국제학석사학위논문

Analysis on the Drug Approval-Patent Linkage System and Implications on the Multilateral Trading System

의약품 허가-특허 연계제도 분석 및 다자통상제도에의 영향

2017년 2월

서울대학교 국제대학원

국제학과 국제통상전공

윤 한 나

Master's Thesis

Analysis on the Drug Approval-Patent Linkage System and Implications on the Multilateral Trading System

by

Hannah Youn

A Thesis Submitted in Fulfillment of the Requirements
for the degree of Master of International Studies,
International Commerce Major

February 2017

Graduate School of International Studies

Seoul National University

Seoul, Republic of Korea

의약품 허가-특허 연계제도 분석 및 다자통상제도에의 영향

지도교수 안 덕 근

이 논문을 국제학 석사 학위논문으로 제출함

2017년 2월

서울대학교 국제대학원

국제학과 국제통상전공

윤 한 나

윤한나의 석사학위논문을 인준함

2017년 2월

위 원 장 박 태 호 (인)

부 위 원 장 이 영 섭 (인)

위 원 안 덕 근 (인)

THESIS ACCEPTANCE CERTIFICATE

The undersigned, appointed by

The Graduate School of International Studies

Seoul National University

Have examined a thesis entitled

Analysis on the Drug Approval-Patent Linkage System and Implications on the Multilateral Trading System

Presented by **Hannah Youn,** Candidate for the degree of Master in International Studies and hereby certify that it is worthy of acceptance

Committee Chair _____
Bark, Taeho

Committee Vice Chair _____
Rhee, Yeongseop

Committee Member _____
Ahn, Dukgeun

Abstract

Intellectual property rights (IPR) are exclusive property rights given to human over their creations for a certain period of time. IPR protection is designed to provide people with rewards and incentives by limiting competition and granting exclusive rights for their use. However, IPR differ from general property rights in that the objective of protecting intellectual property rights is to protect both private and public rights, whereas general property rights only protect individual rights of property owners. IPR protection is a regulation for distribution of information and knowledge, which may substantially affect economic and technological development. Thus, it is important to balance both private and public rights in protecting and regulating intellectual property rights.

Pharmaceutical industry has been facing this issue of balancing both private and public interests. Pharmaceuticals are commodities that are essential to human survival but they simultaneously require strong protection of patent due to significant investments in research and development and clinical testing. The issue extends to international distribution of pharmaceuticals, which reveals the imbalance of pharmaceutical accessibility in developed and developing countries. The World Trade Organization (WTO) has introduced the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which includes regulations on pharmaceutical patents to balance interests of both developing and developed countries. However, the United States, which traditionally supports strong protection on intellectual property rights, started to implement stronger protection of pharmaceutical patents through bilateral free trade agreements (FTAs).

This paper mainly analyzes the “Drug Patent-Approval Linkage System” (the Linkage system), one of the provisions that aims for stronger pharmaceutical patent protection that United States have insisted to include in their FTA provisions. This paper first analyzes the background and outset of the Linkage system in the United States and its amendment process. Then, it studies development trend of the Linkage System in the US FTA provisions along with the impact of implementing stronger intellectual property rights on bilateral or plurilateral FTA (Canada, Australia, Korea, TPP) partner countries. Finally, it provides implications of US-led

stronger protection of intellectual property on global trading system. The unilateral movement of the U.S. would result in creating two-tier trading blocs, influencing other mega-FTAs, and ultimately, threatening the multilateral trading system.

Keywords: Intellectual Property Rights, WTO, TRIPS, Free Trade Agreements, Pharmaceuticals, Drug-Approval Linkage System

Student Number: 2013-22040

Table of Contents

Chapter I. Introduction ---------- 1

1.1 The Nature of Intellectual Property Rights ---------- 1
1.2 Intellectual Property Rights in Pharmaceutical Industry ---------- 3
1.3 Drug Approval-Patent Linkage System and Issues in International Trade ---------- 7

Chapter II. Development of Intellectual Property Rights Protection on Pharmaceutical Patents in International Trade ---------- 9

2.1 General Agreement on Tariffs and Trade (GATT) 1947 and Other Treaties ---------- 9
2.2 WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement ---------- 12
2.3 Free Trade Agreements (FTAs) ---------- 16

Chapter III. The Drug Approval-Patent Linkage Systems in the U.S. and Major FTA Partners of the U.S. ---------- 25

3.1 The United States (1984) ---------- 25
3.2 Canada (NAFTA, 1994) ---------- 35
3.3 Australia (US-Australia FTA, 2005) ---------- 42
3.4 Korea (KORUS FTA, 2012) ---------- 48

Chapter IV. Mega-FTA Adoption of the Drug Approval-Patent Linkage System ---------- 56

4.1 The Linkage System in the Trans-Pacific Partnership (TPP) ---------- 56
4.2 Key Issues in the Negotiations ---------- 58
4.3 Implications ---------- 59

Chapter V. Implications on the Multilateral Trading System ---------- 61

5.1 Two-Tier International Trade Blocs ---------- 61
5.2 Influence on the Mega-FTAs ---------- 63
5.3 Threats to the Multilateral Trading System ---------- 64

Chapter VI. Conclusion ---------- 66

References ---------- 70

Abstract (Korean) ---------- 74

List of Tables

Table 1. Major Changes of the Hatch-Waxman Act after 2003 Amendment ---------- 33

Table 2. Major Changes of the Canada's Linkage System-related Regulations -------- 39

Table 3. Applications under the Patented Medicines (Notice of Compliance) Regulations ---------- 40

Table 4. Average Time on Hold for Drug Submissions ---------- 41

Table 5. Amendment of Domestic Regulation ---------- 52

Table 6. Key Differences in Linkage System among Four Countries ---------- 54

List of Figures

Figure 1. Monthly Patent Trial Claims ---------- 55

Chapter I. Introduction

1. 1 The Nature of Intellectual Property Rights

Intellectual property rights (IPR) are exclusive property rights given to human over their creations of mind for a certain period of time[1]. IPR protection is designed to provide rewards and incentives for inventions by limiting competition and granting exclusive rights for their use. The first international agreement to help creators ensure their intellectual works was the Paris Convention for the Protection of Industrial Property in 1883, covering patents, trademarks and industrial designs. Since then, there have been increasing needs to protect various types of intellectual properties. The range of intellectual property rights gradually extended to copyright and geographical indications.[2] Due to the exclusive rights of use given to the person who created or invented art, literature and scientific works, intellectual property rights are considered a type of private property rights; however, intellectual property rights differ from general private property rights in that the objectives of protecting intellectual property rights include protection of public interest. Protecting intellectual property right itself is not the mere objective but it is the tool to achieve social and economic development. Ultimately, providing incentives of exclusive rights to creators can increase benefits to society. This

[1] World Trade Organization (WTO).
[2] World Intellectual Property Organization (WIPO).

nature of intellectual property rights is more clearly observed when comparing with the principles of general private property rights, which aims to maximize freedom of people under the limit that doesn't violate public interest. When it comes to intellectual property rights, however, it is exactly the opposite. Knowledge is created or reorganized based on the previous information and knowledge. If new knowledge and information are monopolized by a certain person, they cannot be easily reached to other people and thus, it further hinders possibility of other people to develop new knowledge based on those previous knowledge and information. Due to this nature of information and knowledge, intellectual property rights protection should be minimized but only to the level that still motivates creation and invention.[3]

Today, despite the nature of public property in intellectual property rights, there has been growing importance of private property nature of intellectual property in that industries have evolved from traditional manufacturing to information technology and thus, the value of information has greatly increased. Nevertheless, realizing gain from information became much more difficult due to technology advancement such as computers, internet, and telecommunication, which allowed copying information and reproducing products much easier. Increasing difficulties of reaping from products and information resulting from tremendous investment invoked the movement towards stronger protection of intellectual property[4]. The conventional view among economists,

[3] 김재원. "지적재산권의 법철학적 재검토." 慶南法學 15.- (1999): 261-78. Print.
[4] Ibid.

lawyers, public officials, and many lay persons today is that strong and extensive patent protection will result in economic advancement. The United States particularly supports this view. From GATT to the WTO negotiations, the United States has been pressuring other countries to support the economic value of strong patents. The objective of the U.S. position is to protect national interests, but there also is genuine belief in the justification of the position. Other countries have been following the U.S' position, not simply because of the pressure, but because of an honest belief that in the long run strong patent protection will make positive effect on their economic development.[5]

1.2 Intellectual Property Rights in Pharmaceutical Industry

Pharmaceuticals are commodities that are essential to human survival. They maintain and promote health, thereby achieving collective benefits of society as a whole. Pharmaceuticals have played several roles: increased longevity, enhanced quality of life and improved labor force participation and productivity.[6] Essential drugs are the basic needs for almost every public health program aiming at reducing morbidity and mortality. The pharmaceutical expenditure can account for a high proportion of the total health

[5] Mazzoleni, Roberto, and Richard R Nelson. "The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate." *Research policy* 27.3 (1998): 273-84. Print.

[6] Grabowski, Henry. "Patents, Innovation and Access to New Pharmaceuticals." *Journal of International Economic Law* 5.4 (2002): 849-60. Print.

expenditure of a country.[7] Thus, pharmaceuticals have a nature of public goods and their influence on society in any country is not negligible.

Despite the nature of public goods, pharmaceuticals are undoubtedly private goods since they are commodities created by private persons and are traded in markets as other commodities do in any capitalistic economy. Pharmaceuticals' nature of private goods has strengthened through pharmaceutical patent systems.[8] A patent is a property right and a type of intellectual property given to an inventor by a government for a novel, non-obvious and useful creation. The patent owners has the right to bar others from making, using, offering for sale, or selling their inventions for 20 years from the date of patent application filing.[9] In the pharmaceutical industry, patent is especially important in that the pharmaceutical patent is generally equivalent to the product and thus, a patent is critical in protecting extensive investment in research and clinical testing required before entering the market. Since the manufacturing process is easy to copy with only a small amount of cost compared to that required for the research and clinical testing of original drug.[10] Therefore, the role of patent in pharmaceutical industry is crucial.

Beyond the sovereign state's effort to protect patents, the World Trade Organization (WTO) sets international regulations on pharmaceutical patents. The

---

[7] Pecoul, Bernard, et al. "Access to Essential Drugs in Poor Countries: A Lost Battle?" *Jama* 281.4 (1999): 361-67. Print.

[8] 정연, and 권순만. "지적재산권 강화에 따른 제약시장의 변화와 의약품 가격 및 이용에의 영향 -5개 국가의 사례를 중심으로." *한국사회정책* 21.2 (2014): 183-228. Print.

[9] Lehman, Bruce. "The Pharmaceutical Industry and the Patent System." International Intellectual Property Institute (2003). Print.

[10] Ibid.

Trade Related Intellectual Properties (TRIPS) was introduced when the WTO was established in 1995. The TRIPS is an agreement stipulating broader and stricter regulations on pharmaceutical patents, and all WTO member countries, including developing countries that had not previously protect patents for pharmaceuticals, were required[11] to implement the TRIPS agreement in domestic regulations. Moreover, the WTO TRIPS-plus provisions which provide stricter and broader pharmaceutical patent protection than that of the TRIPS, proliferated through U.S. free trade agreements and mega-FTAs, thereby creating a new US-led intellectual property regulations.

As extensive drug patent protections allow patent holders enjoy monopoly of the product during the duration of the patent, it enables the patent holders to keep prices artificially high[12]. After the duration of patent ends, generic drug manufacturers are allowed to produce similar drugs. A generic drug is equivalent to an original drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. When patents or other periods of exclusivity expire, generic drug manufacturers are not required to conduct costly animal and clinical research on ingredients or dosage forms again when they are already approved for safety and effectiveness.[13]. Thus, generic drugs are typically sold at substantially lower price than that of the branded price,[14] and also the existence of competition results in lowering

[11] See Bruce. While countries that have joined the WTO have obligated themselves to provide TRIPS agreement, least developing countries are not required to meet this obligation until 2016.

[12] Lindstrom, Beatrice. "Scaling Back TRIPS-Plus: An Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific." NYUJ Int'l L. & Pol. 42 (2009): 917. Print.

[13] U.S. Food and Drug Administration (FDA). Web.

[14] Ibid.

the price of pharmaceuticals.

Although generic manufacturers face smaller door to extend their businesses, due to strong patent protection, the United States introduced the Drug Price Competition and Patent Restoration Act of 1984, which is known as the Hatch-Waxman Act, to promote faster market entry of generic drugs while protecting the original drug patent. It provides generic manufacturers with a legal tool to challenge pharmaceutical patent holders before patent expires. The Act allows the generic manufacturer to use the information of patented drug when applying for FDA marketing approval before expiration of the patent terms while extending five years of exclusivity onto its patent term. It also allows the generic manufacture to market their product before expiration of the pioneer's patent term if they decide to challenge the patent to be invalid or not infringed. To balance the rights of patent holders against the rights of generic manufacturers, the Act allows the patent holder to file an infringement suit against the generic manufacturer to that claim and prevent the generic's early market entry.[15]

[15] Mehl, Ashlee B. "Hatch-Waxman Act and Market Exclusivity for Generic Manufacturers: An Entitlement or an Incentive, The." Chi.-Kent L. Rev. 81 (2006): 649. Print.

1.3 The Drug Approval-Patent Linkage System and Issues in International Trade

Drug approval-patent linkage system (the Linkage System, hereafter) is the system of linking marketing approval of drugs to the patent of the originator's product in order to bar FDA from granting of marketing approval to any third party during the patent term unless there is consent of the patent owner.[16] This practice is a part of the Hatch-Waxman Act of 1984 which was thus first enacted in the United States.

The applicants of drug marketing approval, the generic producers, are allowed to bring a lawsuit against the patent holders for the patent validity. Conversely, the patent owner is allowed to bring patent-infringement lawsuit against the applicant of marketing approval and the administrative authority hold the application process for limited time.

The Linkage System is one of the WTO TRIPS-plus provisions and thus, it is not required by WTO member countries. However, the United States have led stronger IPR protection beyond TRIPS Agreements by ensuring the Linkage System be included in all of their free trade agreements and mega-FTAs. Among the U.S. FTAs in effect, all of them include the Linkage System in their IPR section, including developing countries such as Bahrain (2006), Oman (2009) and Jordan (2010), that do not have basic infrastructure or well-developed pharmaceutical industry for such a high IPR protection.

---

[16] 박실비아. "미국과 캐나다의 의약품 허가-특허 연계지도 (정보)." *Journal of Pharmaceutical Investigation* 38.3 (2008): 207-15. Print.

Moreover, the recently concluded mega-FTA, Trans-Pacific Partnership (TPP), concluded in October 5th 2015 by signing of twelve countries, included the Linkage System due to the strong assertion from the United States.

The Linkage System has gradually proliferated by the United States through bilateral FTAs, and it has substantially expanded when the TPP was concluded. This phenomenon poses several issues in international trade regime; first, the U.S. takes the leadership in gradually harmonizing the international trade rules to favor towards stronger IP protection through bilateral and mega-FTAs, but not inside the WTO. This movement impairs the development of the international trade system which has been arduously established to limit unilateral actions or the use of imbalances of bargaining power to unfairly achieve trade goals. Second, the exclusion of the WTO in making changes in the level of IPR protection in significant portion of the international trade regime can weaken roles and power of the WTO as an institution to initiate, enforce and regulate international trade rules. Third, the U.S.' strategy towards stronger IPR protection through bilateral and mega FTA undermines the goals to resolve development concerns of the WTO.

Chapter II. Development of Intellectual Property Rights Protection on Pharmaceutical Patents in International Trade

2.1 General Agreement on Tariff and Trade (GATT) 1947 and Other Treaties

Prior to the Uruguay Round trade negotiations under the GATT system, GATT had dealt with intellectual property only in acknowledging an exception that allows measures that are "necessary to secure compliance[17] with laws or regulations including those relating to the protection of patents, trademarks and copyrights and the prevention of deceptive practices."[18]

Other than that, the basic principles of GATT 1947, "national treatment" and "most-favored-nation" were applied to intellectual property rights in the same manner as other goods would have been applied. The Article 3 of the GATT addresses the "national treatment" or "reciprocity" principles that require each signatory Member to grant those from other Member countries no less favorable treatment than it grants to its

[17] 3.(c) (iii) of Article XII of GATT: Restrictions to Safeguard the Balance of Payments
[18] Chaudhry, Peggy E., and Michael G. Walsh. "Intellectual Property Rights." *The Columbia Journal of World Business* 30.2 (1995): 80-92. Print.

own nationals regarding intellectual property protection.[19] National treatment fosters a "level playing field" for industries such as pharmaceuticals.[20] Another provision, the Article 4 of the GATT, deals with "most-favored-nation". "Most-favored-nation" treatment requires signatory countries to provide the same advantage, favor, privilege, or immunity granted to the nationals of any other country, with a few exceptions, immediately and unconditionally to the nationals of all other Members.[21] This provision allows all signatory countries to avoid tariff and non-tariff barriers on both their imported and exported products including pharmaceuticals in that signatory countries are required to provide each other the most favorable treatment they allow to another trading partner.[22]

There were international treaties with regards to intellectual properties before the creation of the GATT 1947. The Paris Convention for the Protection of Industrial Property (1883) was the first major step taken to support creators to ensure that their intellectual works are protected in other countries.[23] The Paris Convention did cover patents, trademarks, industrial designs, utility models, service marks, trade names, geographical indications and the prevention of unfair competition. The general provisions of the Convention are categorized into three main pillars: national treatment, right of priority and common rules. Later, the Berne Convention for the Protection of

[19] Ibid.
[20] Ibid.
[21] Ibid.
[22] Ibid.
[23] World Intellectual Property Organization (WIPO).

Literary and Artistic Works (1886) dealt with the protection of works and the rights of their authors. Relevant art works included novels, short stories, poems, plays, songs, operas, musicals, sonatas, drawings, paintings, sculptures, and architectural works.[24] In 1893, the two secretariats, institutions for administering the Paris and Berne Conventions, were combined to form WIPO's immediate predecessor, the United International Bureaux for the Protection of Intellectual Property, which was best known by BIRPI. Later in 1970, the Convention, or BIRPI, was transformed to become the World Intellectual Property Organization (WIPO).[25] However, these treaties were traditional regulations for intellectual properties and thus, they needed to be amended in accordance with recent development of intellectual properties.[26] Moreover, the WIPO does not have dispute settlement or enforcement mechanism in the organization which has power to be able to enforce a Member to abide by the regulations if it were to violate a regulation. Thus, countries turned to GATT, seeking to enforce rights in the international arena.[27]

[24] World Intellectual Property Organization (WIPO).
[25] Ibid.
[26] 정재환, and 이봉수. "TRIPS 협정의 성립과정과 진전에 관한 연구." *무역학회지* 38.1 (2013): 47-68. Print.
[27] Chaudhry, Peggy E., and Michael G. Walsh. "Intellectual Property Rights." The Columbia Journal of World Business 30.2 (1995): 80-92. Print.

2.2 WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement

The Uruguay Round of trade negotiations began in December 1986, and negotiation agendas included not only goods and other issues but also an agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The GATT members considered that intellectual property was an important negotiation agenda as intellectual properties are normally traded internationally but they have not been properly protected and are unfairly traded or used as non-tariff barriers.[28] Moreover, previous intellectual property protections through international institutions had several problems that made countries turned to GATT/WTO with regards to intellectual properties; first, previous agreements have not reflected changes and development of recent technologies, and thus, they could not effectively protect intellectual properties. Second, the stark differences in perspectives on intellectual property protection between developed and developing countries have made amendment of traditional intellectual property agreements more difficult since changes required consensus among all the member countries. However, strengthening intellectual property protection within the scope of international trade was not impossible. For example, alleviating import regulation on a product while acknowledging stronger intellectual property protection requirement was a possible

[28] Abbott, Frederick., Thomas Cottier, and Francis Gurry. The International Intellectual property System: Commentary and Materials, Part One (1999). Print.

option in the negotiations. Third, although the Paris Convention included enforcement provisions, it was only limited to allowing member countries to rely on the domestic enforcement regulations.[29] However, the GATT/WTO system would have a dispute settlement body and the ruling of the Panel from a dispute has compulsory power upon the losing party which would indirectly force a country to abide by stronger standards of intellectual property protection.[30] Consequently, countries sought ways to discuss international regulations of intellectual property rights in the GATT/WTO negotiations, instead of the WIPO and other institutions.

To deal with these issues, the Uruguay Round Declaration states that TRIPS Agreement desired "to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade."[31] Moreover, the Article 7 of the TRIPS states that "the objectives of the TRIPS are the protection and enforcement of intellectual property rights which should contribute to i) the promotion of technological innovation and transfer and ii) dissemination of technology, for the mutual advantage of producers and users of technological knowledge, and iii) in a manner conducive to social and economic welfare and to a balance of rights and

[29] Articles 9, 10, 19 of Paris Convention, and Articles5.2, 6.2.3, 10.2.1, 13.3, and 16 of Bern Convention.
[30] 정재환, and 이봉수. "Trips 협정의 성립과정과 진전에 관한 연구." 무역학회지 38.1 (2013): 47-68. Print.
[31] Preamble of TRIPS Agreement. WTO.

obligations."[32] As mentioned in the objectives, the TRIPS Agreement attempts to strike the three-way balance: between the invention/creativity and social and technological benefits, between IPR protection and encouragement of inventors and creativity, and lastly, between private rights and social benefits.[33] Most importantly, the significance of TRIPS Agreement is that it was one of the successful agreements drawn from both developed and developing countries by maintaining minimum balance of their needs.

TRIPS Agreement was not a separate agreement but it is included in the general agreement of the Uruguay Round and the WTO; thus, it automatically applies to all the WTO member countries.[34] It sets forth the scope of the intellectual properties but it does not include all the industrial properties that Paris Convention had dealt with. It is because TRIPS Agreement mainly deals with "trade-related" intellectual properties and that the scope of the intellectual properties was limited to areas whose gap of protection levels among countries may become trade barriers. Accordingly, The Part II of the TRIPS Agreement defines a total of seven types of intellectual properties: copyrights, trademarks, geographical indications, industrial designs, patents, lay-out designs of integrated circuits and undisclosed information.[35]

Standards for patents, including pharmaceutical patents, are stipulated under the Articles from 27 to 34 in Section 5 of Part II of the TRIPS Agreement. In general,

---

[32] Article 7 of TRIPS Agreement. WTO.
[33] TRIPS and Pharmaceutical Patents. Fact Sheet. WTO. September, 2006. Print.
[34] WTO TRIPS 협정 조문별 해설 / 특허청 국제협력담당관실 편. Ed. 한국. 특허청, 국제협력담당관실. [대전] : 특허청, 2004. Print.
[35] Ibid.

under the Article 27.1 of the TRIPS Agreement, it provides flexibility for government to achieve aims for its society. For pharmaceutical patents, these provisions allow governments to declare the use of exceptions to patent holders in order to deal with national emergencies, anti-competitive practices, or when the patent owner does not supply the invention, given that certain conditions are met. The flexibility for pharmaceutical patents was defined and enhanced by the 2001 Doha Declaration on TRIPS and Public Health. The enhancement was taken into effect in 2003 whereby it decided to enable developing members that cannot produce medicines to import pharmaceuticals under compulsory license.[36] The Article 30, "Exceptions to Right Conferred", and the Article 31, "Other Use Without Authorization of the Right Holder", of the TRIPS Agreement provide the basis of these exceptions being able to be made by the government.

The objectives of three-way balance (invention-social benefit, IPR protection-innovation, private rights-social benefit) and exceptions clauses are the two most significant achievement of the TRIPS Agreement in that GATT signatories were not only able to embrace both developing and developed countries' concerns and interests but they have also derived agreement from both sides and eventually made TRIPS Agreement in force with establishment of the WTO in 1994.

[36] TRIPS and Pharmaceutical Patents. Fact Sheet. WTO. September, 2006. Print.

2.3 Free Trade Agreements (FTAs)

The level of IPR protection has become stronger since the signing of the Paris Convention in 1883. The GATT of 1947 has made all signatory countries to follow minimum standards for IPR protection and to provide a level playing field in the domestic market for all the other signatory countries. Moreover, the TRIPS Agreement stated more detailed and stricter standards and regulations for IPR protection with enforcement provisions. However, since the TRIPS Agreement attempts to balance interests of developing and developed countries, developed countries were not satisfied with the level of protection that it provided. Since they have failed to achieve their aims in the TRIPS negotiations, the U.S. and other developed member countries shortly began to negotiate for stronger protection of subject matter, broader and more extensive scope of coverage, increased harmonization, stronger enforcement mechanisms, and limiting of "flexibilities" and "special and differential treatment" provisions that were added in the TRIPS Agreement for developing and least developing members through the means of FTAs.[37] These provisions, of which protections go beyond the TRIPS Agreement, are called the "TRIPS-plus" provisions. According to the paragraph 4 to 10 of the Article XXIV of GATT/WTO Agreement, WTO member countries are allowed to form customs union or free trade area without

[37] Mercurio, Bryan Christopher. "TRIPS-Plus Provisions in Ftas: Recent Trends." *Available at SSRN 947767* (2006). Print.

following the guiding principle of most-favored-nation (MFN) of the WTO when it comes to provide more favorable conditions such as lower tariffs and non-tariff barriers. Advanced countries, particularly the U.S., have utilized this FTA exceptions clause to easily reach agreement on TRIPS-plus provisions with their bilateral trade partners.

TRIPS-plus provisions are in many different forms, from simply repeating TRIPS Agreement to eroding flexibility provisions or requiring additional obligations.[38] There are five TRIPS-Plus provisions with regard to patent that are typically included in the US FTAs: i) patent terms extension, ii) compulsory licensing, iii) test data protection, iv) parallel import and v) approval-patent linkage.[39] First, the patent terms extension provision compensates unreasonably shortened patent terms under the TRIPS Agreement. According to TRIPS Agreement, the patent term is up to twenty years; however, in the case of pharmaceuticals, period for test and approval process usually takes 8-12 years in total. This means that this delayed process results in reduction of period for exclusive monopoly rights of pharmaceutical companies in the market.[40] TRIPS Agreement does not have a provision which states that this period should be compensated by patent term extension for pharmaceutical patent holders. In

---

[38] 이로리. "의약품 특허보호 관련 TRIPS-Plus협정의 법적 쟁점 및 시사점." *안암법학* 38.0 (2012): 419-46. Print.

[39] Hitoshi NASU, “Public law challenges to the regulation of pharmaceutical patents in the US bilateral free trade agreements”, in Pogge, Thomas, Matthew Rimmer, and Kim Rubenstein. *Incentives for Global Public Health: Patent Law and Access to Essential Medicines*. Cambridge University Press, 2010. P.79-83.

[40] 이로리. "의약품 특허보호 관련 TRIPS-Plus협정의 법적 쟁점 및 시사점." 안암법학 38.0 (2012): 419-46. Print.

addition, the WTO dispute, Canada-Patent Protection (DS 114), between Canada and the U.S., the Panel of the WTO Dispute Settlement Body has concluded that the inevitably shortened patent term due to the 8-12 years of period for getting a marketing approval from FDA is not inconsistent with the TRIPS Agreement.[41] To balance interests of pharmaceutical companies and the effects of the time delayed, TRIPS-Plus provision of patent terms extension allows patent term extensions resulted from irrational reduction of patent term due to the delayed market approval process or test of pharmaceuticals.[42]

Second, compulsory licensing provision in the TRIPS Agreement is the flexibility provision that the U.S. tried to weaken through bilateral or regional FTAs. In the Doha Declaration on the TRIPS Agreement and Public Health (2001), WTO Member states have once more reaffirmed that there are needs for flexibility provisions in promoting accessibility and R&D of pharmaceuticals.[43] The Article 4 of this Declaration states that:

> "We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be

---

41 김호철, et al. "논문 : 한미자유무역협정(韓美自由貿易協定) 의약품(醫藥品) 지재권(知財權) 협상결과(協商結果) 관련법적(關聯法的) 쟁점(爭點) 분석(分析) (Access to Medicines and Intellectual Property Rights of the Korea-U.S. Free Trade Agreement)." *서울대학교 법학* 50.2 (2009): 615. Print.

42 이로리. "의약품 특허보호 관련 TRIPS-Plus협정의 법적 쟁점 및 시사점." 안암법학 38.0 (2012): 419-46. Print.

43 Ibid.

interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."

TRIPS-Plus provision in relation with compulsory licensing can be in various forms such as to strengthen data exclusivity to indirectly limit the use of flexibility provision, to directly reduce the "Exceptions"[44] to rights conferred and "Other Use"[45] of patent without authorization of patent holders, and to require larger monetary compensation to patent holders after using compulsory licensing.[46] The U.S. FTAs, such as Jordan-US FTA (2001), Singapore-US FTA(2004) and Australia-US FTA (2005), have agreed to limit compulsory license,[47] and it was almost immediately after the adoption of the Doha Declaration on TRIPS Agreement and Public Health (2001) when the U.S. started to turn their attention to bilateral FTAs in order to achieve what they have failed to achieve in the TRIPS Agreement. Limiting flexibility provisions to only those circumstances listed in the FTA provisions can give significant implications on public health in developing countries since it will directly affect pharmaceutical accessibility of those countries.

Third, the test data protection is a regulation which prevents others from using

---

[44] Article 30 of TRIPS. WTO.
[45] Article 31 of TRIPS. WTO.
[46] 이로리. "의약품 특허보호 관련 TRIPS-Plus협정의 법적 쟁점 및 시사점." 안암법학 38.0 (2012): 419-46. Print.
[47] Hitoshi NASU, "Public law challenges to the regulation of pharmaceutical patents in the US bilateral free trade agreements", in Pogge, Thomas, Matthew Rimmer, and Kim Rubenstein. Incentives for Global Public Health: Patent Law and Access to Essential Medicines. Cambridge University Press, 2010. P.79-83.

the test data for certain period of time that patent holders have submitted to the patent office for granting of patents. This provision consequently results in an effect of a delay of generic companies' market entrance.[48] According to the Article 39.3 of the TRIPS Agreement, WTO member countries shall protect test data that involved considerable effort from unfair commercial use as it states that:

> "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

As written above, the Article 39.3 does not specify duration of test data protection or the definition of what "unfair commercial use" and "new chemical entities". Accordingly, these issues are decided by WTO member countries.[49] However, TRIPS-Plus provisions that are in the U.S. FTAs, states that data exclusivity shall be granted for a product at least 5 years of protection regardless of whether it is granted with patent and the data is pre-disclosed or not. The meaning of protection against "unfair commercial use" and "disclosure" is different from granting exclusivity or monopoly right; however,

---

[48] 朴芝炫. "한미FTA 속의 TRIPS-Plus." *국제법학회논총* 53.2 (2008): 85-108. Print.

[49] 이로리. "의약품 특허보호 관련 TRIPS-Plus협정의 법적 쟁점 및 시사점." 안암법학 38.0 (2012): 419-46. Print.

data exclusivity given to non-patented pharmaceuticals in accordance with U.S. FTAs will be used to maintain walls to prevent generic companies to obtain marketing approval. Since this provision applies to most pharmaceutical products that are not granted patents, the scope of data exclusivity is, thus, broader than that of the TRIPS Agreement.[50]

Fourth, parallel import is closely related to the exhaustion applied to the patent holders. Exhaustion means that when a patented product went on marketing by the patent holder or with the approval of patent holder, the patent holder will exhaust its patent rights, and thus, the buyer of the product has freedom of resale the product[51] and the patent holder does not have exclusive rights of the product anymore. Whether it is national exhaustion or international exhaustion, it may create complex problems. If it is national exhaustion, the exhaustion principle only applies domestically, thus making international sales not apply to exhaustion. This means that patent holders still owns the exclusive rights of products sold in foreign countries. Conversely, if it is international exhaustion, it means that exhaustion principle applies to the sales made internationally, which makes patent holders no longer have exclusive rights on products sold in foreign countries.

The Article 28 of the TRIPS Agreement states that “a patent shall confer on its owner the exclusive rights where the subject matter of a patent is a product, to prevent third parties not having the owner’s consent from the acts of making, using, offering for

---

[50] 朴芝炫. "한미FTA 속의 TRIPs-Plus." 국제법학회논총 53.2 (2008): 85-108. Print.

[51] 이로리. "의약품 특허보호 관련 TRIPS-Plus협정의 법적 쟁점 및 시사점." 안암법학 38.0 (2012): 419-46. Print.

sale, selling, or importing for these purposes of that product". The footnote, however, states that "this right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6 of the TRIPS Agreement," which is the "Exhaustion" provision stating that "for the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." Due to this provision, WTO Member countries are free to choose and decide the issue of exhaustion, but the decisions are subject to "national treatment" and "most-favored nation".[52] Therefore, parallel import is not in violation of the TRIPS agreement and there is no regulation on parallel imports. However, in the U.S. FTAs with Australia and Morocco, for instance, the U.S. has banned parallel import while limiting the scope to the only cases that the importer and the exporter have written in the contract to do so. Nevertheless, it effectively prevents the parallel imports and allows different price policy of the same product sold in different nations.[53]

Last but not least, the patent-approval linkage system (the linkage system), as previously explained in the 1.3 of Chapter 1, is the practice of requiring linkage between drug approval (or registration) and protection of patents. The TRIPS Agreement does not

[52] WTO TRIPS 협정 조문별 해설 / 특허청 국제협력담당관실 편. Ed. 한국. 특허청, 국제협력담당관실. [대전] : 특허청, 2004. Print.

[53] 이로리. "의약품 특허보호 관련 TRIPS-Plus협정의 법적 쟁점 및 시사점." 안암법학 38.0 (2012): 419-46. Print.

include patent-approval linkage system, but it mainly appears in the U.S. FTAs. The provision requires the Administration of Food and Drug of a country to reject any generic drug's marketing approval if the drug is patented. Additionally, the Administration is obligated to notify the patent owner that the drug was attempted for marketing approval. The linkage system in U.S. FTAs is criticized for not recognizing the fact that patent is a private-right as TRIPS Agreement states in the Preamble. Due to the linkage provision, the obligation to prevent any patent infringement was handed over to governments and thus, the state is responsible for incorrect decisions on nullifying validity of a patent or no existence of patent infringement. When the Administration of Food and Drug does not have ability to judge patent insistence or invalidity, the linkage system can become significant barriers for legitimate generic companies' market entrance.[54]

These five U.S. FTA provisions (or TRIPS-Plus provisions) show stronger protection of intellectual property rights on drugs than that of the TRIPS Agreement. Within the multilateral trade regime, development of intellectual property protection through Paris Convention, GATT 1947 and WTO TRIPS Agreement was aiming for the balance between the patent holder and user, social and economic welfare and innovation. However, because U.S. FTA provisions draw more emphasis on the patent holders' private rights, they could not be accepted in multilateral trade negotiations but only in the bilateral trade negotiations of the U.S. which makes bargaining in the negotiation much simpler. The linkage system is particularly more challenged since it involves stark

[54] Ibid.

differences of interests between developed and developing countries. It involves substantially important issues such as generic companies in developing countries, drug accessibility, increasing price of drugs and eventually human rights of people in developing countries.

In Chapter 3 and 4, this paper looks into major U.S. FTAs in order to analyze the beginning and development of the linkage system as coming into recent years and issues it brought about both in the U.S. and FTA partners of the U.S.

Chapter III. The Drug Approval-Patent Linkage Systems in the U.S. and Major FTA Partners

3.1 The United States (1984)

The Drug Approval-Patent Linkage System (the "Linkage System") first introduced in 1984 in the United States as a part of the Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"). This Act was introduced to balance two directly conflicting policy goals: to encourage branded pharmaceutical firms to actively invest in R&D while granting generic manufacturers to market generic drugs in order to lower the price.[55] Before introduction of the Hatch-Waxman Act in 1984, the Food and Drug Administration (FDA) required generic manufacturers to satisfy equivalent safety and efficacy requirements as that of the new drugs under the Food, Drug, and Cosmetic Act ("FDCA").[56] Moreover, generic manufacturers were not allowed to use safety and efficacy information of patent holder's data, and were required to conduct their own clinical test.[57] The tremendous expense hindered the development

[55] Matthew, Avery. "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments." *Hastings Law Journal* 60 (2008): 171-1535. Print.

[56] Soehnge, Holly. "The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance between the Interests of Pioneer and Generic Drug Manufacturers." *Food and Drug Law Journal* 58.1 (2003): 51-80. Print.

[57] Matthew, Avery. "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments." Hastings Law Journal 60 (2008): 171-1535. Print.

of many generic drug manufacturers to market their products. Furthermore, conducting clinical tests for FDA approval during the pioneer's patent term had a general notion that it is an act of infringement of a patent. Generic manufacturers had to wait until the patent term expires in order to begin the manufacturing and marketing approval processes for their generic drugs. While generic manufacturers spend time for testing and FTD review, pioneers are granted a de facto extension of their patent terms.[58]

The Congress acknowledged that generic equivalents of these off-patented drugs would save significant pharmaceutical costs for American citizens.[59] In 1984, the Congress successfully passed modern generic pharmaceutical industry by introducing the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act). Hatch-Waxman Act newly provided an Abbreviated New Drug Application (ANDA) for generic drugs. An ANDA applicant is only required to prove that its generic drug has equal active ingredient, the same basic pharmacokinetics, and is bioequivalent to the brand-name drug. A generic applicant is now no longer obliged to provide independent data of safety and efficacy information of the drug, and can instead rely on the pioneer's clinical trial data. By simplifying processes of ensuring quality of generic drugs, the Hatch-Waxman Act have eliminated duplicated costs and enhanced consumer access to affordable drugs.[60] Moreover, the Hatch-Waxman Act also added an exception

---

[58] Mary Atkinson, *PatentP rotectionf or Pharmaceuticals:A Comparative Study of the Law in the United States and Canada,* II PAC. RIM L. & POL'Y J. I8I, 184 (2002).

[59] Matthew, Avery. "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments." Hastings Law Journal 60 (2008): 171-1535. Print.

[60] Ibid.

of experimental use of the drug for patent infringement criteria, given that generic manufacturers may obtain a patented drug product during its patent life and allowed to conduct tests using that product if the purpose of those tests is to submit an application to FDA for approval.[61]

As an application process, all ANDA applicants are required to make one of the following certifications from I to IV for each drug patent that they attempt to market:

I. The drug is not patented or that patent information has not been filed;
II. The patent has expired;
III. The date when the patent expires, and that the generic drug will not go on the market until that date passes; or
IV. The patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the application is submitted.[62]"

The Drug Approval-Patent Linkage System is implemented in this process of applying for paragraph IV certification. The Hatch-Waxman Act stipulates that making a Paragraph IV certification is considered a patent infringement. Thus, the provision requires all Paragraph IV ANDA applicants to notify the patent holder of the application, which includes a detailed factual and legal analysis on the reason why either the patent is invalid or not infringed. This notification is then linked to two special features of paragraph IV certification: the thirty-month stay of ANDA approval, and the 180-day

[61] Ibid.
[62] 21 U.S.C. § 355(J)(2)(A)(vii)(I)-(IV).

marketing exclusivity period.[63] After receiving the notification from a generic manufacturer, the NDA holder has 45-days to file an infringement lawsuit against the ANDA Paragraph IV applicant. If suit is not filed within that time, the ANDA can be approved immediately. However, if suit is filed during that period, the FDA is not allowed to approve the ANDA for 30-months. During this thirty month stay, the FDA can only "tentatively approve" the ANDA, given that it can take effect upon the expiration of the 30-month stay.[64] The purpose of the thirty-month stay is to protect NDA holders with their respective rights for holding a valid patent by allowing them to sue the ANDA Paragraph IV applicant for infringement before the generic manufacturer enters the market.[65]

While the linkage system requires ANDA Paragraph IV applicants to notify NDA patent holders of the fact that they are applying for Paragraph IV ANDA application, the first ANDA applicant is instead granted with 180-day marketing exclusivity as a tool to promote generic industry. The Hatch-Waxman Act states that the first applicant who filed a Paragraph IV ANDA Certification first will be given 180 days of market exclusivity upon entering the market with their generics,[66] if, the ADNA applicant carries out successful defense in patent infringement suit filed by the NDA holder.[67] The FDA will not approve the second or later ANDA applications for the same

---

[63] 21 U.S.C. § 355(J)(5)(A)-(B).
[64] *§*355 (J)(5)(B)(iv)(II)(dd).
[65] Matthew, Avery. "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments." Hastings Law Journal 60 (2008): 171-1535. Print.
[66] 21 U.S.C. § 355(J)(5)(A)-(B).
[67] *See* Mova Pharm. Corp. v. Shalala, 14o F.3d io6o, 1074 (D.C. Cir. 1998)

drug for 180 days after the first Paragraph IV ANDA applicant begins commercially marketing its generic drug.[68] The objective of the exclusivity period is to motivate Paragraph IV patent challenges by granting the first challenger the 6-month marketing exclusivity in return for risking the costs of patent litigation.[69]

The intention of the Congress by introducing the Hatch-Waxman Act was to balance two industries, new drug developers and generic manufacturers; however, soon the Act was proven to have loopholes in the provisions pertaining to the 30-month stay and 180-day market exclusivity as those provisions were susceptible to abusive actions by pioneers.[70] For pioneers, the onset of generic competition can result in huge financial loss. In order to delay this competition, they sought for ways to exploit the Hatch-Waxman Act. The two special features of the Paragraph IV ANDA Certification, the thirty-month stay and the 180-day marketing exclusivity for the ANDA applicant were both abused by the pioneers as described below.

1. The Thirty-Month Stay

As discussed above, when the patent holder file a suit against the Paragraph IV ANDA applicant within 45 days from application, the FDA is prevented from giving approval of the ANDA for thirty months, or until a court rules that the patent is not infringed or invalid.[71] However, this thirty-month stay may provide the patent holder

[68] Matthew, Avery. "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments." Hastings Law Journal 60 (2008): 171-1535. Print.
[69] Ibid.
[70] Ibid.
[71] 21 U.S.C. § 355(J)(5)(B)(iii) (2006).

with several ways to effectively extend the market exclusivity period beyond their normal patent term.[72] First, patent holders may obtain multiple thirty-month stays by using so-called "sham" patents, which claim features peripherally related to the patented drugs, such as metabolites, intermediates, and packaging features.[73] To do that, patent holders need to acquire "sham" patents and submit them to the FDA's Orange Book.[74] The Orange Book is the list of patents of drugs that ANDA applicants must rely on to refer what patents cover the pioneer's drug. Thus, after successfully listing "sham" patents in the Orange Book, the NDA holder could claim that the marketing of a generic equivalent would be infringement of their the newly listed patent.[75] Second, the patent holder could obtain multiple thirty-month stays by submitting new sham patents overtime. This could delay generic market entrance for a few years.[76] Third, the challenger must change its certification from a Paragraph IV to a Paragraph II if the initial patent expires before the first generic challenger receives final ANDA approval. The generic applicant will no longer be given the 180-day exclusivity upon ANDA

---

[72] Lara J. Glasgow, *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?, 41* IDEA 227, 233 (200l).

[73] Matthew, Avery. "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments." Hastings Law Journal 60 (2008): 171-1535. Print.

[74] The *"Orange Book"* is the common name for the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations,* which is published monthly. OFFICE OF GENERIC DRUGS, FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (2008).

[75] Brian Porter, Comment, *Stopping the Practice of Authorized Generics: Mylan's Effort to Close the Gaping Black Hole in the Hatch-Waxman Act,* 22 J. CoNTEMP. HEALTH L. & POL'Y 177, s81 (2005).

[76] Holly Soehnge, *The Drug Price Competition and Patent Term Restoration Act of 1984: Fine- Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers,* 58 FOOD & DRUG L.J. 51,52 (2003).

approval.[77]

2. 180-day marketing exclusivity

As explained above, the first ANDA Paragraph IV applicant who successfully carried out defense against patent infringement litigation against patent holder will be given 180-days of marketing exclusivity. However, patent holders have been able to manipulate the beginning of this exclusivity period which results in generic market entrance delay indefinitely. In the litigation relate to a ANDA Paragraph IV application, the parties can agree on a settlement whereby the first applicant agrees to delay its generic's market entry until a later date (often till right before the patent expiration date). In this case, because the first applicant never entered the market, the 180-day exclusivity period does not start and market entry of that generic is barred since the FDA can only approve the first filer of the ANDAs.[78] These settlements are often so-called "reverse payments," which are cash payments by the patent holder to the Paragraph IV ANDA applicant. Such payments allow patent holders to circumvent competition while they share some of their monopoly profits with generic challengers.[79]

Another way that NDA/patent holders have been impeding generic competition was that the patent holder can give permission to another generic producer to produce

[77] 21 U.S.C. § 355(J)(2)(A)(vii)(I)-(IV).
[78] Holly Soehnge, The Drug Price Competition and Patent Term Restoration Act of 1984: Fine- Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers, 58 FOOD & DRUG L.J. 51,52 (2003).
[79] Matthew, Avery. "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments." Hastings Law Journal 60 (2008): 171-1535. Print.

"authorized generics."[80] An authorized generic drug is produced by the NDA holder, but it is distributed by the third party that packages the drug with its own label and FDA identification number. The authorized generic drug is, thus, the same drug with the patent holder's pharmaceutical, but it is sold at a cheaper price. Because the 180-day exclusivity period only prevents ANDA applicants, the authorized generic producers may sell its original drug during exclusive period. Therefore, as soon as an ANDA applicant wins the case, it soon faces competition from the authorized generic producers, which not only nullifies the benefit of the 180-day exclusivity period but also severely harm ANDA applicant's should-be-protected profits.[81]

Since patent holders have been able to abuse two special provisions under the Hatch-Waxman Act, the linkage system, which is implemented in the Paragraph IV ANDA application, is partially utilized, only to the benefit of patent holder and not to the generic manufacturers. In response to these abusive actions from patent owners and related antitrust litigations spawned by the loopholes described above, the Congress amended the FDCA[82] by introducing the Medicare Prescription Drug, Improvement, and Modernization Act (Medicare Modernization Act or "MMA").[83] A number of provisions were adopted in order to revise Hatch-Waxman Act (2003) (Table 1).

---

[80] The FDA has defined "authorized generic" as "any marketing by an NDA holder or authorized by an NDA holder, including through a third-party distributor, of the drug product approved under the NDA in a manner equivalent to the marketing practices of holders of an approved ANDA for that drug."

[81] Matthew, Avery. "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments." Hastings Law Journal 60 (2008): 171-1535. Print.

[82] Food, Drug, and Cosmetic Act (FDCA)

[83] 이로리. "의약품 특허보호 관련 TRIPS-Plus협정의 법적 쟁점 및 시사점." 안암법학 38.0 (2012): 419-46. Print.

Table 1 – Major Changes of the Hatch-Waxman Act after 2003 Amendment[84]

Classification	Details
Eligibility Requirements for Patent Listing	Clarify types of patents that can be listed - Drug substances(active ingredient) patent - Drug product (formulation/ composition) patent - Method of use patent
Protection of generic manufacturers with regards to patent suit	Patent holders cannot obtain more than one thirty-month stay of approval of the ANDA Required to verify only to the patents registered before the ANDA application When there is no lawsuit within 45-days, ANDA applicant can apply for non-infringement lawsuit. ANDA applicant can request for amendment or remove the patent from the Orange Book
Forfeiture of 180-day exclusivity	A settlement triggers 180-day exclusivity period, and forfeit its rights to exclusivity[85]
Prevention of antitrust action	Patent owner and ANDA applicant both need to report all settlements made between both parties.

The assessment of the 2003 amendment of the Hatch-Waxman Act is rather mixed. Some amendments were very successful in closing some loopholes, but they still have not addressed minor issues or others were simply ineffective. Limiting the multiple 30-month stay was the most effective amendment since it effectively prevented patent holders from intentionally delaying generic manufacturers to enter the market.[86] Nevertheless, minor problems were not addressed. The arbitrary decision of 'thirty-month' was one of them, since the initially suggested duration of the stay was eighteen-

[84] 박실비아. "미국과 캐나다의 의약품 허가-특허 연계지도 (정보)." Journal of Pharmaceutical Investigation 38.3 (2008): 207-15. Print.

[85] Matthew, Avery. "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments." Hastings Law Journal 60 (2008): 171-1535. Print.

[86] Ibid.

months. However, it was increased to thirty months due to the pharmaceutical industry's lobbying effort.[87] Another unaddressed issue was the case when the patent holder's patent expires before FDA approval of the first filer's Paragraph IV ANDA. If a generic manufacturer could not get the approval from FDA by the time the patent expires, the ANDA applicant was forced to amend its ANDA from a Paragraph IV to a Paragraph II certification, resulting in forfeiture of its 180-day exclusivity.[88]

Moreover, the reverse payment settlements were one of the major issues as it bars generic manufacturer's 180-day exclusivity to begin, which, consequently, prevent other generic manufacturers from entering the market. This has allowed the patent holders to enjoy its monopoly profits until the patent expires. The Amendment in 2003 did not completely prevent reverse payments from patent holders. Instead, the MMA only required drug companies to report a several types of settlement agreements to both the FTC and the Department of Justice,[89] on the basis of the Congress' assumption that this would effectively stop pay-for-delay settlements. This issue has shown different decisions among the federal circuit courts of appeals on whether such payments are antitrust violations.[90] It seems that to decide a reverse payment is legal, it requires to

---

87 Gerald J. Mossinghoff, Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process, 54 FOOD & DRUG L.J. 187, 190 (1999).

88 U.S.C. § 355(J)(5)(D)(i)(III) (2006).

89 Medicare Modernization Act, Pub. L. No. lO8-173, 117 Stat. 2o66, § 1112 (effective Dec. 8, 2003) (codified at 21 U.S.C. § 355 nt. (2006)).

90 See BUREAU OF COMPETITION, FED. TRADE COMM'N, AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003: SUMMARY OF AGREEMENTS FILED IN FY 2007 at 2 (2008) (finding that 42% of settlement agreements between pioneers and generic manufacturers during fiscal year 2007 included some form of reverse payment).

have terms that stay within the scope of the patent, whereby the reverse payment settlement must not extend the patent holder's monopoly beyond the normal patent term.[91] In addition, in relation with the issue of 180-day exclusivity that does not start due to reverse payment settlements, the revised Hatch-Waxman Act stipulates that if the first applicant does not enter the market within 75 days after the date that generics of the first applicant's market approval was made effective, the exclusivity right is forfeited.[92] The forfeiture event would also trigger 180-day exclusivity thereby inducing generic manufacturers to enter the reverse payment settlement. The assessment of this amendment is also mixed, since it did not completely bar reverse payment settlement, and did not completely resolve the extension of patent holder's monopoly.

3.2 Canada (NAFTA, 1994)

The linkage system in Canada first adopted in 1993 as one of the requirements for the North American Free Trade Agreement (NAFTA). The linkage system was

[91] Yana Pechersky, Note, To Achieve Closure of the Hatch- Waxman Act's Loopholes, Legislative Action Is Unnecessary: Generic Manufacturers Are Able to Hold Their Own, 25 CARDozo ARTS & ENT. L.J. 775, 796 (2007).

[92] Matthew, Avery. "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments." Hastings Law Journal 60 (2008): 171-1535. Print.

formulated by Industry Canada under the Patent Act, and it is included in the Patented Medicines (Notice of Compliance) Regulations. The Office of Patented Medicines and Liaison (OPML), located in the Therapeutic Products Directorate of the Health Products and Foods Branch in Health Canada administers it.[93] Notwithstanding the flexibility provisions of the TRIPS Agreement that provides basis for the exceptions that can used by the government, such as Article 30, "Exceptions to Right Conferred", and the Article 31, "Other Use Without Authorization of the Right Holder", the NAFTA Article 1709.10 extends its subject matter of the linkage system to the government use of the pharmaceuticals as shown below:

> Where the law of a Party allows for use of the subject matter of a patent, other than that use allowed under paragraph 6, without the authorization of the right holder, including use by the government or other persons authorized by the government, the Party shall respect the following provisions:
> (a) authorization of such use shall be considered on its individual merits;
> (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time. The requirement to make such efforts may be waived by a Party in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national

[93] Faunce, Thomas A, and Joel Lexchin. "'Linkage'pharmaceutical Evergreening in Canada and Australia." Australia and New Zealand health policy 4.1 (2007): 1. Print.

> emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

The domestic procedure to register marketing approval of a generic drug is very similar to that of the United States. A generic manufacturer needs to choose one of these three categories for certification: i) The patent has expired; or ii) The patent is invalid; or iii) No patents are being infringed ("Notice of Allegation"). The third option, "No patents are being infringed" is equivalent to the Paragraph IV certification of ANDA applicant in the Hatch-Waxman which challenges the pioneer's patent and attempts to obtain marketing approval. When there is the third option application, the patent holder has 45-days to file an infringement suit in the Federal Court of Canada. Then the Notice of Compliance prohibits generic drug approval for 24-months, or until the date the resolution of the lawsuit.[94]

The linkage 'evergreening'[95] strategy was also shown in Canada by brand name pharmaceutical companies. The Office of Patented Medicines and Liaison at the Therapeutic Products Directorate of Health Canada suggests that 44% of the 419

[94] Ibid.
[95] The linkage 'evergreening' refers to the strategy of multinational pharmaceutical companies which prolong rent-profits over 'blockbuster' (high total revenue) drugs, using the loopholes of the linkage system in the Hatch-Waxman Act in the U.S.

medicines on the Patent Register are covered by more than one patent.[96] In addition, the Canada's Research-Based Pharmaceutical Companies (Rx&D), a group of multinational brand name industry, suggests that 95% of all successive patents are issued within 10 years from the date of initial patent approval, and thus, all of the patents may be addressed in the same linkage proceeding. If the patent term is only 10 years, the new patents will be filed as old one expires.[97] Between 1998 and 2004, 138 cases have gone to court, and among those cases only 12% have taken more than 24 months to make a decision of the suit.[98] Even in this case, generic manufacturers fail to market the older version of the product in that the main reason for brand name companies to launch a new version of a drug is to make doctors to prescribe the new version of the drug instead of the older version by sending tremendous advertising costs.[99]

In October 2006, the Canadian federal government has found that some brand-name multinational drug companies had been abusing the NOC Regulations. Since Canadian linkage system did not go through sufficient advisory process, the federal government has gone through several amendment processes in order to correct abusive actions of brand-name multinationals. This amendment was influenced by the

---

[96] Office of Patented Medicines and Liaison: Therapeutic Products Directorate statistical report 2004: patented medicines (notice of compliance) regulations. Health Canada 2005.

[97] Faunce, Thomas A, and Joel Lexchin. "'Linkage'pharmaceutical Evergreening in Canada and Australia." Australia and New Zealand health policy 4.1 (2007): 1. Print.

[98] Office of Patented Medicines and Liaison: Therapeutic Products Directorate statistical report 2004: patented medicines (notice of compliance) regulations. Health Canada 2005.

[99] Faunce, Thomas A, and Joel Lexchin. "'Linkage'pharmaceutical Evergreening in Canada and Australia." Australia and New Zealand health policy 4.1 (2007): 1. Print.

amendment of the Hatch-Waxman Act in 2003, and the major revisions are as follows:[100]

Table 2 – Major Changes of the Canada's Linkage System-related Regulations[101]

Classification	Details
Eligibility Requirements for Patent Listing	New drug submission (NDS): the medicinal ingredient, or the use of the medicinal ingredient, and the medicinal ingredient, formulation, dosage form, or use. Supplemental new drug submissions (SNDS): for a change in the formulation, dosage form or use of the medicinal ingredient, the patent contains a claim for the changed formulation, dosage form, or use.
No Requirement to Address Later-listed Patents	Generic manufacturers only required to address patents registered before the marketing approval application No notice of allegation (NOA) may be served until the generic manufacturer files its submission
Requirement to Address Patent	Generic manufactures are only required to address patents if the product uses clinical data and information.[102]
Extension of Application Categories	"Patent holder falsely included the patent that is not qualified to be in the Notice of Compliance patent list" "Generic manufacturer is not registering approval of the claimed purposes of the drug by the patent holder"

Due to continuous effort to expedite legal processes and revision of the linkage system and its patent listing process in 2006, the amendment effectively barred patent holders to obtain multiple patents and 24-month holds. In 2005, out of 164 patent submission, 101 patent challenges (Notice of Allegation) were received. Out of

[100] 박실비아. "미국과 캐나다의 의약품 허가-특허 연계지도 (정보)." Journal of Pharmaceutical Investigation 38.3 (2008): 207-15. Print.

[101] Fetherstonhaugh."Proposed Amendments to Linkage Regulations and Data Protection Published." *Canadian Pharmaceutical Intellectual Property Law Newsletter* (2006). Print.

[102] 박실비아. "미국과 캐나다의 의약품 허가-특허 연계지도 (정보)." Journal of Pharmaceutical Investigation 38.3 (2008): 207-15. Print.

101 Notice of Allegation, 51(50%) of them resulted in court application, and 8 cases of them were granted with prohibition whereas 14 cases were dismissed. However, in 2006 after the amendment, the rate of court application is 68% but the winning rate of generic manufacturer grows to 57%. Rate of court application varies between 2005 and 2010, from 37% to 51%, and winning rate of generic manufacturers is generally higher than that of the patent holders. When the court applications commence, 24-month hold automatically begins, and if there is a court decision before the 24-month ends, the marketing of the generic product is allowed. This linkage process clearly affects in delaying generic product to be marketed.[103]

Table 3 – Applications under the Patented Medicines (Notice of Compliance Regulations)[104]

		2005	2006	2007	2008	2009	2010
Submissions received		164	153	157	248	270	301
Notice of Allegation Received		101	88	104	172	141	165
Court Applications Commenced		51	60	53	73	65	61
Rate of Court Application		50%	68%	51%	42%	46%	37%
Result of Court Application	**Prohibition Granted**	8	6	7	9	2	1
	Prohibition Dismissed	14	14	9	14	2	0

From 1993 when the linkage system first started and to 2007, the average time on told of generic market entrance ranges from 1.7 to 29.8 months. During the early

[103] Ibid.
[104] Fetherstonhaugh."Proposed Amendments to Linkage Regulations and Data Protection Published." Canadian Pharmaceutical Intellectual Property Law Newsletter (2011). Print.

stage, the ranges reach up to 29.8 months, but after the amendment in 2006 and rigorous effort to expedite the legal process, the average time in 2010 had been reduced to 2.2 months.

Table 4 – Average Time on Hold for Drug Submissions[105]

Year	Submissions which are still on hold	Average number of months before NOC Issued
2010	60	2.2
2009	60	7.6
2008	50	17.9
2007	34	2.3
2006	40	1.7
2005	32	3.7
2004	19	4.9
2003	6	9.1
2002	5	7.3
2001	4	12.9
2000	1	8.3
1999	2	5.4
1998	1	14.6
1997	1	29.8
1996	0	20
1995	1	24
1994	1	21
1993	1	6

[105] Ibid.

3.3 Australia

Pharmaceutical 'evergreening' was quite new in Australia prior to the negotiations of Australia-US FTA (AUSFTA). In 2004, when the negotiation had reached the end, it become certain that one of AUSFTA provisions, when adopted into Australian domestic legislation, might cause the pharmaceutical patent extension which has become known as 'linkage evergreening'.[106] Australia's main concerns with regards to linkage system were with the price of medicines and how the linkage evergreening would likely affect its health policy which grants Australian government discretion on drug price. The health policy, the Pharmaceutical Benefits Scheme (PBS), is a tool for achieving one of the central goals of the National Medicines Policy: timely access to the medicines that Australians need, at a cost individuals and the community can afford.[107] The Minister certifies selected medicines to be listed on the PBS which guarantees most cost-effective price with the recommendations of an expert committee. For the selected medicines listed on the PBS, patients are not responsible for the full cost of medicines. Instead, patients are required to make a co-payment with the government. Patients are benefited by the government's capacity to negotiate better deals with large pharmaceutical companies.[108] Because the drug price is closely linked

[106] Faunce, Thomas A, and Joel Lexchin. "'Linkage'pharmaceutical Evergreening in Canada and Australia." Australia and New Zealand health policy 4.1 (2007): 1. Print.

[107] Drahos, Peter, et al. "Pharmaceuticals, Intellectual Property and Free Trade: The Case of the Us–Australia Free Trade Agreement." Prometheus 22.3 (2004): 243-57. Print.

[108] Ibid.

to the PBS, the debate among the Australian public and the government centered on how the PBS will be affected by the result of the AUSFTA negotiations. Among the various elements, the intellectual property aspect of AUSFTA provisions was considered one of the areas that would lead to increased PBS costs. The concern was specifically with the linkage provision in the Article 17.10 of the AUSFTA that they would delay the entry of generic drugs. The Article 17.10.4 of the AUSFTA provides that Australia's Therapeutic Goods Administration (TGA) is required to create a process whereby the patent holder would be notified of an intended generic product's marketing approval and to apply marketing approval based on the safety and efficacy data be prohibited wherever a competing product was claimed,[109] as it states as follows:

> Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety or efficacy information, to rely on evidence or information concerning the safety or efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory:
> (a) that Party shall provide measures in its marketing approval process to prevent those other persons from:
> (i) marketing a product, where that product is claimed in a patent; or

[109] Faunce, Thomas A, and Joel Lexchin. "'Linkage'pharmaceutical Evergreening in Canada and Australia." Australia and New Zealand health policy 4.1 (2007): 1. Print.

(ii) *marketing a product for an approved use, where that approved use is claimed in a patent*, during the term of that patent, unless by consent or acquiescence of the patent owner; and

(b) if the Party permits a third person to request marketing approval to enter the market with:

(i) a product during the term of a patent identified as claiming the product; or

(ii) a product for an approved use, during the term of a patent identified as claiming that approved use, the Party shall provide for the patent owner to be notified of such request and the identity of any such other person.

This provision had made two changes in the procedure of generic's 'springboarding' system. Springboarding is a process that lets a generic drug manufacturer to use the safety and efficacy test data of patented pharmaceuticals when trying to obtain approval from the Therapeutic Goods Administration (TGA). This prevents the generic drug manufacturer from causing duplicated cost and time in order to go through all the process of drug's safety and efficacy testing. This process had significantly reduced time for generics to enter the market.[110]

Before the entry into force of AUSFTA, generics may not springboard during the first five years after the original drug obtained marketing approval. After the five years, the TGA is not concerned with intellectual property issues anymore; it allows

[110] Trade, Australia–US Free, and Pharmaceutical Benefits Scheme. "The Pbs and the Australia–Us Free Trade Agreement." (2004). Print.

generic drugs to apply for marketing approval even when an original patent is still active. When generic manufacturers obtain marketing approval, it is up to generic manufacturers to decide whether or not to enter the market during the patent term. In most cases, generic manufacturers prepare their production and distribution channels during the patent terms, and enter the market as soon as the patent term expires. In other cases, however, generic manufacturers may release their product by disputing the validity of the patent or arguing that their product did not infringe. It is then up to the patent holders whether they sue the generic manufacturers for their patent infringement.[111]

The Article 17.10.4 of the AUSFTA has made changes to the existing springboarding system in Australia that it requires an introduction of certification scheme when applying for marketing approval of generic drugs during the patent life time. Under this process, generic manufacturers are given three choices when they are applying to springboard: i) certify that they will not infringe, ii) apply for a court declaration to settle the uncertainty before certifying, or iii) notify the patent holder of the application and certify to that effect. If generic manufacturer choose to go for the first option, they are responsible for a fine when it is later found to be misleading. The second and the last option incur litigation before rather than after the generics enter the market. Before the entry into force of the AUSFTA, generic manufacturers had options before any litigation takes place since they could enter the market first.[112] Moreover,

[111] Ibid.
[112] Ibid.

the last option is identical to the linkage system which was clearly derived from the Hatch-Waxman Act in the U.S. in 1984 and the Canadian Notice of Compliance Regulation implemented by the introduction of NAFTA in 1993. Since this provision linked the marketing approval regulatory process for generic drug with their patent infringement status, the Therapeutic Goods Act 1989 needed to be amended to incorporate linkage provision from AUSFTA to the domestic regulation. The linkage provision was inserted as a new provision, section 26B. It required marketing approval applicants to declare that the generic would not infringe a valid patent claim, or the patent holder has been notified of the application. [113]

On the other hand, as mentioned above, in Australia there were vigorous public debates over the issue of incorporating linkage system in the domestic regulation. Thus, two more provisions were added along with the linkage system as Section 26C and Section 26D which contain 'anti-evergreening' elements. Section 26C provides that the patent holder must declare that "the proceedings are being commenced in good faith, have reasonable prospects of success and will be conducted without unreasonable delay." If the certificate is found to be erring or inaccurate, the fines up to $10 million may apply. Moreover, Section 26D stipulates that patent holders who try to prevent generic pharmaceutical from entering the market must acquire permission from the government.[114]

---

[113] Faunce, Thomas A, and Joel Lexchin. "'Linkage'pharmaceutical Evergreening in Canada and Australia." Australia and New Zealand health policy 4.1 (2007): 1. Print.

[114] Ibid.

Despite the effort of limiting evergreening, Australia had to go through legislative amendment in 2007 with regards to PBS partly due to the pressure of the Medicine Working Group[115] established by the AUSFTA. In this amendment, the PBS list is divided into two categories, F1 and F2. The category F1 includes medicines that have not previously registered and no biologically equivalent drugs are available. The category F2 includes mostly generic drugs. Then, the government's policy to lower the price of drugs would only apply to F2 categories which includes generic drugs, and had made there is no price reference between F1 and F2. This means that price of new drugs would remain high and evergreening strategies would not also disappear. Although Australian legislation allow springboarding of generic drugs, there is enough motivation of continuing evergreening tactics by patent holders; this would eventually nullify the effect of springboarding legislation.[116]

The difference of Australian case from Canada case was that it successfully adopted anti-evergreening legislation along with the linkage provisions and still maintained its drug price policy of evidence-based pharmaceutical cost-effective analysis. Nevertheless, in relation to the creation of F1 and F2 category, the assessment is still mixed in that it increased preference of generic drugs due to price lowering of

[115] In AUSFTA, Australia and the U.S. had agreed to establish the Medicine Working Group to share each party's pharmaceutical policy and public health and medical issues. This allowed the U.S. to interfere Australian government's policy in relation with medicines.

[116] Faunce, Thomas A, and Joel Lexchin. "'Linkage'pharmaceutical Evergreening in Canada and Australia." Australia and New Zealand health policy 4.1 (2007): 1. Print.

category F2 medicines whereas it would also result in higher price of drugs for some patented drugs.[117]

3.4 Korea

The Korea-US FTA (KORUS FTA), renegotiated and signed in 2010, was no exception to stronger IPR protection strategy led by the U.S. through bilateral FTAs. Although KORUS FTA came into effect in March 2012, the linkage system was postponed for three years due to the domestic adjustment period. The results of negotiation in relation with pharmaceuticals were at the heart of debate among the public. The supporters of the provisions asserts that other than the linkage system, most of provisions in KORUS FTA were already adopted in Korean domestic legislation and adopting the results of negotiation would become an opportunity for Korean pharmaceutical industry to reform from reproducing generics to investing in research and development to become more innovative. However, the opponents rebut that the linkage system would provide multinational pharmaceutical company with stronger protection of their patents which would end up delaying generics to enter the market and thus, it would eventually increase the price of drugs.[118]

---

[117] Ibid.

[118] 조재신, and 김병남. "한미 Fta 의약품 허가-특허 연계제도 도입으로 인한 관련법 개정 및 그 영향에

The provisions related to pharmaceuticals are stipulated in the Article 5 (Pharmaceuticals and medical devices) and Article 18 (intellectual property). It was the first time for Korea FTAs to include a separate Chapter on pharmaceutical and medical devices in FTA text which mainly provides regulations for amount of government benefits on these products. It requires that the pricing of pharmaceuticals should be based on the innovative value and that the price should be determined by the market price. Similar to the situation of AUSFTA negotiation, in KORUS FTA the drug price policy of each Party had become the subject of trade negotiation.

On the other hand, Article 18.8 and the Article 18.9 of KORUS FTA provide provisions with regards to pharmaceutical patents, and the Article 18.9.5 stipulates the linkage system as follows:

> Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, that Party shall:
>
> (a) provide that the patent owner shall be notified of the identity of any such other person that request marketing approval to enter the market during the term of a patent notified to the approving authority as covering that product or its approved method of use; and

---

관한 고찰." *법학연구* 26.1 (2015): 409-43. Print.

(b) implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent notified to the approving authority as covering that product or its approve method of use.

Due to the linkage provision above, the Ministry of Food and Drug Safety (MFDS) was required to notify patent holders the identification of the third party that applied for marketing approval of the patent. Moreover, in accordance with the Article 18.9.5 (b), generic manufacturers must obtain leave from MFDS for marketing approval. This allows MFDS to take necessary measures to prevent any third party's marketing approval application, by simply not granting a leave.[119]

The drug approval system before introduction of KORUS FTA allowed generic drugs to obtain marketing approval before patent expires. As soon as the patent expires, generics could immediately enter the market. This system differs from the U.S. legislation in that there is no regulation that stipulates drug approval application during the patent term as an infringement of a patent. However, after the introduction of the linkage system of the KORUS FTA, generic manufacturers must obtain approval from MFDS if the patent term has not been expired, and MFDS would notify original patent holder that a third party has attempted to obtain marketing approval of a product which utilize their patent. The difference between before and after adopting the linkage

[119] 윤성욱, and Yoon Sung Wook. "의약품 허가-특허 연계제도에 도입에 따른 시사점: Korus Fta를 중심으로 (Introduction of Drug Approval-Patent Linkage System: Implications after the Entry into Force of Korus Fta)." *홍익법학* 12.1 (2011): 535. Print.

system is that the linkage system allows patent holders to file an infringement suit against generic manufacturers[120] while keeping generic manufacturers from entering the market for 9-months. This process of linkage system were also issues in the U.S., and Canada for resulting in evergreening strategies of multinational pharmaceutical companies, and thus, it had to be amended to fill in the legal loopholes in both countries.

To adopt linkage system in administrative process, some domestic legislation had to be amended. With the observation of the U.S. and Canada's amendment processes and Australia's domestic adjustment processes, Korea was able to consider potential issues that may arise before introducing the linkage system. Domestic legislation amendments in Korea have, thus, incorporated important legal elements that should have been incorporated with linkage systems when it was initially introduced in the U.S. and Canada. Before the adoption of linkage system, the patent administration and approval of drugs were administered in two different Ministries, the Korean Intellectual Property Office (KIPO) and the Ministry of Food and Drug Safety respectively. However, the linkage system of KORUS FTA requires them to mutually cooperate in order to 'link' the approval process with the patent. Table 5 shows lists of amendments of Pharmaceutical Affairs Act along with the introduction of the linkage system:

[120] Ibid.

Table 5 – Amendment of Domestic Regulations[121]

Legislation	Provisions	Details
Pharmaceutical Affairs Act	Article 50.2 (Newly added)	Amendment of Patent Registration System · Only those patents obtained before the approval of the drug are allowed to register.
	Article 50.5, 50.6 (Newly added)	Prohibition of Sales · After filing a suit, patent owner may ask Ministry of Food and Drug Safety for prohibition of sales of generic drugs that uses information or efficacy and safety information of their patent.
	Article 69.3 (Newly added)	Settlement Report Requirement · If there is a settlement between the patent owner and generic manufacturer, the details of settlement shall be reported to the Head of MFDS and Fair Trade Commission (FTC)
	Article 50.8. (Newly added)	First Marketing Product Authorization[122] · The first generic manufacturer who challenged original patent and win the case, it will be given with 9-month marketing exclusivity.

Before the amendment, authorized product sellers were able to apply for listing on the green list[123] whenever their patent was approved. However, the newly added Article 50.2 stipulates that only those patents that were applied before approval of the pharmaceuticals can be listed. This is to protect only those patents that were actually utilized during the development of pharmaceutical.[124] In addition, the newly added Articles 50.5 and 50.6 provides that if a generic manufacturer applies for approval on the basis of safety and efficacy information of previously registered

[121] 조재신, and 김병남. "한미 Fta 의약품 허가-특허 연계제도 도입으로 인한 관련법 개정 및 그 영향에 관한 고찰." *법학연구* 26.1 (2015): 409-43. Print.

[122] The First Marketing Product Authorization in Korean is "우선판매품목허가"

[123] The green list, which is equivalent to Orange Book in Hatch-Waxman Act, defines the four types of patents (substances, usage, composition, dosage form) and it becomes the basis of the linkage system.

[124] 유은경. "의약품 허가특허연계제도의 이해와 전망." *FDC 법제연구* 9.1 (2014): 1-5. Print.

pharmaceutical, the patent owner is allowed to file a suit within 45 days, and until the court decision is made the sales of generic drugs is prohibited, provided that decision of patent invalidation would be an exception. Moreover, in order to prevent reverse-payment settlement between the patent holder and the generic manufacturer, the newly added Article 69.3 requires details of settlement should be reported to the Head of MFDS and the Fair Trade Commission.[125] Furthermore, to encourage generic manufacturers to challenge the patent, the first challenger of the patent who wins the case will be given 9-month of the first marketing product authorization that prohibits any other generic manufacture from entering into market.[126]

The amended pharmaceutical act provides that when a generic manufacturer applied for marketing approval, the MFDS shall notify it to patent owner. After notified by the MFDS, the patent owner has 45-days to file a suit. If it decides not to file a lawsuit, the generic is allowed to obtain marketing approval. If it decides to file a suit, marketing approval of the generic is put on hold for the maximum of 9-month, unless there is one of the following court decisions: i) the generic is not included in the scope of the patent ii) the generic is not an infringement of the patent iii) the patent is not valid.[127] If generic manufacturers successfully defend themselves from the

---

[125] 조재신, and 김병남. "한미 Fta 의약품 허가-특허 연계제도 도입으로 인한 관련법 개정 및 그 영향에 관한 고찰." *법학연구* 26.1 (2015): 409-43. Print.

[126] Ibid.

[127] Article 50.6.8. of the Pharmaceutical Affairs Act (Prohibition of Sales)

infringement lawsuit filed by the patent owner, they will be given the First Marketing Product Authorization.

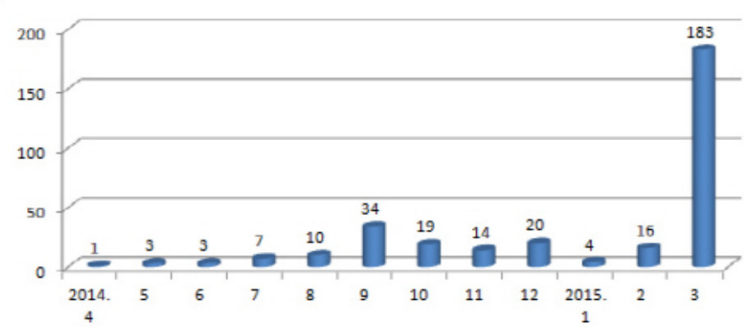
Table 6 - Key Differences in Linkage System among Four Countries

	US	Canada	Australia	Korea
Year of Introduction	1984	1994	2005	2012
Initiation	Enactment of Hatch-Waxman Act	Entry into force of NAFTA	Entry into force of Australia-US FTA	Entry into force of Korea-US FTA
Tools for Marketing Approval Prohibition of Generics[128]	· Patent owner has 45 days after the notification to file a suit · 30-month stay from marketing approval of generics	· Patent owner has 45 days after the notification · 24-month stay from marketing approval of generics	· Introduction of measures that prohibit springboarding during patent term (review infringement of patent)	· Patent owner has 45 days after the notification · Maximum 9-month stay from marketing approval of generics
Amendment and Domestic Adoption Process of the Linkage System	· Amendment in 2003 due to abusive actions by multi-national pharmaceutical firms	· Amendment in 2006 · For 10 years, the linkage system was run as very similar method as that of the U.S. - The linkage system was amended during similar time and with method as that of the U.S.	· Added "anit-evergreening" provisions as a result of vigorous public debate (section 26c, 26d) · Valuing pharmaceutical innovation in different ways: - Aus.: Cost-effectiveness - US: Competitive market	· 3-year delay of introduction of linkage system (from 2015.3)

[128] 유은경. "의약품 허가특허연계제도의 이해와 전망." FDC 법제연구 9.1 (2014): 1-5. Print.

The First Marketing Product Authorization, though, has become an issue in the pharmaceutical industry in that the 9-month marketing exclusivity can become a preference for generic manufactures and it would result in reverse-payment settlements. Although there is a fine against a person who did not report a settlement without justifiable reasons, it is not effective in completely preventing reverse-payment settlements. The MFDS published statistics of monthly patent trial claims and as shown in the Figure 1, patent trial claims hiked during March 2015 when the marketing exclusivity took effect with the linkage system. The number of claims in March 2015 is much higher than all claims applied throughout the year 2014. It can be assumed from the Figure 1 that one of the strategies of generic manufacturers would be to apply patent trial claims to increase chances of getting the First Marketing Product Authorization.[129]

Figure 1. Monthly Patent Trial Claims



[129] 조재신, and 김병남. "한미 Fta 의약품 허가-특허 연계제도 도입으로 인한 관련법 개정 및 그 영향에 관한 고찰." 법학연구 26.1 (2015): 409-43. Print.

Chapter IV. The Linkage System in the Trans-Pacific Partnership (TPP)

4.1 The Linkage System in the Trans-Pacific Partnership (TPP)

The mega-FTA, Trans-Pacific Partnership (TPP) is a trade agreement signed in February 2016 among twelve countries[130] of the Pacific Rim. TPP is the first mega-FTA that is signed among twelve countries, and the U.S. leadership took a large part in drawing an agreement. TPP covers comprehensive economic topics and areas, and intellectual property rights (IPR) is one of them. Pharmaceutical patent in IPR chapter was one of the controversial issues in negotiation since achieving the right balance between incentives to innovate and access to medicine is among the most sensitive and contentious issues in the negotiation of trade agreements.[131] As TPP includes not only developed countries but also developing countries such as Brunei, Chile, Malaysia, Peru and Vietnam, access to medicine unavoidably became a sensitive issue.

Notwithstanding the conflicting positions between developing and developed

[130] Trans-Pacific Partnership Agreement is signed by Brunei, Chile, New Zealand, Singapore, Australia, Canada, Japan, Malaysia, Mexico, Peru, Vietnam and the U.S.

[131] Artecona, Raquel, and Rosine M Plank-Brumback. "Access to Medicines and Incentives for Innovation: The Balance Struck in the Trans-Pacific Partnership (TPP) on Intellectual Property (Patent and Data Exclusivity) Protection for Pharmaceutical Products." (2016). Print.

countries, the linkage system is included in the IPR Chapter. The Article 18.53 of TPP Agreement (TPPA) provides that:

> 1. If a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety and efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory, that Party shall provide:
> (a) a system to provide notice to a patent holder or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use;
> (b) adequate time and opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies in subparagraph (c); and
> (c) procedures, such as judicial or administrative proceedings, and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use.
> 2. As an alternative to paragraph 1, a Party shall instead adopt or maintain a system other than judicial proceedings that precludes, based upon patent-related information submitted to the marketing approval authority by a patent holder or the applicant for marketing approval, or based on direct coordination between the marketing approval authority and the patent office, the issuance of marketing approval to any third person seeking to market a pharmaceutical product subject to a patent

claiming that product, unless by consent or acquiescence of the patent holder.

The Article 18.53.1 required signatory Parties to introduce a notification system and allow enough time and opportunity for patent holders to seek available remedies and the judicial or administrative procedures, expeditious remedies for the timely resolution of patent validity or infringement disputes. This provision is in more advanced form than that of other U.S. FTAs in that it divides requirements into sub-categories to elaborate each requirement and their objectives. Although it does not define the judicial of administrative procedures, a noticeable difference compared with other U.S. FTAs is the Article 18.53.2 provides members with an alternative option to take instead of the particular linkage system. It allows the TPP members to adopt or maintain a system other than judicial proceedings as long as that system precludes the issuance of marketing approval to any third person that does not have a consent or acquiescence of the patent holder. Nevertheless, the fact remains that the objective of the linkage system still clearly exists in the alternative option.

4.2 Key Issues in the Negotiations

The key issue during the negotiation on the IPR chapter, especially regarding the linkage system, was that developing and developed countries had different concerns

regarding pharmaceuticals. Developing countries were concerned with accessibility of medicines which is linked to approval and distribution of drugs while developed countries were concerned with price of drugs as to whether the linkage system affects government's medicines benefit system. As discussed in Chapter 3.3, Australia was most sensitive in issues regarding the effect on the government's discretion on its pharmaceuticals benefits system as it would influence the price of medicines. As developing and developed countries had different approach towards the linkage system and IPR protection, it was difficult to reach an agreement by each issue and thus, the agreement was reached by issue-linkage.[132]

4.3 Implications

The principal negotiating objective for the U.S. in relation with IPR protection was set by Congress, and thus, the standard against which the IP provision of the TPPA are being judged is that of IP protection under U.S. law, the Hatch-Waxman Act. It established a regulatory framework that seeks to encourage the manufacturer and marketing of generic medicine, while retaining incentives for research and innovation

[132] Issue linkage is the bargaining tactic in simultaneous discussion of two or more issues for joint settlement.

for originator products.[133] When TPPA is ratified by the Congress of each member country, it would significantly extend the U.S. law-based IPR protection regime in international trade. TPP may allow the U.S. to have greater influence in the world trading system, especially in the area of IPR, by making a precedent which may influence other mega-FTAs led by the U.S. for instance, Transatlantic Trade and Investment Partnership (T-TIP). As discussed in Chapter I and II, this will become a critical issue in the multilateral trading system.

[133] Artecona, Raquel, and Rosine M Plank-Brumback. "Access to Medicines and Incentives for innovation: The Balance Struck in the Trans-Pacific Partnership (TPP) on Intellectual Property (Patent and Data Exclusivity) Protection for Pharmaceutical Products." (2016). Print.

Chapter V. Implications on the Multilateral Trading System

5.1 Two-Tier International Trade Blocs

Since the onset of the global economic recession, governments have repeatedly circumvented the basic principles of Most Favored Nation[134] and National Treatment[135] under the World Trade Organization (WTO). Countries have sought national and commercial interests in the panic following the global financial crisis.[136] Moreover, there was a rapid economic growth of the large emerging markets and that they have now become strong advocates of the position of developing country at the WTO. They are not so easily being pressured, marginalized or neglected by the advanced countries. The consequence has been the deadlock of the Doha Round negotiations since the establishment of WTO. Due to these reasons, the U.S. and EU have come to believe that mega-FTAs provide a better negotiation forum to achieve their commercial and national

[134] Under the WTO agreements, countries cannot normally discriminate between their trading partners. Grant someone a special favor (such as a lower customs duty rate for one of their products) and you have to do the same for all other WTO members. (WTO).

[135] National treatment: The principle of giving others the same treatment as one's own nationals. GATT Article 3 requires that imports be treated no less favourably than the same or similar domestically-produced goods once they have passed customs. GATS Article 17 and TRIPS Article 3 also deal with national treatment for services and intellectual property protection. (WTO).

[136] Aggarwal, Vinod K, and Simon J Evenett. "A Fragmenting Global Economy: A Weakened Wto, Mega Ftas, and Murky Protectionism." *Swiss Political Science Review* 19.4 (2013): 550-57. Print.

interests, at least in the short to medium term.[137] Since then, U.S. has been very actively seeking bilateral and plurilateral agreements. The U.S. has sought to revitalize APEC as a fuel to create a Free Trade Area of the Asia Pacific (FTAAP) and to expedite negotiations to conclude TPP. As a result, TPP agreement, as the first mega-FTA, was finally concluded in 2015 and signed in 2016, currently waiting for ratification from Congress of each member country.

This process, however, resulted in creating the two-tier international trade blocs whereby the U.S. divides trading partners into countries that are willing to accept the U.S. standards and requirements, and countries that are not. Only those countries that accept higher IPR protection in the free trade agreements are privileged to have trade access to the U.S. market. This two-tier approach, however, would marginalize developing countries in international trade that cannot tolerate U.S. requirements due to domestic circumstances. These countries, then, would likely to lose opportunities to further develop through export. The objective of the WTO is "to provide a forum for negotiating agreements aimed at reducing obstacles to international trade and ensuring a level playing field for all, thus contributing to economic growth and development."[138] However, the two-tier approach of the U.S. is directly against the objective of the WTO in that it divides countries into two blocs based on its own standards, and by only allowing countries that can tolerate their standards to have the U.S. market access, it does not provide a level playing field in the world trading system. Consequently, it

[137] Ibid.
[138] World Trade Organization (WTO).

would contribute to economic growth and development only to the one side of the trading bloc, and not to the other. Marginalized developing countries in international trade would further lag behind, thereby exacerbating the economic development gap between developing and developed countries.

5.2 Influence on the Mega-FTAs

The IPR chapters including the linkage system in U.S. FTAs[139] with Canada, Australia, Korea and others had become precedents for the IPR chapter in TPP negotiations. Likewise, the first mega-FTA, TPP, would become the first precedent for other mega-FTA negotiations which includes the U.S. as a member. Although developing countries such as Oman, Jordan and Bahrain did not have developed pharmaceutical industries or related administrative procedures, the U.S. still urged them to include the linkage system in the IPR chapter in FTAs. By gradually making a norm of its IPR standards in international trade regime, the U.S. attempts to multilateralize higher IPR protection which covers larger scope and stipulates stronger regulations than that of the TRIPS of the WTO. Scholars have assumed that the TRIPS agreement would provide the basics for the IPR chapter for TTIP, but it would also continue the trend of

[139] The U.S. has fifteen FTAs in effect with countries including developing countries such as Morocco, Jordan, Oman, Bahrain, Panama, and the FTAs between these developing countries have included the linkage system in the IPR Chapter.

the TRIPS-plus provisions.[140] In TTIP negotiation, both the U.S. and EU are aiming at a higher standard of IPR protection while acknowledging the importance of IP-intensive sectors in their respective economies. However, since the WTO does not stipulate regulations in relation with data privacy in particular, new provisions would not be easy to negotiate.[141]

5.3 Threats to the Multilateral Trading System

The result of vigorous effort of many people and for a long time to sustain and facilitate multilateral negotiations in the WTO is undermined by the U.S. as it attempts to leverage bilateral or plurilateral trade negotiations to achieve its aim while leaving behind other countries that cannot make an agreement. The deadlock of Doha Round of negotiations may have caused the U.S. and other advanced countries to lose interests in the multilateral trading system; however it might be the advanced countries that have caused the Doha Round to be stalemate as they are not willing to make a deal with fast-growing emerging economies or developing countries since they have not much to gain from the further negotiations. In addition, WTO's principles of single undertaking, one country-one vote and decision-making by consensus make the decision making process

[140] Hufbauer, Gary Clyde, and Cathleen Cimino-Isaacs. "How Will Tpp and Ttip Change the WTO System?" *Journal of International Economic Law* (2015). Print.
[141] Ibid.

more difficult, while it has to embrace the growing size of the membership and diversity and a large number of issues on its agenda.[142] The U.S. has enough reasons to believe that it would not be able to gain more by having further negotiations.

As the U.S. has almost abandoned the multilateral trade negotiations while actively seeking bilateral or plurilateral FTAs, the future of the WTO became murky, at least for the short and medium term. Since TPP is concluded and signed, the trend of mega-FTAs in international trade system will likely to continue. When having no strong leadership in the WTO while there is a strong leadership of the U.S. in the mega-FTA negotiation with "WTO-plus" provisions, the multilateral trading system will continue to be outdated and would not be able to function as the major forum for international trade discussion.

[142] Nakatomi, Michitaka. "Plurilateral Agreements: A Viable Alternative to the World Trade Organization?". *ADBInstitute* (2013). Print.

Chapter VI. Conclusion

Advanced countries have turned their interests to bilateral FTAs when the Uruguay Round of trade negotiation was concluded. They were not pleased with the result of the agreement, including the intellectual property rights provisions. They started to utilize bilateral FTAs to more easily achieve their aims in relation with intellectual property. The U.S. was one of those advanced countries, and especially with the intellectual property rights, the U.S. have actively sought ways to achieve stronger IPR protection through bilateral and plurilateral FTAs.

Acknowledging that developing and developed countries have stark differences in their positions with regards to pharmaceutical patents in intellectual property rights, the U.S. has chosen to adopt TRIPS-plus provisions in their bilateral and plurilateral FTAs, instead of negotiating in the WTO. The approval-patent linkage provision, one of the TRIPS-plus provisions has been one of the most controversial provisions in that it affects the accessibility of medicines of people in developing countries.

The linkage system was first introduced in the U.S. by the Hatch-Waxman Act of 1984, and starting from NAFTA in 1993, the U.S. has pressured its FTA partner countries to include the linkage system in the agreement, regardless of economic, systemic and industrial development level of its trading partner countries. The linkage

systems that are included in the U.S. FTAs show very similar patterns and forms in its requirements. Before the introduction of the linkage system, countries had different administrative offices for patents and pharmaceuticals. However, the linkage system requires the patent office and food and drug administration to cooperate in order to prevent generic manufacturers to obtain marketing approval without notifying patent owner and having permission or acquiescence. The results of amending domestic regulations to adopt linkage system were very similar among Canada, Australia and Korea, but each country also showed some differences. The public debate over linkage system was contentious in all three countries, and thus they have include particular provisions, for instance, Australia included the anti-evergreening provisions with the linkage system and Korea have delayed the introduction of the linkage system for three years after taking into effect of KORUS FTA.

The U.S. had moved further to the mega-FTA to continue with the trend of including TRIPS-plus provisions in IPR chapter of free trade agreements. The Trans-Pacific Partnership (TPP) was concluded in 2015 and signed in 2016 among twelve members, and it clearly included the linkage system and other TRIPS-plus provisions in its IPR chapter. Through TPP, the U.S. have significantly extended its influence in relation with stronger IPR standards in international trade regime, despite the fact that the World Trade Organization (WTO), the multinational trade forum, was not able to draw agreements on TRIPS-plus provisions through the negotiations among more than 160 members.

The U.S.' unilateral approach and its extension of influence on international trade with regards to the linkage system and other TRIPS-plus provisions poses several concerns in the multilateral trading system. First, it creates the two-tier international trade blocs, whereby the U.S. open its market to only those who can tolerate U.S. requirements while leaving behind other countries that cannot tolerate U.S.' unilateral approach to intellectual property rights protection. Second, as the U.S. turned its interest from multilateral trade negotiations to bilateral or plurilateral FTAs, U.S.' IPR standards extends to more and more countries, and thus, it gradually multilateralize its IPR standards to make a norm. This way, the U.S. does not have to go through tough negotiation processes in the WTO but it can achieve its aim through bilateral or plurilateral FTAs where they have much more bargaining power. Third, as the U.S. has abandoned multilateral trade negotiations but is actively pushing forward bilateral or mega-FTAs with the basis of the U.S.' domestic legal frameworks, the U.S. significantly weakens the multilateral trading system which has been vigorously achieved by many people during a long period of time. It is not certain how long the U.S. will continue with its current strategy, it has been undermining the objectives of the WTO which aims for "non-discriminatory" and "fair" trade, and a "level playing field for all."

The U.S. strategy to utilize bilateral or plurilateral FTAs to achieve its aim for stronger IPR protection have been successful and thus, it poses threat to the multilateral trading system. Nevertheless, the WTO negotiation still needs to endorse trade topics such as Trace Facilitation and Non-Tariff Barriers to sustain the multilateral trade forum,

and to learn from recent-trend of trade negotiations in order to move forward or resolve current deadlock situation.

References

Publications

Abbott, Frederick., Thomas Cottier, and Francis Gurry. The International Intellectual property System: Commentary and Materials, Part One (1999). Print.

Aggarwal, Vinod K, and Simon J Evenett. "A Fragmenting Global Economy: A Weakened Wto, Mega Ftas, and Murky Protectionism." Swiss Political Science Review 19.4 (2013): 550-57. Print.

Artecona, Raquel, and Rosine M Plank-Brumback. "Access to Medicines and Incentives for Innovation: The Balance Struck in the Trans-Pacific Partnership (TPP) on Intellectual Property (Patent and Data Exclusivity) Protection for Pharmaceutical Products." (2016). Print.

Chaudhry, Peggy E., and Michael G. Walsh. "Intellectual Property Rights." The Columbia Journal of World Business 30.2 (1995): 80-92. Print.

Drahos, Peter, et al. "Pharmaceuticals, Intellectual Property and Free Trade: The Case of the Us–Australia Free Trade Agreement." Prometheus 22.3 (2004): 243-57. Print.

Faunce, Thomas A, and Joel Lexchin. "'Linkage'pharmaceutical Evergreening in Canada and Australia." Australia and New Zealand health policy 4.1 (2007): 1. Print.

Fetherstonhaugh."Proposed Amendments to Linkage Regulations and Data Protection Published." *Canadian Pharmaceutical Intellectual Property Law Newsletter* (2006). Print.

Gerald J. Mossinghoff, Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process, 54 FOOD & DRUG L.J. 187, 190 (1999).

Grabowski, Henry. "Patents, Innovation and Access to New Pharmaceuticals." *Journal of International Economic Law* 5.4 (2002): 849-60. Print.

Hitoshi NASU, "Public law challenges to the regulation of pharmaceutical patents in the US bilateral free trade agreements", in Pogge, Thomas, Matthew Rimmer, and Kim Rubenstein. Incentives for Global Public Health: Patent Law and Access to Essential Medicines. Cambridge University Press, 2010. P.79-83.

Holly Soehnge, The Drug Price Competition and Patent Term Restoration Act of 1984: Fine- Tuning the Balance Between the Interests of Pioneer and Generic Drug Manufacturers, 58 FOOD & DRUG L.J. 51,52 (2003).

Hufbauer, Gary Clyde, and Cathleen Cimino-Isaacs. "How Will Tpp and Ttip Change the WTO System?" Journal of International Economic Law (2015). Print.

Lara J. Glasgow, Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?, 41 IDEA 227, 233 (200l).

Lehman, Bruce. "The Pharmaceutical Industry and the Patent System." International Intellectual Property Institute (2003). Print.

Lindstrom, Beatrice. "Scaling Back Trips-Plus: An Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific." NYUJ Int'l L. & Pol. 42 (2009): 917. Print.

Mary Atkinson, *PatentP rotectionf or Pharmaceuticals:A Comparative Study of the Law in the United States and Canada,* II **PAC.** RIM L. **& POL'Y** J. I8I, 184 (2oo2).
Matthew, Avery. "Continuing Abuse of the Hatch-Waxman Act by Pharmaceutical Patent Holders and the Failure of the 2003 Amendments." Hastings Law Journal 60 (2008): 171-1535. Print.

MazzMazzoleni, Roberto, and Richard R Nelson. "The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate." Research policy 27.3 (1998): 273-84. Print.oleni

Mehl, Ashlee B. "Hatch-Waxman Act and Market Exclusivity for Generic Manufacturers: An Entitlement or an Incentive, The." Chi.-Kent L. Rev. 81 (2006): 649. Print.

Mercurio, Bryan Christopher. "Trips-Plus Provisions in Ftas: Recent Trends." Available at SSRN 947767 (2006). Print.
Nakatomi, Michitaka. "Plurilateral Agreements: A Viable Alternative to the World Trade Organization?". *ADBInstitute* (2013). Print.

Pecoul, Bernard, et al. "Access to Essential Drugs in Poor Countries: A Lost Battle?" Jama 281.4 (1999): 361-67. Print.

Soehnge, Holly. "The Drug Price Competition and Patent Term Restoration Act of 1984: Fine-Tuning the Balance between the Interests of Pioneer and Generic Drug Manufacturers." Food and Drug Law Journal 58.1 (2003): 51-80. Print.

Yana Pechersky, Note, To Achieve Closure of the Hatch- Waxman Act's Loopholes, Legislative Action Is Unnecessary: Generic Manufacturers Are Able to Hold Their Own, 25 CARDozo ARTS & ENT. L.J. 775, 796 (2007).

김재원. "지적재산권의 법철학적 재검토." 慶南法學 15.- (1999): 261-78. Print.

김호철, et al. "논문 : 한미자유무역협정(韓美自由貿易協定) 의약품(醫藥品) 지재권(知財權) 협상결과(協商結果) 관련법적(關聯法的) 쟁점(爭點) 분석(分析) (Access to Medicines and Intellectual Property Rights of the Korea-U.S. Free Trade Agreement)." 서울대학교 법학 50.2 (2009): 615. Print.

박실비아. "미국과 캐나다의 의약품 허가-특허 연계지도 (정보)." Journal of Pharmaceutical Investigation 38.3 (2008): 207-15. Print.

朴芝炫. "한미 FTA 속의 TRIPs-Plus." *국제법학회논총* 53.2 (2008): 85-108. Print.

유은경. "의약품 허가특허연계제도의 이해와 전망." *FDC 법제연구* 9.1 (2014): 1-5. Print.

윤성욱, and Yoon Sung Wook. "의약품 허가-특허 연계제도에 도입에 따른 시사점: Korus Fta 를 중심으로 (Introduction of Drug Approval-Patent Linkage System: Implications after the Entry into Force of Korus Fta)." 홍익법학 12.1 (2011): 535. Print.

이로리. "의약품 특허보호 관련 TRIPS-Plus 협정의 법적 쟁점 및 시사점." 안암법학 38.0 (2012): 419-46. Print.

정연, and 권순만. "지적재산권 강화에 따른 제약시장의 변화와 의약품 가격 및 이용에의 영향 -5 개 국가의 사례를 중심으로." 한국사회정책 21.2 (2014): 183-228. Print.

정재환, and 이봉수. "Trips 협정의 성립과정과 진전에 관한 연구." 무역학회지 38.1 (2013): 47-68. Print.

조재신, and 김병남. "한미 Fta 의약품 허가-특허 연계제도 도입으로 인한 관련법 개정 및 그 영향에 관한 고찰." 법학연구 26.1 (2015): 409-43. Print.

WTO TRIPS 협정 조문별 해설 / 특허청 국제협력담당관실 편. Ed. 한국. 특허청, 국제협력담당관실. [대전] : 특허청, 2004. Print.

Legal Texts and Documents

Bern Convention.
Food, Drug, and Cosmetic Act (FDCA)
Medicare Modernization Act
Paris Convention
Pharmaceutical Affairs Act (Prohibition of Sales)
TRIPS and Pharmaceutical Patents. Fact Sheet. WTO.
TRIPS. WTO.

Online Sources

World Intellectual Property Organization (WIPO)
World Trade Organization (WTO)

국 문 초 록

의약품 허가-특허 연계제도 분석 및 다자통상제도에의 영향

서울대학교 국제대학원
국제학과 국제통상전공
윤한나

지식재산권은 창작물을 만든 사람에게 일정기간 동안 배타적인 권리를 부여하는 법적 장치이다. 지식재산권을 통해 경쟁을 제한하고 배타적 권리를 인정하는 인센티브를 제공함으로써 창작 인들을 독려한다. 그러나 지식재산권은 일반 재산권하고는 다르다. 지식재산권은 사적재산과 공적재산을 보호하려는데 그 목적이 있는 반면, 일반 재산권은 개인의 사적 재산만을 보호하기 때문이다.

특히 의약품 산업에서는 사적재산과 공적재산의 보호의 균형을 맞추는 것이 중요한 문제이다. 의약품은 인류의 생명과 연관된 공공성을 가진 상품이지만 동시에 대규모 투자의 결과물이기도 하기 때문에 그 특허에 대한 강한 법적 보호가 필요하다. 이 문제는 국제통상의 문제로 확대되는데, 개발도상국은 강한 의약품 특허보호에 따른 수입 의약품의 가격 상승, 그리고 선진국은 수출 시에도 투자에 대한 합당한 법적 보호를 수입국에 요구한다. WTO는 무역관련지적재산권(TRIPS) 협약을 통해 의약품과 관련하여 선진국과 개발도상국의 접근성 불균형을 관리, 규제하고 있다. 그러나, 전통적으로 강한 지식재산권 보호를 주장하는 미국은 TRIPS 보다 더 강한 지재권 보호규정을 자유무역협정(FTA)를 통해 무역 상대국에 도입을 강요하고 있다.

이 논문은 TRIPS보다 높은 수준의 지식재산권 보호 규정인 허가-특허연계제도를 집중적으로 분석한다. 먼저, 미국의 허가-특허연계제도의 도입배경, 개정과정, 그리고 양자무역협정(FTA) 및 복수

간 협정 (Mega-FTA)을 통한 발전과정에 대해서 연구한다. 그리고 더 나아가 미국의 주도 하, 더욱 강해진 지식재산권 보호가 국제통상 제도인 다자간 협정 (WTO)에 미치는 영향을 연구한다. 미국이 일방적으로 주도하는 지식재산권 보호 강화는 결국 국제 통상 구역을 개도국과 선진국으로 나누는 결과를 초래할 것이고, 협상 진행중인 다른 Mega-FTA에 영향을 미칠 것이며, 궁극적으로 오랜 기간 발전해 온 다자통상제도를 위협할 수 있다.

주제어: 지식재산권, WTO, 무역관련 지적재산권 협정, 자유무역협정, 의약품 특허, 허가-특허 연계조항

학번: 2013-22040