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THE REPUBLIC OF KOREA'S TREND OF INVALIDATING PHARMACEUTICAL PATENTS: CAN U.S. PHARMACEUTICAL COMPANIES PREVAIL AT THE KOREAN SUPREME COURT?

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The author also would like to dedicate this article to his parents, Su Kyum Kim and Hae Hwa Shin, for their supports and inspirations to the author. Lastly, the author would like to thank God for granting me His wisdom. I would not have been able to do this if not for Him.

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I. INTRODUCTION

The Republic of Korea (Korea)[1] modified the Korean Patent Act in 1986 to allow pharmaceutical products as patentable subject matter. Since then, the size of the Korean pharmaceutical market,[2] its potential growth rate,[3] and the increasing amount of interstate trade between Korea and United States[4] has made it attractive for U.S. pharmaceutical companies. U.S. pharmaceutical companies could realize substantial profits from the international trade.[5]

However, approaching the Korean pharmaceutical market has become more demanding than before because profit may increase or decrease depending on what strategies a company takes. Among such strategies is obtaining patent protection over high-value pharmaceuticals to prevent competition from generic drugs.

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[1] The Republic of Korea, commonly known as South Korea, will be referred to as Korea. The contents of this paper have no relevance to North Korea, which is officially known as the Democratic People's Republic of Korea.

[2] *See* UNITED STATES INTERNATIONAL TRADE COMMISSION, PUB. NO. 3949,U.S.–KOREA FREE TRADE AGREEMENT: POTENTIAL ECONOMY-WIDE AND SELECTED SECTORAL EFFECTS, INV. NO. TA-2104-24, 64 (Sept. 2007) (Corrected) [hereinafter USITC] ("Korea's pharmaceutical market is ranked among the world's top 12 pharmaceutical markets and is worth approximately $8 billion annually.").

[3] *See id.* ("Sustained growth in the market is expected as the Korean population ages.").

[4] *See* Yong-Shik Lee et al., *The United States - Korea Free Trade Agreement: Path to Common Economic Prosperity or False Promise?*, 6 E. ASIA L. REV. 111, 113 (2011) ("The historic U.S.-Korea Free Trade Agreement (FTA), which is the largest FTA since the North American Free Trade Agreement (NAFTA) and the first FTA between major trading nations in North America and Asia, was agreed upon on April 2, 2007 after 14 months of negotiations, and signed on June 30, 2007.").

[5] *See* USITC, *supra* note 2 ("U.S. exports of pharmaceutical products to Korea were valued at $351 million in 2006. In that year, the United States accounted for 15.8% of Korea's imports of pharmaceutical products.").

This article is intended to help U.S. practitioners in building their own legal strategies. Part I of this article will discuss the invalidation of Korean pharmaceutical patents based on decisions from the Korean Supreme Court. Knowing such trends will provide practitioners (1) an opportunity to approach Korean pharmaceutical industry more efficiently and (2) an idea of what to expect in near future.

Part II of this article will discuss the general definition and legal standard of "selection invention," which is a class of inventions where a known molecule may, in certain circumstances, satisfy the inventive step requirement under Korean patent law.[6] Part III of this article will introduce the Korean Supreme Court's decisions as to selection invention, which have been consistently strict against patent holders.[7] Finally, Part IV of this article will provide a legal explanation and policy justifications for such a strict patentability standard with respect to selection invention.[8]

II. SELECTION INVENTION

A primary purpose and effect of "selection invention" or "selective invention" is to grant a patent right over species when all or part of its genus are known to the public or disclosed in the prior art.[9] The official Korean jurisdiction uses nomenclatures of

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[6] *See infra* Part II; *see also* Patrick P. Hansen & Donald J. Featherstone, *A Brief Review of U.S. and Korean Patent Invalidity Decisions for CMP Slurry Patents*, 8 NANOTECHNOLOGY L. & BUS. 85, 89 (2011) ("In Korea, selection inventions are becoming very important in the pharmaceutical field, as many new drugs are based on improvements to known molecules and compounds.")

[7] *See infra* Part III.

[8] *See infra* Part IV.

[9] *See* Jay A. Erstling & Ryan E. Strom, *Korea's Patent Policy and Its Impact on Economic Development: A Model for Emerging Countries?*, 11 SAN DIEGO INT'L L.J. 441, 452 (2010); *see also* Supreme Court [S. Ct.], 2001Hu2740, Apr. 25, 2003 (S. Kor.) ("The so-called selective invention means an invention which states the element of the preceding or already publicized invention as its superordinate concept and whose elements entirely or partly

"superordinate concept" and "subordinate concept," [10] which corresponds respectively to "genus" and "species." Hereinafter, due to reader's familiarity, the article will consistently use nomenclatures of genus and species.

A. Novelty

The Korean Patent Act does not explicitly define "novelty"[11]; however, article 29 defines "prior art" and states that an invention may be patentable unless it is anticipated by the prior art. [12] Generally, in selection invention, novelty is destroyed when a prior art reference discloses a chemical composition that is the subject matter of an invention. The Korean Supreme Court has held that a prior art reference also discloses the composition when the composition is such that it would have been "recognizable" at the time of the filing date to a person having ordinary skill in the art.[13] Therefore, the destruction of novelty may also occur when the prior art discloses a structurally similar chemical compound to the subject matter of a claimed invention.

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consist of subordinate concepts derived from the above superordinate concept.").

[10] Translated authority provided by Korean Intellectual Property Office uses subordinate concept and superordinate concept in defining selection invention. The subordinate–superordinate relationship corresponds to the genus-species relationship. *See* Supreme Court [S. Ct.], 2001Hu2740, Apr. 25, 2003 (S. Kor.).

[11] Erstling, *supra* note 9, at 450.

[12] *Id.* at 471 n.163; s*ee also* Teukheo beob [Patent Act], Act. No. 950, Dec. 31, 1961, art. 29.1-.2 (S. Kor.) ("Inventions having industrial applicability may be patentable unless they fall under any of the following subparagraphs: 1. Inventions publicly known or worked in the Republic of Korea or in a foreign country prior to the filing of the patent application; 2. Inventions described in a publication distributed in the Republic of Korea or in a foreign country prior to the filing of the patent application or inventions made accessible to the public through telecommunication lines prescribed by Presidential Decree.").

[13] Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

Korean courts have been consistently hostile toward patentees in applying this novelty standard.[14] This is especially true when the claimed composition is structurally similar to the prior art.[15] Currently, a prior art reference disclosing a certain molecule[16] will likely destroy the novelty of a mirror-image molecule[17] or its salt,[18] regardless of substantive differences in chemical properties between the two molecules.[19]

B. Inventiveness

"Inventive step" or "inventiveness" is analogous to the concept of non-obviousness in U.S. patent law.[20] Article 29.2 of the Korean Patent Act provides that an invention is not patentable when a person having ordinary skill in the art could easily have made the

[14] *See* Hansen & Featherstone, *supra* note 6, at 89 ("Similarly, Korean patentees have faced hurdles such as high standards for patentability. For example, the Korean Supreme Court decision in Sanofi-Aventis v. CJ set forth extremely strict standards for the patentability of selection inventions.").

[15] The Korean courts have generally rejected patentability or invalidated the patent of a chemical composition that is structurally similar to that of the prior art. *See, e.g.*, Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.); Supreme Court [S. Ct.], 2008Hu3520, Mar. 25, 2010 (S. Kor.).

[16] *See infra* Part. III.A.1.i.

[17] *See* Supreme Court [S. Ct.], 2008Hu3520, Mar. 25, 2010 (S. Kor.) (holding that disclosing a chemical equation of heptanoic acid enantiomer in its embodiment destroys patentability of an invention of which heptanoic acid enantiomer is a subject since a person having ordinary skill in the art will easily recognize the existence of heptanoic acid enantiomer).

[18] *See* Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.) (denying a patentability of an enantiomer as the hydrochloride salt when the prior art discloses racemate as the hydrochloride salt).

[19] Merely disclosing the chemical equation of a composition in the specification may destroy the novelty of an invention of which the composition is a subject matter. *See id.* ("It is not necessary that the comparison invention No. 1 disclose the method of separation or the possibility of separation as alleged in the plaintiff's ground of appeal.").

[20] Erstling, *supra* note 9, at 451.

invention prior to the filing of the patent application.[21] In selection invention, an invention will be considered to possess inventiveness if there is either "qualitative" or "conspicuously quantitative difference" in effect between the prior art and the invention.[22] Some commentators refer to a "conspicuous quantitative difference" as "superior working effect over the prior art."[23]

"Qualitative difference" refers to differences between the medicinal purpose of the invention and that of the prior art.[24] Therefore, there is no "qualitative difference" if there are significant similarities between a medicinal purpose of the claimed composition and that of the prior art.[25] However, a claimed composition, which is qualitatively similar to a prior art, still possesses inventiveness if its working effect is superior over that of the prior art.[26] The Korean Supreme Court has set a very high

[21] Teukheo beob [Patent Act], Act. No. 950, Dec. 31, 1961, art. 29.2 (S. Kor.).

[22] *See* Supreme Court [S. Ct.], 2001Hu2740, Apr. 25, 2003 (S. Kor.) ("[S]ubordinate concepts possess either effects different in quality from the preceding invention, or there exist conspicuous differences in effect as measured quantitatively between them.").

[23] The biggest law firm in Korea, Kim and Chang, uses "superior working effect" to describe invention's qualitative difference over the prior art. *See generally* Jay Young-June Yang, Jay J. Kim & Mee Sung Shim, *The Korean Supreme Court Applies Strict Patentability Standards Against Selection Inventions*, KIM & CHANG QUARTERLY UPDATE OF KOREAN IP LAW & POLICY, Mar. 25, 2010, at 1-3, *available at* http://www.ip.kimchang.com/ip/frame2.jsp?lang=2&b_id=113&m_id=161.

[24] *See* Supreme Court [S. Ct.], 2001Hu2740, Apr. 25, 2003 (S. Kor.); *see also* Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.) (discussing "differences in quality").

[25] *See* Supreme Court [S. Ct.], 2002Hu2846, Dec. 10, 2003 (S. Kor.) (denying patentability of a selection invention because it shared a common medicinal purpose with the prior art).

[26] Supreme Court [S. Ct.], 2001Hu2740, Apr. 25, 2003 (S. Kor.) ("A patent can be granted to a selective invention on the conditions that . . . subordinate concepts possess effects different in quality from the preceding invention, or if

standard for working effect when a claimed composition is structurally similar to those shown in the prior art. Therefore, it is extremely hard for an applicant or patentee to claim patentability of an invention if the claimed composition is, for example, a certain isomer (mirror image) or salt of a known chemical compound.[27]

C. Disclosure Requirement

For the selection invention category, an invention is not patentable unless the patent application explicitly discloses either qualitative or quantitative working effects in its specification.[28] Explicitly stating such effects means either (1) the specification must be specific as to the qualitative differences that any such difference be verifiable, or (2) that the specification quantitatively describes the invention's working effect as to verify that such effect is superior.[29] Merely stating that an invention is "very excellent" compared to the preceding invention will not suffice.[30] Further, such information must be more than stating the claimed composition's typical physical properties that are naturally considered by a person having ordinary skill in the art.[31]

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not, at least, there exist conspicuous differences in effect as measured quantitatively between them.").

[27] *See, e.g.,* Supreme Court [S. Ct.], 2001Hu2740, Apr. 25, 2003 (S. Kor.); Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.); Supreme Court [S. Ct.], 2008Hu3520, Mar. 25, 2010 (S. Kor.).

[28] Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.) ("[T]he detailed description of the selective invention must explicitly state the [qualitative or conspicuous quantitative] effects compared to the preceding invention.").

[29] *Id.*

[30] Supreme Court [S. Ct.], 2005Hu3338, Sept. 6, 2007 (S. Kor.).

[31] *See* Supreme Court [S. Ct.], 2008Hu3469 & 3476 (consol.), Mar. 25, 2010 (S. Kor.) (holding that the application has failed to meet disclosure requirement when it disclosed nothing "other than physical nature that an ordinary technician naturally considers when he or she makes salt compounds of medicinal substance.").

Subsequent cases seem to require that such difference be verifiable to a person having ordinary skill in the art.[32] The applicant or patentee needs not undergo any experiments verifying such superior working effect; instead, explicitly disclosing such working effect will suffice unless suspicions as to its superior working effects are raised.[33] If there are suspicions as to the claimed composition's effects, the applicant or patentee can overcome them by submitting specific comparative experimental data.[34] Such comparative experimental data must relate to the claimed composition's intended medicinal purpose.[35]

III. PATENTABILITY STANDARD OF PHARMACEUTICAL PRODUCTS

While there are few Korean Supreme Court decisions regarding selection invention,[36] the Korean Supreme Court has addressed the

[32] *See generally* Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

[33] *See* Supreme Court [S. Ct.], 2001Hu2740, Apr. 25, 2003 (S. Kor.) ("[I]t is enough that the specifications of a selective invention state explicitly the above mentioned kinds of effects compared to the preceding invention, and the results of comparative experiments verifying conspicuousness of its effects in concrete need not be stated.").

[34] *See id.* ("[I]f suspicions as to its effects are raised, an applicant for a patent may allege and prove its effects after the date of patent application by means of submitting specific comparative experimental data, etc.").

[35] *See* Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.) (stating that acute toxicity experiment is not relevant in proving invention's superior working effect since "it is just significant in examining whether it can be used as a medicinal product.").

[36] Such cases include: Supreme Court [S. Ct.], 2001Hu2375, Dec. 26, 2002 (S. Kor.); Supreme Court [S. Ct.], 2001Hu2740, Apr. 25, 2003 (S. Kor.); Supreme Court [S. Ct.], 2002Hu1935, Oct. 24, 2003 (S. Kor.); Supreme Court [S. Ct.], 2002Hu2846, Dec. 10, 2003 (S. Kor.); Supreme Court [S. Ct.], 2005Hu3338, Sept. 6, 2007 (S. Kor.); Supreme Court [S. Ct.], 2008Hu3469 & 3476, Mar. 25, 2010 (S. Kor.); Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.); Supreme Court [S. Ct.], 2008Hu3520, Mar. 25, 2010 (S. Kor.); Supreme Court [S. Ct.], 2010Hu3424, Nov. 5, 2010 (S. Kor.).

issue at various times since 2002[37] and, most recently, in 2010[38]. A recurring discussion in the Korean Supreme Court's holdings is whether selection inventions are, in fact, patentable.

Several important trends have emerge from these decisions and are worthy of note. First, the Korean Supreme Court has historically invalidated patents on selection inventions and, until recently, a patentee had never prevailed at the highest court.[39] Second, while the earliest case on this issue was a dispute between individuals, the rest of the cases were disputes between non-Korean pharmaceutical companies and either the Korean Intellectual Property Office (KIPO) or Korean pharmaceutical companies.[40] Third, the patentee or patent applicant against whom the Korean Supreme Court has held was always a non-Korean pharmaceutical company. In summary, a non-Korean pharmaceutical company had never successfully defended a selection invention at the Korean Supreme Court until one very recent opinion.[41] This section will discuss *Sanofi-Aventis v. CJ et al.* (Sanofi)[42] as it is the strictest and arguably most unreasonable in terms of its patentability standard. This section will further discuss the impact of *Sanofi* by analyzing Korean Supreme Court's decisions regarding selection invention thereafter.

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[37] Supreme Court [S. Ct.], 2001Hu2375, Dec. 26, 2002 (S. Kor.).

[38] Supreme Court [S. Ct.], 2010Hu3424, Nov. 5, 2010 (S. Kor.).

[39] *See id.* (reversing and remanding the Korean Intellectual Property Tribunal and Patent Court's holding, which denied the invention's inventiveness).

[40] *See* Supreme Court [S. Ct.], 2001Hu2375, Dec. 26, 2002 (S. Kor.).

[41] For the First time, the Korean Supreme Court in 2010Hu3424 held in favor of the non-Korean Company. *See* Supreme Court [S. Ct.], 2010Hu3424, Nov. 5, 2010 (S. Kor.).

[42] Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

A. Sanofi *Patent*

The Korean Supreme Court's consistent, strict application of the novelty and inventiveness standards reflects the its hostility against patentees and patent applicants. Such tendency peaked in the *Sanofi* case,[43] in which the Korean Supreme Court set extremely high novelty and inventiveness standards.[44] This section will provide a scientific background to the invention in *Sanofi*, followed by a case summary and discussion of its significance.

1. Scientific Background

The issue in *Sanofi* was the patentability of an enantiomer patent in light of the applicant's prior patent directed towards a racemate. This section will provide general understanding of nomenclatures such as enantiomer and racemate, which are key concepts to understand dispute in *Sanofi*.

i. Enantiomers and Racemates

The term chirality refers to a geometric property of an object that is not identical to its mirror image, for example, a person's right and left hands.[45] When molecules are chiral, the same chemical formula can describe molecules with different three-dimensional structures.[46] Enantiomers are chiral molecules of opposite orientation with only one point of chirality.[47]

Again, the concept of enantiomers, non-identical mirror images, is illustrated by a person's right and left hands. The right and left hands are mirror images of each other, but they are not

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[43] Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

[44] *See* Yang et al., *supra* note 23, at 1.

[45] Jonathan McConathy & Michael J. Owens, *Stereochemistry in Drug Action*, 5 PRIMARY CARE COMPANION J. CLIN. PSYCHIATRY 70, 70 (2003).

[46] *See id.*

[47] *Id.*

superimposable and thus not identical. Similarly, enantiomers are identical in their chemical composition and structure in two dimensional spaces, but are not superimposable as they are not identical in their orientation in three dimensional spaces.[48]

A racemate is a mixture of those enantiomers, usually in equal amounts.[49] When an active ingredient of a drug is in the form of an enantiomer, the drug is usually referred to as an enantiomer drug. Vice versa, a racemate drug refers to a drug of which the active ingredient is in the form of a racemate. Further, patents covering enantiomer drugs are referred to as enantiomer patents, whereas a racemate patent refers to a patent primarily covering a racemate drug.

Although there is a high degree of structural similarity between racemates and enantiomers, racemates and enantiomers may differ greatly in a terms of biological and pharmaceutical properties.[50] Two enantiomers constituting a racemate may also differ significantly in various respects[51] because the active site of certain enzymes may only react to one enantiomer and not the other,[52] similar to how a right-handed glove does not fit on a person's left hand. Therefore, academic tendency is to view two enantiomers as two separate properties unless proven otherwise.[53] Further, an

[48] *Id.*

[49] *Id.*.

[50] *See id.* at 71 ("In these cases, it is critical to distinguish the single enantiomer from the racemic form because they may differ in their dosages, efficacies, side effect profiles, or even indicated use.").

[51] *Id.* at 72 ("The 2 enantiomers of a chiral drug may differ significantly in their bioavailability, rate of metabolism, metabolites, excretion, potency and selectivity for receptors, transporters and/or enzymes, and toxicity.").

[52] *See id.* at 71.

[53] *Id.*

enantiomer's pharmaceutical activity can be unpredictable absent clinical trials and experiences.[54]

a. Pharmaceutical Practice

In the preparation of pharmaceuticals, laboratory synthesis of chiral molecules initially results in racemate drugs.[55] Thus, pharmaceutical companies must separate the enantiomers from one another before investigating the pharmaceutical activities of the enantiomer drugs. The problem is that separating the enantiomers is usually difficult,[56] and pharmaceutical companies often spend significant time and money on separation.[57] Therefore, evidence that a company has successfully separated the enantiomers from the racemate may facilitate patentability if the jurisdiction places weight on the separation effort and process.

2. Procedural Background

i. History of Plavix®

In 1972, while seeking an agent that might have improved anti-inflammatory properties, Sanofi-Aventis (Aventis) scientists discovered that compounds known as thienopyridines have the property of inhibiting blood platelet aggregation.[58] Thereafter,

[54] *See id.* at 72 ("The decision to use a single enantiomer versus a mixture of enantiomers of a particular drug should be made on the basis of the data from clinical trials and clinical experience.").

[55] Jonathan J. Darrow, *The Patentability of Enantiomers: Implications for the Pharmaceutical Industry*, 2007 STAN. TECH. L. REV. 2, 9 (2007).

[56] *See id.* ("Due to the difficulty in separating the enantiomers from one another, many chiral drugs were initially sold in racemic form.").

[57] For instance, Sanofi had given up commercial development of the racemate PCR 4099, which "had been proceeding since 1980 and had reached Phase I human trials at a cost stated to be tens of millions of dollars," to develop enantiomer of PCR 4099, which also took years. Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1081 (Fed. Cir. 2008). Therefore, a racemate patent usually precedes an enantiomer patent.

[58] *Id.* at 1078.

Aventis scientists continuously put effort into finding chemical modifications and derivatives of thienopyridines in order to discover optimum anti-platelet aggregation properties with minimal undesirable effects.[59]

Sanofi eventually selected a compound designated as PCR 4099 for commercial development.[60] Further, Aventis found that a hydrochloride salt of the compound was suitable for tableting PCR 4099.[61] Aventis filed a patent application covering PCR 4099 as a hydrochloride salt in a number of countries including the United States and Korea.[62] However, as PCR 4099 still raised toxicity issues, Aventis continued its research toward finding a more optimum version of the agent.[63]

Aventis's subsequent research focused on separating PCR 4099, which was a racemate mixture, into enantiomers, and Aventis discovered that, after spending significant time and money on separation, one of the enantiomers provided all of the favorable antiplatelet activity without significant neurotoxicity.[64] Aventis named that enantiomer "Clopidogrel."[65] Aventis also found that hydrochloride salt, which had been suitable for tableting the PCR 4099, was not suitable for Clopidogrel.[66] Aventis's research also revealed that bisulfate was suitable for tableting Clopidogrel.[67]

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[59] *Id.* at 1078-79.

[60] *Id.* at 1079.

[61] *Id.* at 1082.

[62] *Id.;* Patent Court [Pat. Ct.], 2006Heo6303 & 8330, Jan. 18, 2008 (S. Kor.).

[63] Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1079 (Fed. Cir. 2008).

[64] *Id.* at 1081.

[65] *Id.* at 1081-82 ("More years of development ensued for the dextrorotatory enantiomer, to which Sanofi gave the common name Clopidogrel.").

[66] *Id.* at 1082.

[67] *Id.*

Thereafter, Aventis filed a patent application covering Clopidogrel as the bisulfate (Clopidogrel Bisulfate) in the United States and Korea, as well as other countries.[68] Later, Aventis launched Plavix®, which included Clopidogrel bisulfate as an active ingredient.[69]

ii. Judicial History

KIPO granted Aventis a patent (the '448 patent)[70] covering PCR 4099 in 1983. Five years later, Aventis filed another patent application[71] covering Clopidogrel and its salt, and was granted a patent (the '969 patent).[72] To summarize, the earlier '448 patent is a racemate patent while the subsequent '969 patent is an enantiomer patent.

As a result of the successful filing of the '969 patent, other pharmaceutical companies were prohibited from producing generic products of Plavix® so long as either the '448 or '969 patent survived.[73] After 2003, the '969 patent prevented other

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[68] *Id.*

[69] *Id.* at 1077.

[70] Kor. Patent No. 1,019,840,005,448 (filed Jul. 13, 1982); *FAQ - Korea*, EUROPEAN PATENT OFFICE, http://www.epo.org/searching/asian/korea/faq.html#faq-406 (last updated Mar. 10, 2011) (Korean patents have a term of protection of 20 years from the date of the filing).

[71] Kor. Patent No. 1,019,880,009,969 (filed Feb. 17, 1987).

[72] The '969 patent claimed Clopidogrel in its claim 1, and further claimed Clopidogrel as the hydrochloride salt and hydrogen sulfite salt respectively in claim 2 and 3. Therefore, the nature of the subject matter broadly presents two issues before the Korean Supreme Court: first, whether an enantiomer of chemical compound is patentable when the prior art discloses its racemate; and second, whether the enantiomer as the specific salt is patentable when the prior art disclose the racemate as the salt. Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

[73] *See* DONG-YUN KIM, KOREAN ECONOMICS, A DISPUTE BETWEEN KOREAN AND FOREIGN PHARMACEUTICAL COMPANIES, http://sgsg.hankyung.com/apps.frm/news.view?nkey=2562&c1=03&c2=06.

pharmaceutical companies from producing generic versions of Plavix®.[74] While generic versions of Plavix® would have been prohibited until 2011, seventeen Korean pharmaceutical companies sought to remove this barrier early by invalidating the '969 patent.[75] The main argument was that the '969 patent was anticipated by the '448 patent.[76] The Korean Intellectual Property Tribunal and Patent Court held the '969 patent invalid, and Aventis appealed the case to the Korean Supreme Court.[77]

iii. Holding

In *Sanof*, the Korean Supreme Court affirmed the Korean Intellectual Property Tribunal and Patent Court's holding, which invalidated the '969 patent by denying its novelty and inventiveness.[78] With respect to claim 1 of the '969 patent, the Korean Supreme Court denied Clopidogrel's novelty as anticipated by the '448 patent because the '448 patent covered the Clopidogrel.[79] With respect to claim 2, the Korean Supreme Court held that, because the '448 patent discloses the Clopidogrel and PCR 4099 as the hydrochloride salt, the Clopidogrel as the hydrochloride salt is easily recognizable to a person having ordinary skill in the art in a light of the '448 patent.[80]

As to claim 3, the Korean Supreme Court compared the subject matter's pharmaceutical working effect with that of PCR4099 as the hydrochloride salt, which was disclosed in the '448 patent. The Korean Supreme Court held that a two-fold pharmaceutical

[74] *See infra* Part. V.B.1.ii.

[75] Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

[76] *See* Yang et al., *supra* note 23, at 2.

[77] *See* Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

[78] *See id*.

[79] *Id*.

[80] *Id*.

working effect of the invention compared to that of the prior art was not superior since it was widely known that a certain enantiomer may have greater working effect than that of a racemate or another corresponding enantiomer.[81]

3. Significance

Sanofi is significant in two respects. First, it was the first Korean Supreme Court case to determine the patentability of an enantiomer patent. Second, it set an extremely high standard of patentability for selection inventions. Opinions vary regarding what makes *Sanofi* strict as to patentability. Some argue that it heightened the novelty requirement.[82] Others argue, mistakenly, that it denied the invention's patentability for lack of written description about quantitative differences, despite an actual superior working effect.[83] One may also argue that the decision is strict because its literal impact is to deny patentability of a certain composition merely because a degree of its working effect is well-known.[84]

i. Heightened Novelty Standard

One may argue that the novelty standard set by Sanofi is much stricter than that used in other leading patent jurisdictions.[85] Such an argument is well-supported by the fact that the current Korean common law will likely invalidate an enantiomer patent if a prior racemate patent mentions the existence of the subsequently

[81] *Id.*

[82] *See generally* Yang et al., *supra* note 23, at 2.

[83] *Id.*

[84] *See generally* Cha-Ho Jung & Hyeen Shin, *Legal Review on Selection Invention's Novelty of Optical Isomer*, 49 SEOUL NAT'L U. L. REV. 355 (2000).

[85] *See* Yang et al., *supra* note 23, at 2 ("First, its novelty standard is much stricter than those in other leading patent jurisdictions. Here, the Court held that an enantiomer *per se* and its medicinal use lacks novelty over a prior art racemate and its medicinal use – by comparison, the novelty of the enantiomer's medicinal use would be upheld in Japan.").

claimed enantiomers that comprise the racemate.[86] In contrast, some countries have undergone deeper analysis, and sometimes have upheld the novelty of an enantiomer patent regardless of the raceamte patent's mentioning of the enantiomers. For example, some courts look at whether (1) the species of certain genus are so characteristically (not structurally) similar that disclosure of a genus in the prior art is necessarily a disclosure of every species,[87] or (2) the method of separating a certain optical isomer from its racemate is well-known or specifically disclosed.[88] Korea instead applied a per se analysis resulting in an extremely heightened standard for selection invention novelty for enantiomer patents.

ii. Heightened Inventiveness Standard

One may also argue that *Sanofi* created a significantly heightened inventiveness standard. Such an argument is supported by the fact that the Korean Supreme Court held that a two-fold superior working effect is not sufficient when such superior working effect is obvious.[89] Therefore, one impact of *Sanofi*'s holding is to require, at a minimum, a two-fold working effect for the enantiomer drug to be "superior."

iii. Lack of Description of Qualitative Difference

Some argue that the *Sanofi* decision is strict because the Korean Supreme Court denied inventiveness of the patent for lack of description as to quantitative differences in the specification despite the invention's actual superior working effects over the

[86] *See* Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.); *see also infra* Part. V.A.2.ii.

[87] *See* Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 999 (Fed. Cir. 2006) ("It is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus.").

[88] *See* EPO Case T-0296/87 (Aug. 30, 1988), *available at* http://www.epo.org/law-practice/case-law-appeals/recent/t870296ep1.html.

[89] *See* Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.); s*ee also infra* Part. IV.A.2.a.

prior art.[90] However, such an argument is flawed since a lack of description as to quantitative difference was not an issue in the case. Rather, the Korean Supreme Court stated that the invention's qualitative difference over the prior art was clearly described in the specification.[91] Therefore, such arguments may have been made due to confusion between quantitative and qualitative differences.

IV. POST-SANOFI DECISIONS

Sanofi was very influential in terms of legal impact. All three subsequent Korean Supreme Court cases involving selection invention cite *Sanofi* as binding precedent in reviewing the novelty of an invention at issue.[92] Two of those cases denied the novelty pursuant to *Sanofi*.[93] This section will discuss these two cases.[94]

A. Warner-Lambert Co. Patent

In 2008, the Korean Supreme Court dealt with another selection invention patent case in which enantiomers of R-Trans

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[90] Yang et al., *supra* note 23, at 2.

[91] *See* Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.) (stating that the pharmacological effects of anti-platelet aggregatory and anti-thrombotic and the effect of acute toxicity experiment "are explicitly stated in the detailed description of patent invention of this case.").

[92] Supreme Court [S. Ct.], 2008Hu3469 & 3476, Mar. 25, 2010 (S. Kor.); Supreme Court [S. Ct.], 2008Hu3520, Mar. 25, 2010 (S. Kor.); Supreme Court [S. Ct.], 2010Hu3424, Nov. 5, 2010 (S. Kor.).

[93] Supreme Court [S. Ct.], 2008Hu3469 & 3476, Mar. 25, 2010 (S. Kor.) (concerning a dispute between Warner-Lambert Co. and Korean pharmaceutical companies as to an invalidation question); Supreme Court [S. Ct.], 2008Hu3520, Mar. 25, 2010 (S. Kor.) (concerning a dispute between Warner-Lambert Co. and KIPO as to a patentability question).

[94] 2008Hu3469 & 3476 and 2008Hu3520 are based on the same facts except that 2008Hu3469 & 3476 is an appeal against Korean pharmaceutical companies, and 2008Hu3520 is an appeal against KIPO. Supreme Court [S. Ct.], 2008Hu3469 & 3476, Mar. 25, 2010 (S. Kor.); Supreme Court [S. Ct.], 2008Hu3520, Mar. 25, 2010 (S. Kor.).

and S-Trans heptanoic acid were claimed as patentable.[95] At the same time, the prior art disclosed the racemate of R-Trans and S-Trans heptanoic acid.[96] The Korean Supreme Court, citing *Sanofi*, held that enantiomers of those heptanoic acids are recognizable when the prior art discloses the racemate, and hence, the Korean Supreme Court denied the novelty of those claimed invention.[97] The Korean Supreme Court further clarified that the method of separating an enantiomer from its racemate is not relevant in examining novelty requirements.[98]

B. Eli Lilly

The most recent Korean Supreme Court case regarding selection invention is *Eli Lilly* from 2010.[99] Though the issue before the Korean Supreme Court was not the patentability of an enantiomer invention, one must note that *Eli Lilly* is the first selection invention case in which the Korean Supreme Court did not invalidate the patent at issue.[100]

V. WHY SO STRICT?

As discussed previously, the Korean Supreme Court has been consistently hostile toward patentees, and such hostility peaked in

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[95] Supreme Court [S. Ct.], 2008Hu3469 & 3476, Mar. 25, 2010 (S. Kor.); Supreme Court [S. Ct.], 2008Hu3520, Mar. 25, 2010 (S. Kor.).

[96] Supreme Court [S. Ct.], 2008Hu3469 & 3476, Mar. 25, 2010 (S. Kor.); Supreme Court [S. Ct.], 2008Hu3520, Mar. 25, 2010 (S. Kor.).

[97] Supreme Court [S. Ct.], 2008Hu3469 & 3476, Mar. 25, 2010 (S. Kor.). However, the Court does not specify the class to which the invention is recognizable.

[98] *See id.* (stating that even if the lower court erred in finding that the prior art disclosed a method of separating an enantiomer from its racamate, such error had no impact on the decision, because disclosing such a method is not necessary in denying novelty of an invention at issue unless the subject matter of an invention is of the separating method).

[99] Supreme Court [S. Ct.], 2010Hu3424, Nov. 5, 2010 (S. Kor).

[100] *See infra* Part IV.C.

Sanofi as the Korean Supreme Court suggested strict patentability standards of selection invention.[101] This section provides legal analysis and persuasive policy justifications for such a strict standard. This section will further discuss the significance of *Eli Lilly*,[102] which may be a signal for much changed attitude toward non-Korean pharmaceutical companies in the future.

A. Legal Explanation

The *Sanofi* holding is strict in that it greatly heightened both novelty and inventiveness standards.[103] This section will discuss how such standards were legally heightened.

1. Heightened Novelty Standard

The *Sanofi* decision lacks a detailed inquiry, the presence of which may have resulted in a different outcome. Pursuant to *Sanofi*, structural similarity between a claimed composition and the prior art is grounds for a *per se* denial of the composition's novelty.[104] The most persuasive legal explanation for such *per se* analysis of novelty standards is a lack of the Korean Supreme Court's judicial experience, which is especially true in the context of intellectual property law.[105] Such lack of judicial experience is shown circumstantially from (1) the fact that the Korean Supreme Court has sometimes misapplied inventiveness criterions to novelty standards and (2) the Korean Supreme Court's failure to

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[101] *See supra* Part III.A.

[102] Supreme Court [S. Ct.], 2010Hu3424, Nov. 5, 2010 (S. Kor.).

[103] *See generally* Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

[104] *Id.*

[105] *See* Sang-Jo Jong, *Contributory Patent Infringement in Korea*, 2 WASH. U. J.L. & POL'Y 287, 287 (2000) ("Partly due to a lack of experience, courts have sometimes failed, in the course of interpreting provisions of the Patent Act, to balance the interests of the patentee and the interests of the general public.").

distinguish scientific common knowledge and subject matter of an invention.

i. Conceptual Misapplication

One may easily find that the Korean Supreme Court conceptually misapplies inventiveness criterions to novelty standards. Such conceptual misapplication occurs when the Korean Supreme Court cites the perspective of a person having ordinary skill in the art in judging novelty.[106] Generally speaking, such conceptual misapplication heightened novelty standards by blurring the line between novelty and inventiveness.[107] The following discusses how the Korean Supreme Court conceptually misapplied inventiveness criterions in *Sanofi*.

Article 29.1 of the Korean Patent Act defines novelty and Article 29.2 defines inventiveness.[108] As is the case in the United States,[109] only Article 29.2 discusses a "person having ordinary skill in the art" as a criterion for evaluating the inventiveness of an

[106] *See* Jung & Shin, *supra* note 84, at 390 (stating that citing the perspective of a person having ordinary skill in the art is a conceptual misapplication when judging the novelty standard).

[107] *See generally id.* at 390.

[108] *See* Erstling, *supra* note 9, at 451 ("The basis for the requirement of an 'inventive step' is found in Article 29.2 of the Korean Patent Act, which provides that no patent for an invention may be granted if the invention could easily have been made before the filing of a patent application by a person with ordinary skill in the art to which the invention pertains." (internal quotation marks omitted))*; see also* Teukheo beob [Patent Act], Act. No. 950, Dec. 31, 1961, art. 29 (S. Kor.).

[109] *See* 3 CARL R. MOY, MOY'S WALKER ON PATENTS § 9:1 (4th ed. 2013) (footnote omitted) ("[35 U.S.C. § 103(a)] states that an invention is not patentable if it would have been 'obvious' over the 'prior art' at the time the invention was made. Obviousness is to be judged from the objective perspective of 'a person having ordinary skill in the art' to which the invention pertains.").

invention.[110] Therefore, using such a person's perspective in judging the novelty of an invention itself is a conceptual misapplication of the law.[111]

In *Sanofi*, the Korean Supreme Court committed this conceptual misapplication. As to Clopidogrel as the hydrochloride salt, *Sanofi* denied its novelty by reasoning that the presence of the invention is easily recognizable to a person having ordinary skill in the art from the prior art disclosing Clopidogrel and racemate as the hydrochloride salt.[112] Regardless of whether the invention was recognizable to such a person, *Sanofi* uses the perspective of a person having ordinary skill in the art in denying novelty of the invention.[113] Erroneously, under the Korean Supreme Court's reasoning, even though an invention at issue is not of the same invention disclosed in the prior art, the invention is anticipated for lack of novelty if the presence of the invention is recognizable to a person having ordinary skill in the art.

a. Lack of Distinction between Scientific Common Knowledge and Subject Matter of an Invention

In denying novelty of the invention, *Sanofi* cited the racemate patent disclosing PCR4099 and its enantiomers (Clopidogrel), which are the subject matter of the '969 patent.[114] Therefore, the Korean Supreme Court held that the subject matter of the racemate

[110] *See* Jung & Shin, *supra* note 84, at 391 (stating that while Korean Patent Act article 29.1 defines novelty and 29.2 defines inventiveness, the words "a person having ordinary skill in the art," are only stated in 29.2).

[111] *See* Jung & Shin, *supra* note 84, at 390 (stating that citing a perspective of a person having ordinary skill in the art is a conceptual misapplication in judging novelty standard).

[112] *See* Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

[113] *Id.*

[114] *Id.*

patent was not only PCR 4099, but also Clopidogrel.[115] However, the prior art neither stated that such enantiomers were substantially separated nor provided a clear motivation to indicate the enantiomers as its subject matter.[116] Regardless, the Korean Supreme Court held that prior art disclosed the Clopidogrel because it was scientifically common knowledge. Thus, *Sanofi*'s holding makes a prior art patent an anticipating reference even when the subject matter of the claimed invention has not been enabled by the prior art.

Perceiving scientific common knowledge as the subject matter of an invention may be problematic. Though it is widely known that one of an enantiomer separated from its racemate may have greater pharmaceutical effect than that of its racemate, a lot of products are not available in the form of an enantiomer, since separating the enantiomer from its racemate is a very difficult process on which pharmaceutical companies usually spend considerable time and money.[117] As such, the United States, along with Europe and Japan, have held that "knowledge that enantiomers may be separated is not anticipation of a specific enantiomer that has not been separated, identified, and characterized."[118]

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[115] *Id.* ("[E]ach enantiomer stated in the comparison invention No. 1 refers to dextro enantiomer and levo enantiomer and their mixture refers to racemate, so all of them, i.e., dextro enantiomer, levo enantiomer, and racemate, are the objects of invention of the comparison invention No. 1.").

[116] *See* Patent Court [Pat. Ct.], 2006Heo6303 & 8330, Jan. 18, 2008 (S. Kor.).

[117] *See* Jung & Shin, *supra* note 84, at 392 (stating that the fact that Aventis invested a significant amount of money and time in developing a method of separating enantiomers from its racemate evidences that enantiomers are not easily separable from its racemate); *see also* Darrow, *supra* note 55, at 9 ("Due to the difficulty in separating the enantiomers from one another, many chiral drugs were initially sold in racemic form.").

[118] Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1084 (Fed. Cir. 2008).

Despite the significant process of separating an enantiomer from its racemate, the Korean Supreme Court held in *Sanofi* that anticipating an enantiomer patent does not require disclosure of the process in the prior art.[119] However, the patent was directed to the chemical structure itself, whereas if the patent had included a claim to the method of separation it may have been patentable.

In conclusion, while other leading jurisdictions require further analysis on top of the mere presence of enantiomers,[120] the Korean Supreme Court's oversimplified holding in *Sanofi* substantially heightened the novelty standards by stating that scientific knowledge of the presence of an enantiomer in a racemate mixture anticipates a patent claiming an isolated enantiomer.

2. Heightened Inventiveness Standard

In examining whether the drug's working effect is superior over the prior art, *Sanofi* further required that the working effect not be derived from routine experimentation, regardless of drug toxicity. [121] The possible legal explanation for a heightened inventiveness standard is relatively more obscure and complex than that of a novelty standard. However, one may find *a reason*

[119] *See* Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.). Interestingly, the lower court held that mentioning the enantiomer itself is merely stating scientifically common knowledge unless the prior art discloses the separating method specifically. Accordingly, the lower court held that merely disclosing scientifically common knowledge itself does not deny novelty of the invention. *See* Patent Court [Pat. Ct.], 2006Heo6303 & 8330, Jan. 18, 2008 (S. Kor.) (holding that disclosing enantiomers without (1) the method of separating those enantiomers from its racemate, (2) any experiment performing such separation, or (3) any motivation specifying enantiomers as subject matter is merely stating common scientific knowledge that racemate may exist in a form of one of enantiomer).

[120] Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1084 (Fed. Cir. 2008).

[121] Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

for heightened inventiveness in unclear inventiveness criterions and misunderstanding of the nature of Article 29.2.

i. Predictability

Sanofi held that the working effect of the invention is obvious, and hence, inventiveness must be denied.[122] Therefore, pursuant to *Sanofi*, superior working effect must not only be quantitatively superior, but also unpredictable. *Sanofi* seems to deal with the predictability very broadly. What the Korean Supreme Court found is not that an enantiomer drug always has a superior working effect over racemate drugs, but rather, that one of the enantiomer separated from the racemate *may* have superior working effect (superior enantiomer) over the other enantiomer (inferior enantiomer).[123] Therefore, *Sanofi* concludes that it is obvious that an enantiomer drug consisting of superior enantiomers has, at least, a two-fold working effect over the racemate drug since superior enantiomers replace inferior enantiomers.[124]

The predictability within the context of the *Sanofi*'s holding departs from one scientific possibility–that one enantiomer *may* be superior over the other, not that one enantiomer *will likely* be superior over the other. Therefore, *Sanofi*'s conception of the predictability is a very low threshold.

ii. Toxicity

In *Sanofi*, the Korean Supreme Court declined to consider toxicity of the enantiomer drugs as part of the predictability analysis.[125] Rather, the Korean Supreme Court considered toxicity separated from a drug's beneficial activity, and stated that the

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[122] *Id.*

[123] *Id.*

[124] *Id.*

[125] *See id.* (holding that a drug's toxicity will not be considered as a part of the inventiveness).

invention's toxicity is only relevant in examining whether the invention can be used as medicinal product.[126]

The Korean Supreme Court's non-consideration of the toxicity for predictability heightened the inventiveness criteria as well. In *Apotex*,[127] in which the United States Court of Appeals for the Federal Circuit dealt with same issue as was before the Korean Supreme Court in *Sanofi*, experts for both sides agreed that Clopidogrel's degree and kind of stereoselectivity [128] was unpredictable since "activity and toxicity were more likely to be positively correlated, such that a reduction in toxicity would be expected also to reduce the beneficial activity." [129] Therefore, consideration of toxicity as a part of predictability would have brought a different result regarding inventiveness. Still, in *Sanofi*, the Korean Supreme Court considered the drug's beneficial activity only and asked whether such activity was predictable or not regardless the drug's toxicity.[130]

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[126] A drug is patentable under selection invention unless its toxicity exceeds the minimum threshold set by the court. *See* Patent Court [Pat. Ct.], 2006Heo6303 & 8330, Jan. 18, 2008 (S. Kor.) ("[Toxicity] is just significant in examining whether it can be used as a medicinal product.").

[127] *See* Sanofi-Synthelabo v. Apotex, Inc., 550 F.3d 1075, 1078 (Fed. Cir. 2008).

[128] *Id.* at 1081 (Clopidogrel "provided all of the favorable antiplatelet activity but with no siginificant neurotoxicity, while the other enantiomer produced no antiplatelet activity but virtually all of the neurotoxicity.").

[129] *See id.* at 1087.

[130] Therefore, *Sanofi*'s test may not treat the following inventions differently: one invention that is highly superior in beneficial activity with high toxicity, and the other invention that is highly superior in beneficial activity with almost no toxicity. Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

iii. Inventiveness Criterion

The *Sanofi* decision does not specify a class of persons to whom such working effect may be obvious.[131] While one may infer from Article 29.2 that such a class may be persons having ordinary skill in the art, even assuming such is problematic since the Korean Supreme Court seems to misunderstand the nature of Article 29.2.[132]

Inventiveness of selection invention derives from Article 29.2, which denies inventiveness when a person having ordinary skill in the art could easily have made the invention.[133] Therefore, literal application of Article 29.2 to selection invention will not always deny inventiveness of an enantiomer patent by the prior art, which discloses the enantiomer's racemate, since the fact that the enantiomer drug's working effect is obvious or predictable does not necessarily indicate that the enantiomer drug could have been easily made.[134] However, rather than asking whether the invention could have easily been made, the Korean Supreme Court asks whether the working effect is "obvious or well-known" to a person having ordinary skill in the art.[135]

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[131] *See generally id.*

[132] *See* Teukheo beob [Patent Act], Act. No. 950, Dec. 31, 1961, art. 29.2 (S. Kor.) ("[A]n invention could easily have been made before the filing of a patent application by a person ordinarily skilled in the art to which the invention pertains, the patent for such an invention may not be granted.").

[133] *See id.*

[134] It is general knowledge that one enantiomer may behave differently than another. *See* Darrow, *supra* note 55, at 8. However, such knowledge will not enable a person having ordinary skill in the art to practice an enantiomer drug since one must separate enantiomers first, and the separation is difficult process. *Id.* at 9.

[135] Supreme Court [S. Ct.], 2008Hu736 & 743 (consol.), Oct. 15, 2009 (S. Kor.).

B. Protectionism?

Though patentability of selection invention may be legally unreasonable, interestingly, such legally unreasonable standards serve the primary rationale of Korean Patent Act.[136] This section provides possible explanation of the strict standard of selection invention in a term of policy justification by finding a causal connection between the strict standard and its impact on Korea's pharmaceutical industry and its public. This section will first discuss the primary rationales of the Korean Patent Act, and then discuss how strict patentability standards of selection invention serve those rationales well.

1. Rationales of the Korean Patent Act

Narrowly, the rationale of the Korean Patent Act is to "contribute to the development of industry" by protecting and utilizing invention.[137] Broadly, the Korean Patent Act tries to further the public's interest.[138] Therefore, the rationales of the Korean Patent Act are well-defined as dual in nature such that an invention that may undermine the industrial development or public interest is not patentable.[139] Such dual nature of the Korean patent

[136] Teukheo beob [Patent Act], Act. No. 950, Dec. 31, 1961, art. 1 (S. Kor.) (stating in Article 1 that the "purpose of the [Korean Patent Act] is to encourage, protect and utilize inventions, thereby improving and developing technology, and to contribute to the development of industry.").

[137] *See* Erstling, *supra* note 9, at 448 ("[The Korean Patent Act] seeks both to protect and encourage inventions while at the same time promoting industrial development."); *see also* Teukheo beob [Patent Act], Act. No. 950, Dec. 31, 1961, art. 1 (S. Kor.).

[138] *See* Teukheo beob [Patent Act], Act. No. 950, Dec. 31, 1961, art. 32 (S. Kor.) ("An invention likely to contravene public order or morality or to injure public health may not be patented.").

[139] *See* KOREAN INTELL. PROP. OFFICE, A HISTORICAL ANALYSIS OF KOREAN PATENT ACT 3 (2007) (stating that an invention is not patentable if providing protection over the invention undermines industrial development or

system overrides an inventor's patent rights so that giving incentives to patentees is deemed incidental in achieving the primary rationales.[140] The fact that inventors' rights are limited and open to governmental interference circumstantially supports this notion.[141]

i. Impacts of the Korean Supreme Court's Decision on Korean Pharmaceutical Industry

The Korean Supreme Court's consistent hostility toward patentees and applicants via strict novelty and inventiveness standards has several economic and social impacts, which perfectly serve the primary rationales of the Korean Patent Act.[142] Those impacts include (1) to confer economic benefits and competitiveness to Korea's domestic pharmaceutical industry via

public interest as the Korean Patent Act intends to achieve both individual and public interest).

[140] Article 1 does not mention rights of inventors. Rather, it mentions "protecting invention" through which, the Article 1 states, industrial development will be encouraged. *See* Teukheo beob [Patent Act], Act. No. 950, Dec. 31, 1961, art. 1 (S. Kor.).

[141] Compared to that of the United States, an inventor's rights under the Korean Patent Act are more limited and open to governmental interference. For instance, a patentee has an obligation to work the patented invention. *See* KOREAN INTELL. PROPERTY OFFICE, *supra* note 138, at 5 (stating that a patentee's right over an invention may be interfered with if the patentee does not work or insufficiently works the invention pursuant to Korean Patent Act article 107 or 116); *see also* Erstling, *supra* note 9, at 458 (discussion of the exceptions through which patentee's exclusive right may be interfered and third party's non-exclusive license to work a patented invention in a limited circumstances). Further, the fact that patent rights are freely assignable circumstantially supports the fact that inventors' rights under Korean patent law are of less importance than that of the United States. S*ee* Erstling, *supra* note 9, at 453 ("Korea achieves an open marketplace under its patent law by providing that patents and their associated rights are freely assignable and otherwise transferable.").

[142] *See infra* Parts III.A, IV.

the preventing evergreening [143] strategy of non-Korean pharmaceutical industry, and (2) to lower drug prices so that the public may easily access the drug over which non-Korean pharmaceutical companies failed to gain or maintain patent rights.

ii. Industrial Development

Strict novelty and inventiveness standards of selection invention effectively prevent pharmaceutical companies' evergreening strategies. This section explains why hostility toward evergreening strategies inevitably leads to substantial benefits to Korean pharmaceutical companies. Generally speaking, there exists a strong causal connection between the Korean Supreme Court's hostility toward patentees and applicants and the Korean Patent Act's primary rationale of industrial development.

The idea that pharmaceutical products can be patentable is recent to the Korean Patent Act. Pharmaceutical products themselves were not patentable subject matter pursuant to Article 32 until 1986,[144] primarily because the Korean pharmaceutical industry was not competitive enough to survive due to the leading pharmaceutical companies' monopoly over the products.[145] During the period when patent protection over pharmaceutical products

[143] *See* Janet Freilich, *The Paradox of Legal Equivalents and Scientific Equivalence: Reconciling Patent Law's Doctrine of Equivalents with the FDA's Bioequivalence Requirement*, 66 SMU L. REV. 59, 104-05 (2013) ("Evergreening . . . occurs when a pharmaceutical company that has lost both FDA exclusivity and patent protection on the active ingredient of its drug seeks to extend its monopoly by protecting the drug with a series of peripheral patents that allow for additional FDA exclusivity and further patent protection.").

[144] *See* Sang-Hyun Song & Seong-Ki Kim, *The Impact of Multilateral Trade Negotiations on Intellectual Property Laws in Korea*, 13 UCLA PAC. BASIN L.J. 118, 120 (1994).

[145] Sang-Youn Hwang, *A Prospect and Development Direction of Korean Pharmaceutical Industry*, SHINYOUNG SECURITIES RESEARCH CENTER, 2000, at 26.

was limited,[146] Korean pharmaceutical companies learned how to manufacture finished drugs and active pharmaceutical ingredients (API),[147] which became their major source of revenue.[148]

Such protection over domestic pharmaceutical industries ended in 1986 due to bilateral trade negotiations.[149] The United States asked Korea for stronger protection over pharmaceutical products, and Korea amended the Korean Patent Act to provide patent protection over chemical substances.[150] Such protection was also conferred over pharmaceutical products *per se*.[151]

Yet, one must note that the primary rationales of the Korean Patent Act were not the driving forces to such amendment. While the Korean Patent Act pursues industrial development and public interest, such an amendment was a result of recognizing a need for

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[146] *See* Song & Kim, *supra* note 143, at 122 ("Since then the Patent Act has been revised several times, but protection for inventions of chemical substances per se was not allowed until 1987. Until then, only process patents were available for chemical inventions.").

[147] World Health Organization, *Definition of Active Pharmaceutical Ingredient*, at 3 (2011), *available at* http://www.who.int/medicines/areas/quality_safety/quality_assurance/DefinitionAPI-QAS11-426Rev1-08082011.pdf ("Any substance or combination of substances used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings.").

[148] Hwang, *supra* note 144, at 26.

[149] *See* KOREAN INTELL. PROPERTY OFFICE, *supra* note 138 at 206 ("As a result of bilateral agreement between Korea and United States, Korean Patent Act modified so that invention of pharmaceutical products, method of making the products, and pharmaceutical purpose become patentable.").

[150] *See* Song & Kim, *supra* note 144, at 121-22.

[151] *See id.* at 122 ("As a result of the Korea-US trade negotiations in 1986, the Patent Act was amended to allow patent protection for chemical substances, pharmaceuticals, and agrochemicals. The patent term was also extended from twelve years to fifteen years. The amended Patent Act became effective July 1, 1987.").

foreign investment.[152] Stated another way, Korea started providing patent protection over pharmaceuticals when Korean pharmaceutical companies were still not competitive against non-Korean pharmaceutical companies. Because of this lack of competitiveness in the Korean pharmaceutical industry, the industry started investing in Research and Development on me-too drugs (also known as generic drugs),[153] which have relatively low barriers to entry compared to other pharmaceuticals.[154]

Therefore, the fact that selling generic drugs is a major source of profit for Korean pharmaceutical industries justifies the Korean Supreme Court's willingness to donate inventions–once claimed to be selection inventions–to the public by invalidating or rejecting patentability of the invention, thereby leaving the invention available to all pharmaceutical companies.

iii. Public Interest

The Korean Supreme Court's hostility toward patentees and applicants of selection inventions also confers some public interest by minimizing the social cost of patenting. The likelihood of invalidation or rejection of selection invention patents will encourage other pharmaceutical companies to manufacture generic

[152] *See id.* at 120 ("Realizing that foreigners will not invest in high-tech industries without adequate protection of their technologies, Korea reached a consensus on the positive role of intellectual property rights ("IPR") in economic development.").

[153] *Definition of Me-too drug*, MEDICIENNET.COM (June 14, 2012), http://www.medterms.com/script/main/art.asp?articlekey=33748 (defining me-too drug as "a drug that is structurally very similar to already known drugs, with only minor differences.").

[154] Hwang, *supra* note 144, at 26 (stating that Korean pharmaceutical companies in the 1980s used a strategy of developing generic drugs, which had a relatively low entry barrier, since Korean pharmaceutical companies had not had competitive development capacity of the products).

products of the rejected or invalidated invention.[155] Such hostility toward monopoly will likely lower the drug price to which the invention pertains,[156] and give the public alternative versions of the invention.[157] This public interest will be served the most where pharmaceutical industry, like the Korean pharmaceutical industry, has "strong portfolio of generic products rather than expensive, branded drugs."[158]

iv. Turning Point?

Out of the Korean Supreme Court cases involving selection invention, only one case, *Eli Lilly*, declined to invalidate a patent. [159] There, Hanmi Pharmaceutical Co., Ltd., a Korean company, brought a defensive action against Eli Lilly & Co., seeking to invalidate a patent. The patent at issue had more than one kind of quantitative and qualitative working effects. Therefore, the issue before the Korean Supreme Court was whether all of such working effects must be different than or superior to the prior art in order to possess inventiveness.[160] In reversing and remanding the case to the Korean Intellectual Property Tribunal and Patent Court, the Korean Supreme Court declined to invalidate the patent by holding that inventiveness will be found even when only part of

[155] *See* Beom-Su Shin, *Invalidation of Plavix Enabling Generic Products*, DOCTOR'S NEWS (Jan. 18, 2008, 3:33 PM), http://www.doctorsnews.co.kr/news/articleView.html?idxno=44797 (interviewing one of respondent of the Sanofi Patent, who stated that the company will continue produce generic products of Plavix).

[156] *See* 1 CARL R. MOY, MOY'S WALKER ON PATENTS § 1:32 (4th ed. 2013).

[157] *See id.* at § 1:33.

[158] GBI Research, *South Korea Pharmaceutical Market Outlook 2013*, RESEARCH AND MARKETS (May 2013), http://www.researchandmarkets.com/research/7d5t8r/south_korea.

[159] Supreme Court [S. Ct.], 2010Hu3424, Nov. 5, 2010 (S. Kor.).

[160] *Id.*

those working effects are quantitatively different than or superior to that of the prior art.[161]

It is significant that patentees of selection inventions at issues before the Korean Supreme Court had always been non-Korean pharmaceutical companies. The Korean Supreme Court, for the first time, declined to invalidate a non-Korean company's patent of selection invention. Hence, one may argue that *Eli Lilly* is a turning point of the Korean Supreme Court's trends that have unwaveringly favored its domestic pharmaceutical companies, and possibly signaling more favorable outcomes toward non-Korean pharmaceutical companies. The reasoning supporting this argument is two-fold.

First, *Eli Lilly* lowered the selection invention's patentability standard for the first time. *Eli Lilly* is not the first case dealing with an issue of multiple working effects. The Korean Supreme Court faced the same issue in 2001Hu2740 (*Pfizer*). However, the Korean Supreme Court's holding in *Pfizer* was contrary to that in *Eli Lilly*.[162]

In turn, The Korean Supreme Court had to overrule its holding in *Pfizer*. This is significant because *Eli Lilly* is the first case that actually lowered patentability standards, in favor of a patentee by overruling its prior decision.[163]

Second, *Eli Lilly* seems to recognize this dispute as one between a foreign company and a domestic company, rather than one between a patentee and an alleged infringer. Such a view is

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[161] *See Id.*

[162] *See* Supreme Court [S. Ct.], 2001Hu2740, Apr. 25, 2003 (S. Kor.) (holding that all working effects of claimed selection invention must possess superior working effects over the prior art).

[163] *See* Won-Joon Kim, *The Inventive Step Decision when Partial Components of the Selection Invention have Noticeable Effects*, 17 INFORMEDIA L. 1, 26 (2013).

implicitly indicated by the language of *Eli Lilly*. The Korean Supreme Court, when writing its opinions, always discloses the "main issues" by its own language. The Korean Supreme Court briefly gives readers an idea as to (1) the issues, (2) what will be discussed, and (3) a brief holding of the case. Generally speaking, the "main issues" section functions as a self-characterization of the opinion.

Interestingly, *Eli Lilly* stated, in its "main issues," that the opinion reversed the lower court's holding, which denied inventiveness of patented selection invention, when the dispute was brought by a company against "foreign company." [164] Therefore, the language identifying a patentee as a "foreign company" may indicate that the Korean Supreme Court mitigated the selection invention's patentability standard as a response to its hostile decisions toward foreign non-Korean pharmaceutical companies. The fact that identifying a patentee as a "foreign company," limited to the cases regarding selection invention, has never been used before by the Korean Supreme Court further supports this position.

VI. CONCLUSION

Korean jurisdiction has been extremely strict against patentees of selection invention. Such hostility was especially true when an invention is either (1) structurally similar, or (2) only different in orientation to that of a prior art. Unless *Sanofi* is overturned, U.S. pharmaceutical companies will rarely succeed in seeking patent protection over those inventions and therefore, the evergreening strategy will likely fail as well. Though the *Eli Lilly* case favored a U.S. pharmaceutical company, in the future, one cannot rest easy by relying on only one case. More Korean Supreme Court decisions will help predicting future invalidation trends regarding the patentability of selection inventions.

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[164] *See* 2 Supreme Court [S. Ct.], 2010Hu3424, Nov. 5, 2010 (S. Kor.).