the non-availability of this in the revocation grounds has been well criticized,<sup>1654</sup> especially in the context of the allegedly overly broad claims in the field of chemistry and biotechnology.<sup>1655</sup> Some decisions by the BOA illustrate that the circumstances that

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1651 *Burk/Lemley*, 89 Va. L. Rev. 1575, 1681-83 (2003).

1652 *Merges/Nelson*, 25 J. Econ. Behav. Organ. 1, 22-23 (1994).

1653 The claims shall [...] be supported by the description.

1654 *Brandi-Dohrn*, GRUR Int 1995, 541; *Wibbelmann*, EIPR, 1997, 515.

1655 *Roberts*, EIPR, 1994, 371, 371, 373 (also arguing that European law must be changed to include Art. 84 lack of support objections in opposition grounds before EPO).

were relevant to Art. 84 EPC might also be relevant to Art. 83 EPC, and, therefore, the claim could be revoked.<sup>1656</sup>

### c) Conclusion

If one could prove that a part of a claimed invention in the basic patent was not sufficiently disclosed in the specification, to the extent that the claim would be nullified, the discrepancy (See Figure 11) would be resolved to the same extent and more freedom to operate would be created. However, proving that some compounds claimed in the basic invention do not show the claimed effect would not help the patentee of a species selection invention to exploit the invention without concerns, because the species invention must show the expected technical effects. Thus, although consideration of a stringent disclosure requirement for the basic invention would help to solve the discrepancy, it would not help the selection patentee to acquire the freedom to operate.

### F. Conclusion

A species selection invention is importantly distinguished from the other selection inventions in the sense that it can be developed to the product that is available for the first time in the form of medication. The technical contribution of other selection inventions lies mainly in the isolation or the separation thereof from the mixture in the prior art. The patents on earlier med-

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1656 *Exxon/Fuel oils*, T 409/91, OJ EPO 1994, 653, 662 (noting “the reasons why the invention defined in the claims does not meet the requirement of Article 83 EPC are in effect the same as those that lead to their infringing Article 84 EPC as well, namely that the invention extends to technical subject-matter not made available to the person skilled in the art by the application as filed, since it was not contested by the appellant that no information was given to perform the claimed invention successfully without using the structurally defined class of additives.”); *Genentech/Human t-PA*, T 923/92, OJ EPO 1996, 564, 584 (holding “in order to fulfill the requirement of Article 83 EPC, the application as filed must contain sufficient information to allow a person skilled in the art, using common general knowledge, to carry out the invention within the whole area that is claimed. Claims which by omission of an essential feature extend to subject-matter which, after reading of the description, would still not be at the disposal of the person skilled in the art, are objectionable under both Article 83 and Article 84 EPC.”).

ications that were generally purified or isolated were also granted on the basis that they were available for the first time in a therapeutic and commercial manner. However, one may doubt whether it is proper to apply similar standards a century later. The proposals from the various perspectives were made to promote the R&D on the more ambitious projects and thereby to bring more NMEs and fewer second generation inventions to the public.

The findings and proposals on species selection inventions were as follows: Firstly, providing the broader scope of patents to species selection inventions does not appear to be appropriate to promote R&D, because the equivalent protection in this industry is neither easy nor properly applicable, and because granting a broader scope of patent would increase the dead-weight loss. Secondly, in contrast, the already broad scope of the genus patent could stop the species selection patentee from exploiting his invention. Application of the lesson from the *eBay* case, implementation of the statutory compulsory license system or improved use of the reverse doctrine of equivalence would be desirable to resolve this blocking issue. Thirdly, considering that the pharmaceutical industry is sensitive to the term of protection, and that the patent term extension system is more favourable to second generation inventions, the R&D for which take a shorter period of time than the basic invention, a provision guaranteeing a fifteen year effective patent term was proposed for the species selection inventions to promote research on NMEs. Fourthly, regarding the novelty requirement, the appreciation and application of the requirement in the *Olanzapine* decision of “clear and unambiguous” prior art disclosure to destroy a claimed invention, was recommended. Lastly, in consideration of some of the specificities in the pharmaceutical industry, such as high uncertainty along the way to marketing approval and high post-invention costs, both factors were recommended as secondary considerations in assessing the inventive step of species selection inventions.

The following proposals were made on the other selection inventions. Firstly, since the case law on the patent term extension seems to encourage more investment in second generation inventions, it was proposed that, if the biologically active moiety is the same and the first one enjoyed a patent term extension, no further patent term extension should be granted. Secondly, to judge the inventive step requirement, it was suggested that the therapeutic contribution of other selection inventions be one of the secondary considerations. Other systems, such as prizes or reimbursement schemes for medication, consider the genuine technical contribution of a drug invention as the therapeutic contribution. Similarly, in assessing the inventive step, the

Korean Supreme Court considered whether the claimed invention contributed to showing the pharmaceutical effects over the basic inventions. Thus, it was recommended that the therapeutic contribution be considered in judging the inventive step of other selection inventions.

The discrepancy between the scope and the disclosure of the genus claim that was firmly established by the *Olanzapine* decision, was discussed. Even though the stringent disclosure requirement of the basic invention can help to decrease this discrepancy, it will not help the species selection patentee to acquire the freedom to operate because the selection invention must show the expected result claimed in the basic patent.