國立交通大學

科技法律研究所

碩士論文

強制授權補償金之研究

A Research on the Remuneration of Compulsory License

研究生：鄭宛菁

指導教授：倪貴榮 博士

中華民國一百零一年七月


E
S
A
1896

摘要

新專利法於民國一百年十一月二十九號三讀通過，第八十八條條第三項規定：「強制授權之審定應以書面為之，並載明其授權之理由、範圍、期間及應支付之補償金。」修正了舊法第七十六條第五項「特許實施權人應給與專利權人適當之補償金，有爭執時，由專利專責機關 核定之。」其改變了目前雙方就強制授權補償金有爭執時先由雙方協商，若協商不成再由政府介入仲裁之作法。修改成智慧局在核准強制授權時必須一併審定補償金額，申請人如未依審定金額支付，專利權人就可以申請廢止強制授權。因此新法提供專利權人更周全之保護。

然我國就一般強制授權及醫藥強制授權供國內使用並未明文規定詳細之適當補償金的核定標準，故本文之研究目的在於，透過學說上相關論述及其他國家補償金之研究，整理出一套相關單位未來決定補償金時可供參考的模式。本研究分成一般專利強制授權與醫藥專利強制授權兩部分，首先就學說上對於補償金的不同看法作整理；並介紹各國實務操作上決定補償金的做法以及相關指導方針。在實證研究的部分，採取質性研究作為研究方法，藉由訪談智慧局專利部之科長，了解我國過去及未來決定補償金之操作模式。

Abstract

In Taiwan, the new amendment of Taiwanese Patent Act was passed by the Legislative Yuan in November 29th, 2011 and will come into effect in the end of 2012. Article 88 of the New Patent Act stipulates ”A decision on an application for compulsory licensing shall be made in writing, and shall indicate the reasons, scope, time period, and the required compensation.” However, the provision does not specify the approach of how to determine the compensation at issue regarding compulsory license. The remuneration issue is also rare in the academic studies in Taiwan. The thesis intends to introduce the international practices and experiences of compensation setting in compulsory licensing cases to find the feasible approaches for domestic administrative process in Taiwan.

Compensation for compulsory license can be divided into two categories, the general compulsory license and the pharmaceutical compulsory license regarding public health issues. In respect of the general compulsory licensing, the cases in the U.S. are largely depended on. In pharmaceutical cases, the thesis focuses on the report conducted by the UNDP and the methods of calculation used in Canada, Japan, taking into account other approaches proposed by the researchers and scholars. For empirical study, by interviewing the official of the authorities concerned who is in charge of the affairs, the author elaborates an in-depth analysis from the government’s perspective.

Table of Contents

Chapter I *Introduction*

1. Motive and Purpose of Research

After the TRIPS Agreement, a global standard of intellectual property rights binding all WTO member state was established. The globalized trends of patent protection were driven by countries with advanced technology as well as strong economic power seeking to urge countries with loose patent protection to strengthen their patent laws. Due to disparate level of development among the member countries of WTO, the influence of globalized patent protection on nation's domestic interests conflicts with each other. Developed countries sought for rigid legislations. On the contrary, strict patent protection would impede technology exploitation and access to essential medical treatments in less developed countries without sufficient necessary infrastructure. As a result, during the negotiations and preparations for the international agreement of intellectual property rights protection, there were many compromises made by the involving countries.

Compulsory license came along with the compromise between the developed countries and the less developed countries. Therefore, the language used in Article 31 of the TRIPS Agreement is full of ambiguity and subject to flexible interpretation. Advocates of public interest tend to explain the context of compulsory license broadly, making compulsory licensing mechanism easier to be invoked when necessary. As for proponents of stronger patent protection, they interpret the provision relatively narrowly and limited. Whatever stance a nation takes, since the TRIPS has permitted such licensing means, the issuance of compulsory license is deemed as a countermeasure against patent abuse or public crisis.

No matter for what good reasons, compulsory licensing takes away the owner's

property right essentially. In order to compensate the affected patent owners of non-voluntary licensing, the TRIPS Agreement requires nation to pay “adequate” remuneration for the licensor. However, the definition and specific requirement in regard of adequate remuneration are not stipulated in TRIPS, and thus leave considerable room for each WTO member nation’ discretion.

Despite that economic returns are the most important concerns for patent holders, there are only few articles written by the scholars dealing with the issue of adequate compensation. An international standard of royalty setting in remuneration can be difficult considering various situations facing each countries and hugely different financial affordability among WTO member nations. Nevertheless, a flexible working system adjusting to each country’s need could be a feasible way to make the compensation decision more predictable and transparent, which would lead to an efficient licensing process and thus benefit both the patent holders as well as the authorities concerns.

In Taiwan, the new amendment of Taiwanese Patent Act was passed by the Legislative Yuan in November 29th, 2011 and will come into effect in the end of 2012. Article 88 of the New Patent Act stipulates ”A decision on an application for compulsory licensing shall be made in writing, and shall indicate the reasons, scope, time period, and the required compensation.” However, the provision does not specify the approach of how to determine the compensation at issue regarding compulsory license. The research on the remuneration issue is also scarce.

Therefore, this thesis intends to introduce the examples and experiences of compensation setting in compulsory licensing cases worldwide to find the feasible approaches for domestic administrative process in Taiwan. At the same time, by introducing the compulsory licensing cases in Taiwan and interviewing the official of the authorities concerned who is in charge of the affairs, it also elaborates an in-depth

analysis from another perspective. Considering the lack of experiences about determining compensation in Taiwan, the research may provide some references for future cases.

2. *Research Methodology*

In order to establish a model for the references of remuneration in compulsory licenses, both the academic research and practices in the real world were studied and analyzed. Compensation for compulsory license can be divided into two categories, the general compulsory license and the pharmaceutical compulsory license regarding public health issues. The discussion within the thesis would also follow the pattern of dichotomy. In respect of the general compulsory licensing, the cases in the U.S. are largely depended on. As for the pharmaceutical aspect, the thesis focuses on the report conducted by the UNDP (United Nations Development Programme) and the methods of calculation used in Canada, Japan, taking into account other approaches proposed by the researchers and scholars.

According to the UNDP report conducted by James Packard Love, it indicates numerous royalty-setting ways concerning non-voluntary licensing in both the developed and developing nations. Besides, in pharmaceutical aspect, it introduced four methods in determining the compensation of compulsory licenses and each provides different points to the consideration of setting the royalties. By comparing those various royalty setting methods, it may draw some conclusions for the administrative decisions in Taiwan.

As a result of the empirical study in the thesis, the official of the authorities concerned (Intellectual Property Office) in Taiwan provides her personal opinions on the remuneration issues, which allows us to look at such issue from the government's

perspective and makes the study more complete.

3. *Structure of the Thesis*

Chapter 1 introduces the general idea of compulsory license and explains the motive and purpose of focusing on the remuneration part of non-voluntary licensing. Chapter 2 starts with the history of patent protection, providing the background of the formation of patent system and its serving purposes. These factors evaluated for the developing legislative decree concerning patent protection would become the reasons why each nation took different approaches to accomplish their legislations. Some countries cared more about public welfare. The other counties fought for their patent holder's private interests. However, both benefits were considered in the evolution of patent laws domestically and internationally. Before the concept of private property appeared, the transfer of new technology and the promotion of innovations that had benefited the society might be the first priorities. Private interests could be merely reflecting advantages when the government pursued the public welfare. But after the notion of personal property began to formed, more and more efforts and capital were poured into the pool of research and development of new technology. Thus, the section tells the story of historical overview on patent protection which sowed the seeds of controversy of compulsory license and how economic interests became the core of patent protection.

Chapter 3 deals with the contradicting ideas of compulsory license and promoting innovation. Since patent rights enable its owners to have the exclusive rights of authorization, patent holders are entitled to sell their patented inventions at will as long as there is a buyer. Nevertheless, under certain circumstances governments may step in the trade and make the rules of the trading when it is

necessary for various grounds. Compulsory license is a balancing tool for public interests and patent protection adopted by the TRIPS agreement. The part illustrates the justifications and legal resources of compulsory license based upon the international agreements and scholars' opinions. Also, it introduced some of the most worth referring cases worldwide in order to give an example of how the mechanism can be used to achieve better good for the nations, especially in the public health. However, the patent holders' right cannot be taken without proper compensation and that lead us to the discussions in Chapter 4 and 5.

Chapter 4 and 5 deals with concrete legal texts in the international agreements and the specific remuneration guidelines used by certain countries and proposed by the scholars. The most relied document is the UNDP report conducted by James Packard Love. The various royalties setting reflected the approaches that different countries adopted based upon their overall evaluation. Adequate remuneration is interpreted differently from market to market. Thus, the part suggests that it is difficult and almost impossible for every nation taking the same standardized method. Therefore, a more flexible mechanism which is able to adjust to varied situation is preferable.

Chapter 6 introduces the two compulsory licensing cases in Taiwan. Upon the empirical study, the official of Taiwan Intellectual property Office was interviewed to deliver her personal opinions on the subject of "adequate remuneration" and the ensuing actions after the issuance of compulsory licenses in Taiwan. This might give the readers a general idea of the Taiwanese government' perspective when it comes to compensation in such cases.

Lastly, Chapter 7 concludes the thesis and proposed some personal suggestions to the remuneration issues in compulsory licenses, which may be slightly helpful for the further study in the future.

Chapter II *Historical Overview on Patent Protection*

The controversy of patent protection has centered on the seesaw battle between the protection of private interests to promote innovation and public welfare for the purpose to facilitate access to technology. This chapter presents an evolution of the development of patent protections, setting the stage for later discussed issues and concepts at the heart of the patent rights system that would be further expounded in the thesis. Thus, this would serve to describe the motivations and reasons for the increasingly growing costs of patented products, especially in medicines. Moreover, after the establishment of the WTO, the integration of global trade has combined each nation's economy worldwide as co-existing community. Recently, much emphasis has been put in the preservation of human rights as well as the balancing interests between countries with disparate economic and technological power. The growing trends of the protection of public health also turned a new leaf of the history of intellectual property rights systems. All these catalysis brought forth urges to amendment and improvement of the design of patent legislations worldwide, including the remuneration of patent exploitations and compulsory licenses in certain aspects.

1. The Development of Patent Protection

A patent is an official document granted by a nation that conveys certain legal rights.[1] Patent owners are able to exclude others from using the patented invention for a period of time. The most common and strongest argument for

[1] Cynthia M. Ho, *Patent Breaking or Balancing? : Separating Standards of Fact from Fiction under TRIPS*, 34 N.C. J. INT'L L. & COM. REG. 371, 381 (2009).

patent protection is to improve innovation by offering inventors commercial benefits. According to some scholars,[2] the primary functions of patents contain: metering devices for society to measure an invention's value; allowing inventors to obtain commercial benefits from the result of their activities; and facilitating more efficient use of available resources as well as providing access to new resources.[3]

Moreover, patents can be deemed as stimulation to promote invention and innovation by allowing patentees to obtain rents from the fruits of their previous efforts. The rewarding systems can be reached in two ways: the one is requiring users of the inventions to pay for them directly. In order to make this happen, it is necessary to establish legal methods that allow inventors to put a price on their inventions. That is precisely the role that patents and trade secrets perform. The other way is let the inventors obtain the rents by providing rewards with public funds or other privileges. Under this condition, governments play the role of allocating rents to inventors. Users of the inventions still pay for them in an indirect way, through taxes. In that sense, so will tax-paying non-users.

Furthermore, the patent system can improve technological innovation, which social welfare and economic growth deeply depend on. Advanced technology provides efficient utilization on current scarce resources. At the same time, it creates new way to exploit new resources. Therefore, to maintain sufficient supply to the society needs, a steady and continued flow of inventions be developed and made available is necessary. These reasons all contribute to the design of patent system nowadays: to reward inventors and to prospect the markets.

---

[2] See, *e.g.*, ARTHUR R. MILLER & MICHAEL H. DAVIS, INTELLECTUAL PROPERTY – PATENTS. TRADEMARKS, AND COPYRIGHT IN A NUTSHELL 14-15 (2d ed. 1990); J. SCHMIDT – SALEWSKI & J. L. PIERRE, DROIT DE LA PROPRIETE INDUSTRIELLE 1-7 (1996).

[3] NunoPires de Carcalho, *The Primary Function of Patents*, 1 J. L. TECH. & POLICY 25, 74 (2001).

However, looking from the other side, in the ancient times, societies around the world had lived and evolved technologically without any patent system, without a system that a private patent owner can exclude others from using their technological creations. In the long history, governments promoted and encouraged innovations relying on public awards, and in the technology fields, the economic interests of inventions were kept under protection through secrecy.[4]

The protection of intellectual property rights dates back to the debate between Aristotle and Hippodamus of Miletus in the 4th century B.C.[5] During the period of time, the level of protection depends on social and economic values in different situations taking into account of the balancing interest between inventors and consumers. Thus, it varied greatly between countries.

The systematic protection of intellectual property rights took shape in the Renaissance. As one of the oldest forms of intellectual property rights, in 1474, the first patent law was created in Venice as a means to protect coveted knowledge possessed by local glass artisans. Being a merchant city, its corporations or guilds were very powerful. The guilds adopted the Venetian patent law to hinder introduction of their local craft to strengthen the industry.

Then came the second early legal text on patents, "the Statue of Monopolies", enacted by the English Parliament and approved by King James I in 1623.[6] The Statue of Monopolies extinguished all monopoles granted by the king that had no technical content and expressly permitted those which covered new manufactures. In this way, the people benefited from the grant would be the true and first

[4] NUNO PIRESDE CARVALHO, THE PATENT REGIME OF PATENT RIGHTS 2 (2th ed. 2005).
[5] Carlos Primo Braga & Carsten Fink, *How Stronger Protection of Intellectual Property Rights Affects International Trade Flows, in* INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH 19, 40 (K.E.F. Markus & Carsten Fink ed., 2005).
[6] KLAUS BOEHM, THE BRITISH PATENT SYSTEM 16 (Cambridge Univ Press, 1967).

inventors of those manufactures.[7]

From Middle Age privileges to modern patents, there were some significant changes: old privileges were granted in an environment characterized by a lack of economic freedom. Thus, unless the inventors received a special authorization or privilege, they were not able to exploit their knowledge but only had the right to exclude others. The privileges, therefore, were primarily a permission to carry out a trade and use the invention, as a royal favor, which otherwise was limited to the corporations. However, today's patents enable the patent owners to use their innovations as well as to exclude others from exploitations.

Another evolution of patents is the nature of their addressee. The early patents were granted to people who introduced the new technology, not the inventers. Later, the addressee became the true inventors of the innovations. Thanks to the improvement in communication technology, the dissemination of technology was more quickly from one country to another. So the introducers bringing new technology from foreign countries were no longer the only available means to technology transfer.

But the most important change was the possibility of transferring those rights to a third party. It was probably stemmed from the revolutionary notion that the rights generated by patents were property rights in essence. The thought allowed individual inventors to negotiate with capitalists and thus intensify the exploitation of new technology advances. This might be one of the most important factors leading to the Industrial Revolution and the simultaneous acceleration of technological evolution.[8]

Still another change with great influence was that, entrepreneurs started to

[7] Carvalho, *supra* note 4, at14.
[8] JENNY UGLOW, THE LUNAR MEN – THE FRIENDS WHO MADE THE FUTURE 295 (2002).

establish research and development department in order to further the technology innovations. By gathering inventors together as teams of employee, the patent laws were the first time called upon to regulate the relationship between the employers and the employed inventors. After patents became one of the corporate assets, the requests of higher level of international patent protection ensued.

The research and development for innovation is considerably expensive than simply copying something that has already been developed. The advocates of patent protection argued that if inventors were stripped off with a sizable sum of benefits for their innovations, the consequence would be fewer finance and investment in the R&D projects. Thus, the decrease of willingness in innovation will impede the advance of technology. For companies, there are many ways to limit competition in the markets. They can make use of "lead time" by hindering disclosure of their innovations or by brand advertising. Yet the most essential one may be ensuring monopoly advantage by government granting patent rights to secure market exclusivity. This is particularly in pharmaceutical industry provided that the innovations are relatively straightforward to imitate once they have been developed.[9]

In addition, pharmaceutical products take immense investment of time and money to become profitable medicine, its average time to develop a drug successfully is about ten to twelve years.[10] Based on the logic, stronger patent protection will reduce risk and uncertainty for investors, which in turn will serve to stimulate innovative enterprises. Uncertainty is extremely costly. That is why companies give such great importance to the ability to establish and ensure their

[9] Wesley M. Cohen ET AL., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or not)* (2000), NBER Working Paper Series 7552, *available at* http://www.nber.org/papers/w7552

[10] SHUMANI L. GEREDA, THE AFTERMATH OF CANADA'S IMPLEMENTATION OF THE DOHA DECLARATION ON THE FUTURE OF PHARMACEUTICAL INNOVATION 16 (2004).

intellectual property rights as soon as possible as a potential market develops. As the world has changed greatly in the past decades as markets, networks and legislation become more globalized, it brought forth a new slew of reasons for industries to press legislations to be implemented throughout the globe for the economic concerns.

2. The Paris Convention

In the nineteenth century, there were international fairs exhibiting new creations of technology and achievements of engineering. The fairs accorded manufacturers the opportunity to promote and advertise their inventions in order to meet prospective buyers. In return, the inventors had to start the full exploitation of the creations in the granting country within a very short period after the grant. This made the exhibitors ineligible for patent protection on grounds of lack of novelty, unless applications were previously filed. As a result, it was very difficult for foreign inventors or inventors residing abroad to obtain patent rights in the countries hosing the exhibitions among that time.[11]

Therefore, in 1873, during the preparation of the Vienna fair, a group of foreign entrepreneurs expressed their fear of continuing participating in those international exhibitions without valid legal patent protection. As a consequence, the seed for establishing an international system of intellectual property rights was planted by the Paris Convention. It is notable that the Paris Convention was not created for the harmonization of international set of norms and principles, but

[11] Carvalho, *supra* note 4, at 71-72.

merely a mechanism facilitating technology articulation. However, it was the first multinational treaty for patent protection.[12]

Between 1883 and 1967, when the Paris Convention was for the last time substantively modified, its text was revised seven times. Considering the original purpose for the Convention was permitting the articulation of foreign patent systems, it established three basic principles[13]:

i. The National Treatment Principle

Under the Paris Convention, Article 2 (1), it stipulates that ”nationals of any country of the Union, as regards the protection of industrial property, enjoy in all the other countries of the Union the advantages that their respective laws now grant, or may hereafter grant, to nationals. […] Consequently they shall have the same protection as the latter, and the same legal remedy against any infringement of their rights […].”The principle obliges members to grant patent rights to foreigners only if nationals are entitled to obtain the same rights. In other words, members may deny patent protection to foreigners as long as the protection is also denied to their own nationals.[14]

ii. The Principle of Priority

According to the Paris Convention, Article 4 (A)(1) and (B), once an application is regularly filed in one of the countries of the Paris Union, any subsequent filing in any of the other countries of the

[12] *Id*.
[13] *Id*. at 71-76.
[14] *Id*.

Union before the expiration of a twelve-month period shall not be invalidated by reason of any acts accomplished in the interval, such as another filing, the publication or exploitation of the invention, and those acts cannot give rise to any third-party right or any right of personal possession.[15]

iii. The Principle of Independence

Under this principle, a patent applied for in one country of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether Union Member or not. The principle should be understood in an unrestricted way, applying to aspects of nullity and forfeiture as well as regards of patents' normal duration. In short, the expiration of the protection of a patent in one country does not affect the same invention to lapse in another Union Member. In this sense, this principle of independent may also stand as an obstacle to the introduction of international exhaustion of patent rights by Union Members.[16]

The Paris Convention was initially signed by many countries for the purpose to permit the articulation of national patent systems. Therefore, in early times the patent law systems were designed embedding with the mercantilist ideology that preside their creation. It is then believed that, patents could convince foreign inventors to immigrate to the granting countries. Nowadays, technology transfer is

[15] *Id.*
[16] *Id.*

still deemed as one of the most valued factors of patent protections. For instance, the Paris Convention, which is incorporated by reference into the TRIPS Agreement[17], authorizes the grant of compulsory licenses for failure to work a patent. It deems that 'failure to work' is an abuse in law for which the remedy is compulsory license.

3. The Uruguay Round and TRIPS

For the development of global standards of patent protections and enforcement mechanisms, three related elements were involved in the mid-1990s: First, intensive lobbying by corporate intellectual property owners to induce the United States and the European Union to pressure developing countries to protect foreign intellectual property rights; Second, the successful effort by the United states and the European Union to move intellectual property negotiations from the WIPO to the GATT, leading the adoption of the TRIPS Agreement; Third, pressure from these same states and non-state actors for intellectual property protection standards that exceed those found in TRIPS.[18]

In 1980s, there was a growing awareness in the United States, as well as in other industrialized countries, that the strategic role of technology and the protection of intangible properties would dominate economic growth and international trade. Such awareness led U.S.-based multinational corporations whose business models and profit margins depended on intellectual property

[17] Agreement on Trade-related Aspects of Intellectual Property Rights art. 2, Apr. 15, 1994 Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instrument—Result if the Uruguay Round, 33 I. L. M. 1125 (1994) [hereinafter TRIPS].

[18] LAURENCE R. HELFER& GRAEME W. AUSTIN, HUMAN RIGHTS AND INTELLECTUAL PROPERTY 35 (2011).

protection to lobby the U.S. government to strengthen the intellectual property laws and enforcement mechanisms in developing nations. In accordance with the urge by entrepreneurs, the U.S. Trade Representative (USTR) investigated these countries and recommended retaliatory trade measures if their governments refused to bolster IP protection and enforcement measures.[19]

Thus, the proponent of stronger intellectual property protection standards, enforcement mechanisms, and sanctions rules dealt with and essential question: in which forum should they pursue this agenda? As a result, there was the establishment of the World Intellectual Property Organization (WIPO), a specialized international organization established in the late 1960s with the mandate to "promote the protection of intellectual property throughout the world.[20]" WIPO's Secretariat planned to reach the goal by hosting international conferences at which states negotiated new multilateral intellectual property treaties, administering existing intellectual property agreements, and offering technical assistance and advice to national intellectual property offices, especially in developing countries.[21]

Although WIPO was equipped with the mandate of IPR protection and relevant expertise, developed countries regarded this organization as an inhospitable venue. Therefore, the efforts were reallocated to remake the international intellectual property regime to GATT. The reasons for the "regime-shifting" strategy were firstly, they were concerned about the result of patent treaty negotiations that WIPO hosted in the 1980s Secondly, GATT was characterized with the features that facilitated the adoption of more expansive

[19] Trade Act of 1974 § 301, 19 U.S.C § 2242(a)(1)(A) (2006).
[20] Convention Establishing the World Intellectual Property Organization, art.3(i), July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S 3 (as amended Sep. 28, 1979).
[21] *See* WIPO, Summary of WIPO Technical Assistance for the Least Developed Countries, available at http://www.wipo.int/ldcs/en/ip/tech_assistance.html.

rules, enforcement mechanisms, and sanctions opportunities.[22]

In GATT, the European Union and the United States possessed greater negotiating leverage. Also, the ability to link intellectual property to trade rules expanded the one of agreement among nations with divergent interests. For the developing countries, they accepted a grand bargain: more access to the markets of industrialized states for agricultural products, textiles, and other products in exchange for including intellectual property protection rules and enforcement mechanisms in the global trading system.[23] Moreover, the GATT dispute settlement system was far more effective than the moribund international adjudication mechanisms associated with the WIPO conventions.[24]

In 1994, During the Uruguay round of the General Agreement on Tariffs and Trade (GATT), all members were agreed to adhere to a common set of international rules. After a great deal of pressure toward developing countries to strengthen their domestic laws in patent protections, an urge to enact global standards of legislations in IPR systems was launched by the developed countries.

The interests and needs in IPR protections were hugely disparate between developed and developing nations. In fact, the developing countries initially rejected the inclusion of IPRs and services issue in the WTO agreement for the reason that they were afraid that the economic incapability and limited budget would obstruct the establishment of the systems. The discussion revolved around the legitimacy of intellectual property trade treaties. The advocates for strong patent laws alleged that in order to guarantee the fruits of patent owners' work by

---

[22] Laurence R. Helfler, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE INT'L L. J. 1, 19-23 (2004).

[23] Ernst-Ulrich Petersmann, *Constitutionalism and International Organizations*, 17 NW. J. INT'L L. & BUS. 398, 442 (1997).

[24] Frank Emmert, *Intellectual Property in the Uruguay Round – Negotiating Strategies of the Western Industrialized Countries*, 11 MICH. J. INT'L L. 1317,1343 (1989); *see also* Monique L. Cordray, CATT v. WIPO, 76 J. PAT. & TRADEMARK OFF. SOC'Y121, 131-32 (1994).

protecting them from use or copy by others who had not invested their time, knowledge and money into improving innovation. They assumed that ensuring the right to intellectual property through patents would encourage creativity, investment in the R&D, and the willingness to bare the risks and uncertainties of industry-endeavors.

For example, the United States, at the head of advocating strong patent laws, had already passed a revision on their Trade and Tariff ct, specifying that the U.S. government could take retaliatory measures against any country considered to fail to provide adequate protection for intellectual property. This same act was revised in 1988, where it was specified that the U.S. Trade Representative would publish a list of countries which were not providing satisfactory levels of intellectual property protection.[25]

On the other hand, developing countries, who opposing the adoption of treaties on IPR protection originally, believed that IPR protections would serve as an incentive for foreign investment and technology transfer. Developing countries such as India, which had stronger and more innovative industrial development realized that a strong IPR system would help further incentivize industry ventures.[26] Thus, they finally softened the initial attitude of objection.

The TRIPS Agreement was completed and became officially enforced for the first time in January 1, 1995 under the Marrakesh Agreement, regardless of the conflicting interests involved. The adoption of TRIPS meant a significant sign of the obligation on all members to develop intellectual property protection legislations pursuant to TRIPS regulations, the WTO reach a compromise with

[25] Jean O. Lanjouw, *Intellecual property and the availability of pharmaceuticals in poor countries*, 3 INNOVATION POLICY AND THE ECONOMY 91, 92 (2002).
[26] Sykes, Alan O., *TRIPs, Pharmaceuticals, Developing Countries, and the Doha 'Solution'* (February 2002). U Chicago Law & Economics, Olin Working Paper No. 140. *available at* SSRN: http://ssrn.com/abstract=300834 or doi:10.2139/ssrn.300834

internationalization of shared liability and considerable political input.[27] The principal goal of TRIPS was to ensure that all members in WTO meet the minimum requirements established for IPR, with some additional flexibility depending on different national legal systems. The official objective of the WTO was to supervise and liberalize international capital trade. Therefore, as WTO members, it has become an indispensible requisite for countries to be able to participate in the global market. In the membership of the WTO, following the TRIPS provisions and introducing these norms into national legislative system was a mandatory request.

However, although the conflicting and divergent interests involved in the debates of TRIPS arrived at a more broadly acceptable system, the global architecture of IPR protections had generated resistance and dissatisfaction among developing nations. Those objections could be damaging in a variety of ways. Developing countries were driving changes to the system of patent rights and using targeted campaigns to lower particular drug prices. Regardless of the merits of individual results, it was a process of change that is both costly and extremely unpredictable in its effect. The uncertainty that creates in future markets and pricing opportunities is itself a strong deterrent to private sector involvement in drug research for the developing world. Generally speaking, dissatisfaction with the patent system in the realm of health may also lead to a distrust of the intellectual property system. This possibility should concern anyone who considers patents to be an important stimulus to innovative effort. Furthermore, regardless of what treaties are signed and laws passed in the poorer countries, reliable and consistent patent systems there can only be established with local

[27] S. P. Shukla, *From GATT to WTO and Beyond* (2002), http://www.wider.unu.edu/publications/working-papers/previous/en_GB/wp-195/

support.[28] Effective enforcement cannot be imposed from the outside.

In full awareness of the difficulties of the enforcement of TRIPS, developing and least developed countries were provided a transition period at the end of which their legislations would have to adjusted to TRIPS regulations. For example, developed countries were given one year to incorporate the TRIPS agreement into their legislation, developing countries were provided with 5 years period which they would be able to slowly begin applying the patent system for technology which had not enjoyed patent protection at the moment in which the TRIPS agreement was signed. As for least developed countries, they were afforded a longer transition period. For these countries, full implementation of the TRIPS cannot be required to accomplish within 10 years.[29]

The most powerful balancing tool for developing countries is the exceptions of patent protection listed in Article 31, allowing the governments of nations to take away patent holder's right in authorization based upon the objective and purpose set out in Article 7 and 8 in the TRIPS. Article 7 and 8 recognizes Members' right to implement the obligations under the TRIPS Agreement in a manner consistent with public policies conducive to social and economic welfare.

These transition clauses and flexibility provisions softened TRIPS's hard edges. Nevertheless, those edges were quickly sharpened again by the bilateral and regional trade pacts that the United States and European Union negotiates with many developing countries. Commentators refer to these agreements as "TRIPS Plus" treaties because they[30]: (1) contain intellectual property protection standards more stringent than those found in TRIPS; (2) oblige developing

---

[28] Controller General of Patents Designs and Trade Marks, *Patents: Twenty-second Annual Report*, 1993-94 (1996) (Nashik, India: Government of India Press), http://www.ipindia.nic.in/

[29] TRIPS Agreement. Art. 65,66.

[30] Helfler, *supra* note 22, at 40.

countries to implement TRIPS fully before the end of its specified transition periods; or (3) require such countries to accede to or conform to the requirements of other multilateral intellectual property agreements.[31] By negotiating with developing countries on a one-on-one basis or in small groups, the United States and European Union sought to "push harmonization forward at a pace that is greater than is apparently possible within the framework of the WTO."[32] The result was what some commentators derisively labeled as a "one size ('extra large') fits all" approach to intellectual property protection.[33]

4. Concluding Remarks

The patent protection has evolved from a political tool that government used to promote inventions directly, for instance, governments provided personal awards, wages, privileges, and monopolies to inventors, into a system of individual private rights concerning large economic benefits. In early times, government-funded initiatives are the oldest of the mechanisms for promoting invention,[34] but it did not mention the grant of patents.[35] Later on, privileges and monopolies granted by Kings permitting the inventors the right to exploit the trade in which the invention belonged. For example, artisans were attracted with financial assistance, tax exemption, and the permission to carry out their trade.

In other cases, artisans and introducers of foreign techniques were sometimes

[31] ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, REGIONALISM AND THE MULTILATERAL TRADING SYSTEM 111-22 (2003).
[32] Peter Dorahos, *BITs and BIPs*, 4 J. WORLD INTELL. PROP. 791, 792-807 (2001).
[33] James Boyle, *A Manifesto on WIPO and the Future of Intellecual Property*, 2004 DUKE. L. & TECH. REV. 9, 3 (2009).
[34] U.S. CONST., Article I, Section 8, cl. 8.
[35] John Boyle, *Patents or Premiuns*, 26 J. PAT. OFF. SOC'Y446, 450-51 (1944).

granted a monopoly, assuring they would have no competition. Then the Paris Convention went into force in 1883 as an initiative to permit the articulation of national patent system, which by then had been enacted in many countries. As entrepreneurs started to pour investments of massive money and time into the development and research of technology, they asked for more stringent legal structure to protect their intellectual properties containing monetary interests.

According to the scholar Carvalho, the patent system exists because it is the only known legal institution that allows inventors to put a price on technology and at the same time permits society to measure, through the competitive interplay of market forces, the adequacy of such a price with relative efficiency. The cornerstone justification of the patent system is the reduction of transaction costs as compared to state patronage and trade secrets.[36]

Levels of IPR protection in a given country have been directly related to its level of economic development. The fact embedded with important implication for the conflicting interests in the international organizations and treaties. The least developed and developing countries had weaker IPR protection system. The contributing factor was that these countries had not felt a need to develop stringent system. In their conditions, these countries tended to consider their ability to develop innovations was very limited and thus there were no supporting reasons to protect innovations. Accordingly, to create stronger IPR protection systems would basically bring the nations no good but ensure monopolies for foreign companies. However, with economic growth and industry development, the urge to devote more resources to innovative activities become a need for industrialized nations.

With the enactment of the TRIPS, the Agreement set out a minimum requirement of the IPR protection for all members to abide by, which caters to developed nations'

[36] Carvalho, *supra* note 4, at 25.

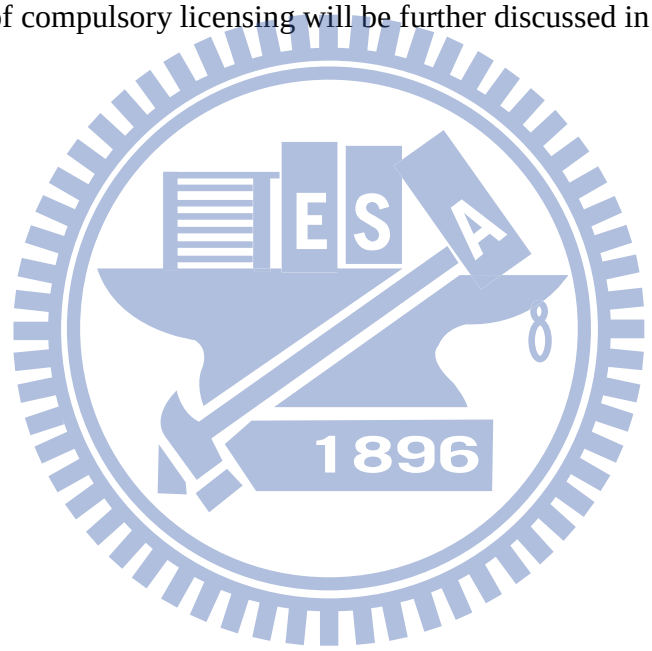
seeking to push harmonization of patent protection among different nations. Indeed, both TRIPS and TRIPS Plus treaties had strengthened intellectual property protection global standards and enforcement mechanisms. But it is important to realize an implication of the less-known effect: TRIPS increased tensions between international intellectual property regime and other international regime, such as human rights. The concerned issues arose in areas where two international regimes overlapped, which brought forth the later Doha Declaration. Over the last several years, developing countries and civil society group have made great effort to launch a range of new initiatives for the purpose of seeking to realign fundamentally the intellectual property protection rules embodied in TRIPS.[37]

The call for global harmonization of IPR systems that led to the TRIPS Agreement has different effects in countries with different economic development. It was assumed that there is an inherent trade-off which must be made when developing intellectual property legislation between corporate profit and access to health. For example, patents for pharmaceuticals were only gradually adopted by countries as they reached a certain level of development, where GDP had become sufficiently high to withstand the price-pressures patent legislation entails. When it comes to the balancing between patent protections and public health concerns, there are always divergent opinions presented. To illustrate, pro-patent-protection advocates allege that strong legislations speed up the introduction of drugs into the market. However, it must be considered that, in many cases, market exclusivity actually slows down the process. For instance, a multinational company may choose to delay the introduction of the innovations into the markets as long as there are concerns over the introduction of other drug innovations. In that sense pharmaceuticals will be introduced to

[37] Amy Kapczyniski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Prpperty*, 117 YALE L. J. 804 (2008).

developing countries at a lower rate than it would have without protection.[38]

A great deal of debates, which is about the appropriate set of policies for the purpose of coping with the problems posed by the patent system on developing countries' access to innovations, has centered on means of lowering prices in the markets within these countries. Most of the options proposed in accordance with the TRIPS have focused on equitable pricing system. When it comes to equitable pricing methods, compulsory license has, by far, been the most used TRIPS flexibility by developing and the least developed countries to promote their access to innovation. The mechanism of compulsory licensing will be further discussed in the next chapter.



[38] N. N. Mehrotra, *Patent Act and Technological Self-reliance: The Indian Pharmaceutical Industry*, 24 ECONOMIC AND POLITICAL WEEKLY 1059, 1059-1064 (1989).

Chapter III *Compulsory License and Innovation*

As discussed in the above chapters, the patent protection can preserve the promotion of innovation as well as the private advantages of patent owners. Nonetheless, the protection of patents clashes with the public welfare from time to time. The seesaw battle over the patent protections and public interests reflects on the enactment of Article 31 of the TRIPS agreement, which empowered members of the WTO the right to issue compulsory licenses.

A compulsory license is an authorization for a third party, against or regardless of the patent owner's will, to perform acts that would legally require the authorization from the patentee. The intent to include compulsory license provisions under TRIPS was to enable countries to adopt a means of introducing generic versions of products under patent protection when there is necessity. By allowing the manufacture of generic version patented products, the authorities concerned can drive down the price of patented goods through the way of overriding the right of exclusivity of patented technology, and thus rearrange the competition for the targeted markets.

There are two opposite voices in the process adopting compulsory license within the TRIPS Agreement during the preliminary arguments. Developed countries, heading by the United States, were hostile to the compulsory license provision. However, developing countries contended that compulsory license stands as a powerful leverage to protect their markets against the downfall of the patent system within their fragile markets. It was not surprising that the two groups took disparate stances. Industrialized nations possess most of the patents in the world, seeking to create more stringent global patent protection standards in order to secure their existing profit margins. Thus, in favor of their interests, a narrow, restrict

circumscribed basis for which compulsory licenses could be granted would be preferred. They argued that compulsory license would be detrimental to innovations in the long run. Facing with the risk of losing profitable and substantial return on the investments, corporations might be discouraged in further research and development in technology.

On the contrary, the developing countries with less technological innovations called for more loose statutes which can provide them with considerable room on the grounds for granting licenses. The issuing of compulsory licenses permits generic version of patented products to enter into the domestic markets, promoting access for the citizens to technology innovations. Thus, such mechanism can facilitate distribution of patented technologies and improve access to technology in cases where the patent system fails to achieve.

1. Provision of Compulsory License under TRIPS

The debates of appropriate legislative systems in patent laws, which is for the purpose of coping with the problems brought forth by patent protections, in developing countries were the means of lowering prices of drugs in pharmaceuticals. The access to medicines for their citizens is the first priority for the governments in developing and the least developed countries. At the initial stages of the development of the TRIPS Agreement, there was an emphasized acknowledgement that the social, political and economic conditions of developing and the least developed nations were far disparate from those of developed nations. In this sense, to incorporate TRIPS provisions into the national legislative system

would pose difficulties for the countries with poor economic condition.

To deal with this problem, the agreement has stipulated the provisions that states can appeal to in cases where there is patent abuse or national emergency. As a matter of fact, to strike a balance between private and public benefits, those provisions were enacted in order to expressly establish a means of dealing with the cases when patent protection system poses a threat to the welfare of public health.

1.1. Conflicting Perspectives Towards Patent Protections

Before entering into the subject of compulsory license under the TRIPS, it is notable that there is a spectrum of views on patents benchmarked by two very distinct and seemingly irreconcilable perspectives, which would lead to disparate interpretations of the TRIPS provisions in article 31. One is to think of patents as mere privileges. The other is to conceive patents as uber-rights.[39]

On one end, patents are deemed as a "mere" privileges granted by a nation and are inherently subject to limitations to ensure that patents do not impede other socially desirable goals. In this view, the conception of patents is that, they are only tools subject to limitations. Promoting innovation is only one of the goals that competing with one another societal goal that inherently contemplates the need for balance. For instance, scholar Baker, who is associated with the Health Global Access Project, which is dedicated to eliminating barriers to access to HIV treatment, stated that "Patents are not 'property' in the traditional sense – they are government granted rights that are intended to balance the interests of innovators and the public at large, and which are granted by governments with express and

[39] Cynthia M. Ho, *Intellectual Property in International Perspectives: Institute for Intellectual Property & Information Law Symposium*, 46 HOUS. L. REV. 1047, 1053-1055 (2009).

implied conditions…"[40]

Under this perception, if patents are conceived as a tool to promote innovation, which is in competing relationship with other societal goals, to ensure that the patent protection system is serving its purpose is reasonable. Therefore, assumed that patents are playing the role of incentive to innovation, to the extent that patents fail to achieve such goal, or even interfere with additional innovation, modifications are necessary. In accordance with this view, governments can set out limits or craft exceptions to typical patent remedies if doing so would promote greater innovation, such as the use of patented inventions by researchers.[41]

Looking back on the history to patent protections, the requirement of nations to require patent owner to" work" the patent locally is in consistence with the "mere privileges" opinion. The requirement to manufacture the patented product locally was for the purpose of technology transfer to local citizens. Considering the privilege view is centered with the concept of balancing various societal goals, it is obvious that proponents would in favor of giving each nation more flexibility to determine when and whether to grant patents and how to define their scope. In this way, an international agreement would not cater to their appeal.

However, to the extent that an international agreement was required, those advocates might be amenable to an agreement with permission for nations to have discretion to recognize their competing interests and adjust their policy on patent protections accordingly. In fact, some of the language in TRIPS can be seen as the result of the standing point of this view: Article 7 and 8 of TRIPS[42] stipulate the other objectives and purposes on the road of pursuing patent protection, and

[40] Posting of Brook K. Baker, Pharma's Seven Deadly Lies About Thai Compulsory Licenses, to IP Disputes in Medicine (Feb. 1, 2007), *at* http://www.cptech.org/blogs/ipdisputesinmedicine/2007/02/pharmas-seven-deadly-lies-about-thai.html.
[41] Ho, *supra* note 39.
[42] TRIPS, *supra* note 17, arts 7-8.

Article 31 explicitly considers the rights of third parties in limiting the rights of patent owners.[43]

At the other end of the spectrum, patents are seen as strong property rights that should seldom, if ever, be encroached. This perspective views patents right as greater private property rights, which will necessarily lead to better social goods.[44]Thus, it is called "Patents as uber-right" believers. In this view, it sees any possible limitation on patent rights as extremely suspect. The advocates of this perspective suggest that limits on patents should be exercised with caution because the nature of the patent right is mostly based upon the right of exclusivity.[45]

For those who regard patents as uber-right consider that patents deserve an superior status for the reason that they provide the necessary reward to fuel innovation that benefits the whole society. In respect of the high price of patented drugs, much of the emphasis was put on the long path towards drug discoveries. As for the fact that high-pricing drugs have impeded access to essential medicines, proponents of this stance implied that the problem is one of poverty , which should be solved outside patent laws.[46]

One of the representatives of this view, for example, is Fred Hassan, Chairman and CEO of major pharmaceutical company Schering-Plough, he stated that "IP protection for pharmaceutical innovation creates a wonderful cycle. It rewards and incentivizes the huge investments needed to create new medicines. Then, on expiration of the patents, the innovation becomes freely available to all. Generic drugs are thus the direct result of IP-fueled innovation. They would not

[43] Ho, *supra* note 39.
[44] *Id*.
[45] *Id*.
[46] See Richard P. Rozec, *The Effects of Compulsory Licensing on Innovation and Access to Health Care*, 3 J. WORLD INTELL. PROP. 889, 896-97 (2000).

exist without IP. And IP, we would not see new advances in medicines that in turn would become generic drugs."[47] In short, he suggested patent protection resulted in low cost generics.

Professor Martin Adelman has similar idea by suggesting that the question of access to medicine often overlooks the facts that "without patents there would be far fewer drugs around for people to access. One cannot have access to something that does not exist."[48] Those who believed in patents as an uber-right suggest that any limitations will sacrifice research into these neglected diseases. For instance, in response to Brazil's compulsory license of the HIV medicines, the major pharmaceutical company Merck alleged that "this expropriation of intellectual property sends a chilling signal to research-based companies about the attractiveness of undertaking risky research on diseases that affect the developing world, potentially hurting patients who may require investment and innovative life-saving therapies."[49]

The uber-right perspective has a tendency to not see a conflict between strong patent rights and competing interests, such as public health. The reason for that is patents rights is a necessity when it comes to innovation, and in the long run possible long-term benefits trump any current access problems. Thus, the proponents of this view would in favor of adopting string international patents standards with minimal exceptions. The permitted situations of granting

---

[47] Fred Hassan, Chairman & CEO, Schering-Plough Corp., Keynote Address at U.S. Chamber of Commerce 5th Annual Intellectual Property Summit, Fueling Innovation: To Be Our Best for a Better World (Oct. 8, 2008), http://www.phrma.org/about_phrma/ceo_voices/fueling_innovation_to_be_our_best_for_a_better_world.

[48] Martin J. Adelman, Compulsory Licensing of Drugs: TRIPS Context 1, Paper Presented at ATRIP Annual Meeting in Tokyo, Japan (Aug. 4, 2003), available at http://www.atrip.org/upload/files/activities/tokyo2003/s02-Adelman_art.doc.

[49] Press Release, Merck & Co., Statement on Brazilian Government's Decision to Issue Compulsory License for STOCRIN™ (May 4, 2007), *at* http://www.merck.com/newsroom/press_releases/corporate/2007_0504.html.

compulsory licenses should be minimized as much as possible due to the decrease in willingness to investment and research under licenses. In addition, they further argued that strong patent systems would improve the economic status of nations by promoting foreign direct investment.[50]

Compulsory license, serves as the most controversial flexibility under TRIPS to preserve the advantages of IPR systems as well as make up for the side effects patent protections have engendered, is used by governments to address public welfare. The pros and cons were discussed and debated intensely among nations and scholars.

1.2. The Interpretations of Article 31 in the TRIPS Agreement

Article 31 of the TRIPS Agreement stipulates basic conditions that must be observed by governments when granting compulsory licenses. Article 31 deals with non-authorized uses that do not meet with one of the three conditions established by Article 30. Article 30 establishes three conditions that any derogation from the exclusive rights must observe: (1) exceptions must be limited; (2) they may not unreasonably conflict with the normal exploitation of the patent; (3) they may not unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties. Only when a person who has not obtained and authorization from patent holder needs to use a patented invention in a way that is not in consistence with Article 30, will Article 31 come into play.[51]

[50] See, e.g., Frederick M. Abbott, *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 VAND. J. TRANSNA'L L. 689, 898 (1989).
[51] Carvalho, *supra* note 4, at 315.

Compulsory license is an authorization granted by governments, which substitute their authority for the consent of patent holders, for a third party in against or regardless of the paten owner's will. It may be granted to two categories of users: the government (or a government agency) or third parties working for the government (such as public contractors); as well as a third party. However, the language in Article 31 does not distinguish the conditions, such as duration and price, based on the specific nature of the licensee, whether a government or a private firm. Therefore, except for formalities and process required for granting compulsory license, governments and private companies are on the same footing. Article 31 of the TRIPS stipulates:

"Where the law of a Member allows for other use[52] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(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 that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member 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 emergency or

[52] "Other use" refers to use other than that allowed under Article 30.

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;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such

use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second

patent."

Due to the vagueness of languages in Article 31, there is no explicit proclamation of the permitted grounds of issuing compulsory licenses. As a result, it leaves considerable room for adjudication and scholars to interpret the clause. Some says the grounds of granting compulsory licenses were therefore open to nation's discretion, and the requirements set out in Article 31 are merely standards of process which should be followed in issuance of such license. The debate of the controversy of compulsory licenses in TRIPS never subsides when it comes to interpretations of the context of Article 31. Most of them were centered on the justification to narrow or broad interpretations of such issue left by the TRIPS Agreements.

1.2.1. Broad interpretations on the grounds of compulsory license

For those who see patent protection as privileges competing with other social interests may in favor of a broader interpreting flexibility in order to give nations more discretion in respect of granting compulsory licenses under their own balancing policy. For example, views in such tendency might suggest that, apart from certain provisions, Article 31 does not generally prohibit any grounds for compulsory licensing means that national discretion to compel a license is implicitly wide-ranging, including a various public interests concerned.[53]

To further support this view, there are several interpretive guidance

[53] *Mexico – Taxes on Soft Drinks: Mexico – Tax Measures on Soft Drinks and Other Beverages*, WT/DS308/AB/R, adopted 24 March 2006 [384].

consistently indicates that Article31 can take precedence over Article 27.1[54] and 28.1[55], which ensure patent owners right on exclusivity. This guidance includes the following reasons: firstly, the titles of the exceptions in Article 30 and 31 make these clauses adopted prior to the patents' rights in accordance with the well-establish rule of *lexspecialis derogate legigenerali*, which conveys that specific law prevails over general law. To affirm that Article 31 is generally subject to Article 27 could limit its application in ways that were not intended either by the negotiators or indeed by the text of TRIPS Agreement. For instance, the WTO panel in the *Canada- Pharmaceutical Patents* case interpreted Article 27.1 flexibly.(The adopted Panel or Appellate Body reports create legitimate expectations among WTO members, and therefore should be taken into account while facing relevant disputes. These reports can provide guidance for the future panel in respect of dispute settlement.[56])Indeed, the Panel ruled that compulsory licensing should be subject to non-discrimination required in Article 27.1. Nevertheless, it emphasized that it "does not prohibit bona fide exceptions to deal with problems that may exist only in

[54] Article 27.1 of the TRIPS Agreement states that "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

[55] Article 28.1 of the TRIPS Agreement stipulates "A patent shall confer on its owner the following exclusive rights:

(a)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 sale, selling, or importing for these purposes that product;

(b)where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process."

[56] *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996[14]; see also *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998[21.5].

certain product area."[57] It can be inferred that Art. 31 is a self standing Article. Therefore, different treatment resulting from compulsory licenses does not necessarily amount to "discrimination" under Article 27 as long as the intent of the measures is in goodwill.

Secondly, the principle in the Vienna Convention on the Law of Treaties (VCLT) seeks conformity to the objectives and principles[58], which is Article 7 and 8 of the TRIPS Agreement, as a whole. According to Dispute Settlement Body (DSU) Article 3.2[59], the provisions of the WTO covered Agreement should be clarified in accordance with customary rules of interpretations of public international laws. Based on the *US – Gasoline*, *US – Shrimp*, *Japan – Alcoholic case*, the VCLT has been long recognized as the customary rules of interpretation of public international law.[60]

The Panel of the WTO dispute settlement expressed their opinions in the *Canada- Pharmaceutical Patents*[61], finding that, "Both the goals and the limitations stated in Articles 7[62] and 8.1[63] must obviously be borne in

[57] *Canada – Pharmaceutical Patents: Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000, DSR 2000:V, 2289.[7.92].

[58] Vienna Convention on the Law of Treaties, Art. 31.1. It stipulates: "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their contex and in the light of its object and purpose."

[59] The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.

[60] *See United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, adopted 20 may 1996, at [17]; see also *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998, at [114]; *Japan – Alcohol*: *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996, at [10].

[61] *Canada – Pharmaceutical Patents*, supra note 57, at [7.26].

[62] Article 7 of the TRIPS states: " The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

[63] Article 8 of the TRIPS Agreement states:

"1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to

mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes."[64]

Article 7 articulates that one of the key goals of the TRIPS Agreement is to strike a balance between the protection of intellectual property rights and other important socio-economic policies pursued by WTO Members. IPRs should work 'in a manner conducive to social and economic welfare'. This means that the recognition and enforcement of intellectual property rights are subject to higher social values (as further developed in Art. 8.1 of the Agreement)[65].The TRIPS Agreement must be viewed as a means for the realization of public policy objectives via the 'inducement to innovation' and the access to the result thereof by those who need them.[66]

Article 8 is an important provision for framing national laws that respond to particular public health and other public interests. It makes clear the measures may be adopted in order to prevent or remedy abuses of intellectual property rights.[67] This suggests that measures adopted by Members to address public health, nutrition and matters of vital socio-economic importance should be presumed to be consistent with TRIPS. Discretion to adopt measures is built into the Agreement. So long as sectors and measures are identified in good faith, the sovereign discretion of the Member adopting such measures should be accepted and

protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. "

[64] CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS 284-87 (2007).

[65] *Id.*, at 99.

[66] *Id.*, at 94.

[67] *Id.*, at 104.

respected.[68]

In that sense, it can be inferred that wide-ranging grounds of compulsory licenses pursuant to national laws balancing various public interests are permitted by the TRIPS Agreement in the perspective of "patents as mere privileges".[69]

1.2.2. Narrow interpretation on grounds of compulsory license

On the contrary, for the advocates for strong patent protections, who deem patents as uber-right, compulsory licenses can, therefore, only be granted on the following limited grounds:

(1) To remedy a practice determined after judicial or administrative process to be anti-competitive (Article 31(k));

(2) To permit the exploitation of a patent which cannot be exploited without infringing another patent (Article (l));

(3) To prevent abuses which might result from the exercise of the exclusive rights conferred by the patent (Article 5 (A)(2)(3) of the Paris Convention);

(4) To repress the lack of or insufficient working of the patented invention (Article 5 (A)(2)(3) of the Paris Convention);

(5) Public interest (of which cases of national emergency or other circumstances of extreme urgency or of public non-commercial use (Article 31(b))[70]

In point of this view, the grant of compulsory licenses based on

[68] CAMBRIDGE UNIVERSITY PRESS, RESOURCE BOOK ON TRIPS AND DEVELOPMENT 127 (2005).
[69] Correa, *Supra* note 64, at 390.
[70] Carvalho, *supra* note 4, at 318.

wide-ranging grounds may be violations of Article 28.1. The main problem with compulsory licenses is that they harm both patentees and the countries where they are granted. On the patent owners' side, the granting of compulsory license basically denies their right protected by the TRIPS Agreement: the right to say "no". On the side of countries granting the compulsory licenses, they have actually producing the results of discouraging any attempt to establish and independent, research-based industry that may meet the demands of the local markets.[71]

These two side effects contribute to the consequence that compulsory licenses will kill any initiative to use creation in the development of new products because technology is easily copied, thus bring greater disadvantage to the society. Before the implementation of the TRIPS, evidence has shown that the countries using compulsory license scheme extensively resulted in the vanishing of local research-based industry within the fields affected by the licenses. For example, during the Uruguay Round, the U.S. research-based pharmaceutical industry made a strong case that without effective patent protection, no pharmaceutical industry based on genuinely inventive activity could survive. In addition, Canada was frequently indicates that, as an illustration of a country whose pharmaceutical industry had been reduced to manufacturing copied products due to the lack of patent protection.[72]

The fact that Article 31 does not define the grounds on which compulsory licenses may be granted does not mean that governments may grant those license under unrestricted discretion, such as on frivolous or on

[71] *Id*.
[72] *Id*. at 316.

no grounds. Considering the rule that compulsory licenses are exceptions to patent right on exclusivity, it should be understood in a restricted way. In other words, governments can only grant compulsory licenses in very exceptional circumstances and when there are serious reasons to justify the grant.[73]

The TRIPS Agreement is not completely silent about the grounds of issuing compulsory license. For one reason, Article 27.1 established that government may not grant compulsory licenses on grounds of lack of local working. National laws may still require the working of the patented invention, but patent owners should be allowed, under Article 27.1 of the TRIPS Agreement and Article III.4 of the GATT 1994, to discharge themselves from the obligation by importing the patented products. For another, compulsory license should not be granted for the mere reason that the patent owner has refused to license the patent to a third party. It must be borne in mind that the essence of patent right is to say "no" to any third party in respect of authorization. Refuse to let the patent owner the possibility of saying "no" is an unacceptable derogation of the patent rights itself, which would be a violation of the core objective of the standards adopted by the TRIPS Agreement. Additionally, in consistence with Article 31 (b) of the TRIPS Agreement, prospective licensee should seek to obtain a voluntary license prior to requesting a compulsory license. In this sense, the patent holders are entitled to deny engaging in licensing agreement.[74]

[73] *Id.*
[74] *Id.*, at 317.

2. The Impact of The Doha Declaration on TRIPS

The introduction of TRIPS brought forth a great deal of health care problems for many less-developed countries. According to reports from some developing countries, 5 or more years after adopting the TRIPS, there was a decrease in the effectiveness of their public health system. [75] Thus, the legitimacy of Pharmaceutical patent protection in developing countries as well as the inefficacy of the provisions granted by TRIPS – particularly, the compulsory license provision was questioned and criticized due to the aggravation of the HIV/AIDS epidemic and the development of expensive patented treatment. Activists accused the International Intellectual Property Institute (IIPI) of "allowing multinational drug companies and developed country government to avoid their responsibilities for the deaths of many millions of people… and deliberately to finesse this culpability"[76]

During the 2001 WTO Ministerial Conference, the Africa group (an alliance of sixty nations) urged for the revision of intellectual property protection in pharmaceutical respect. They argued the less-developing countries should be given the freedom to utilize patented innovation in the case that these countries were promoting public health. Further, they requested this flexibility be amended so that those countries that lacked domestic pharmaceutical manufacturing capacities would be able to import crucial medicines under compulsory license from other countries.[77]

---

[75] Jean O. Lanjouw & Iian Cockcurn, *Do Patent Matter? Empirical Evidence After GATT.* NBER Working Paper Series 7495 (2000), *available at* http://www.nber.org/papers/w7495.pdf

[76] Gillespie-White, L., *What did Doha Accomplish? The Doha Declaration on Intellectual Property Rights and Access to Medicines* (2001), http:// www.iipi.org/ Views/Doha 1101.pdf

[77] Joint communication from the Africa Group, *Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement* (2003),

Initially, those countries received little support for their request. Developed countries take a stance arguing the completeness of the TRIPS Agreement with no need to amend. But the issue of the HIV/AIDS was still put on the agenda for the 4th Ministerial Conference in Doha, Qatar, on November 9-14, 2001 as a compromise. The official objective of the Conference was to confer on which commerce could serve to help developing countries. The result of the Conference was the publication of three texts: The Ministerial Doha Declaration, The Declaration Related to TRIPS and Public Health, and the decision to implement related issues of the conference. The Declaration Related to TRIPS and Public Health is the document that patent protections concerned, which is the so-called "the Doha Declaration" in this thesis. At first, United Stated and Switzerland refused to accept the Doha Declaration, but the Declaration was finally adopted "on the basis of last minute compromises".[78]

2.1. The Legal Status of the Doha Declaration

An important issue is whether the Doha Declaration, which explicitly gives members flexibility on the grounds of issuing compulsory license, constitutes a subsequent agreement among the parties that may be considered as part of the appropriate context in interpreting TRIPS. If positive, the declaration then provides crucial clarification that countries have "the right to determine what constitutes a national emergency or other circumstances of extreme urgency" with regard to compulsory license. Some scholars argued that the Declaration is a mere political statement of no interpretive weight.[79] Others concluded it is, in fact, a

http://www.iatp.org/documents/taking-forward-the-review-of-article-273b-of-the-trips-agreement

[78] Carlos M. Correa, *TRIPS and Access to rugs: Towards a Solution for Developing Countries without Manufacturing Capacity*, 17 Emory Int'l L. Rev. 389, 389-406 (2003).

[79] *See* U.S. Gen. Accounting Office, Intellectual Property--U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification 3 (GAO 2007) (noting that the United

subsequent agreement.[80]

According to scholar Gathii, the legal status of the Doha declaration under international law discloses at least three possibilities:[81]

2.1.1. As a subsequent agreement under Article 31. §3(a) of the VCLT regarding the interpretation of the TRIPS Agreement.[82]

Under recent WTO Appellate Body jurisprudence, there is precedent for giving a subsequent agreement between parties to a WTO treaty the same legal status as the WTO treaty.[83] The Doha Declaration emerged from the WTO decision-making framework and was issued by the Ministerial Conference at Doha. This is consistent with the WTO's established practice of decision-making by consensus.[84] Declarations negotiated through the legislative process

---

States considers the Doha Declaration to be a political statement that does not modify TRIPS); Press Release, Pharmaceutical Research and Mfrs. of America, WTO Doha Declaration Reaffirms Value of Intellectual Property Protection (Nov. 14, 2001), *available at* http://www.phrma.org/mediaroom/press/releases///14.11.2001.310.cfm (stressing that the Declaration was a "political statement"); Press Release, U.S. Trade Representative, Zoellick Says World Has Chosen Path of Hope, Openness, Development and Growth (Nov. 14, 2001) *available at* http:// www.ustr.gov/Document_Library/Press_Releases/2001/November/USTR_Zoellick_Says_ World_Has_Chosen_Path_of_Hope,_Openness_Development_Growth.html (referring to USTR remarks on Doha Public Health Declaration as a "political signal"). Even some who are sympathetic to the need to accommodate pub-lic health and TRIPS have characterized the Doha Public Health Declaration as a political statement. *See*, e.g., Walden Bello, Learning from Doha, Dec. 7-9, 2001, http://www.focusweb.org/publications/2001/learning-from-doha.html (suggesting that the importance of the Declaration should not be exaggerated in light of the fact that some statements are merely political); James Love, Consumer Project on Technology, Views on the Draft Declaration on the TRIPS Agreement and Public Health, Nov. 13, 2001, http://www.focusweb.org/publications/2001/views-on-draft-declaration-on-trips-and-health.html.

[80] *See*, e.g., Carlos Correa, *Implications of the Doha Declaration on TRIPS Agreement and Public Health* 45(WHO 2002), *available at*http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf; Steve Charnovitz, *The Legal Status of the Doha Declarations*, 5 J. Int'l Econ. L. 207, 211 (2002); Carmen Otero Garcia-Castrillon, *An Approach to the WTO Ministerial Declaration on the TRIPS Agreement and Public Health*, 5 J. Int'l Econ. L., 212, 212 (2002); James Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 Harv. J.L. & Tech. 291, 314-16 (2002).

[81] James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health under the Vienna Convention on the Law of Treaties*, 15 Hav. J. L. & Tech 2, 299 (2002).

[82] *See* VCLT, May 23, 1969, art.31, §3(a), 8 I.L.M. 679, 691-92

[83] *Japan – Alcohol*: *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996 [24].

[84] Art. IX(1) of the Agreement Establishing the World Trade Organization, 1994. Art. Art.IX(2)provides that the "Ministerial Conference and the General Council shall have the exclusive

of the WTO have been used to interpret substantive provisions of WTO treaties. Thus, the Doha Declaration proposes a balancing approach to interpretation of the TRIPS Agreement and interpreting specific provisions of the TRIPS Agreement.

2.1.2. As evidence of subsequent practice establishing the understanding of WTO members regarding interpretation of the TRIPS Agreement

Pursuant to the Declaration's exhortation that all provisions of the TRIPS Agreement be read in light of its objectives and principles, it is untenable to suggest that the invocation of compulsory licensing under Article 31 to address a public health emergency would necessarily be overridden by the provision of Article 27.1 on patent right or even the rights to normal exploitation and legitimate interests of patent owners referred to in Article 30.

Article 31 § 3(b) of the VCLT describes the role of subsequent practice in treaty interpretation:"subsequent practice…establishes the agreement of the parties regarding its interpretation."[85] "Agreement " includes both agreement in writing, such as the Doha Declaration, as well as agreement manifested by conduct, such as subsequent practice.[86]

2.1.3. As a declaration of commitment and intent that does not constitute an enforceable legal obligation

The Doha Declaration's legally binding status depends on the

---

authority to adopt interpretations of…[WTO]agreement ." It further provides that the interpretation of the WTO Agreement such as TRIPS would be made on the recommendation of the Council overseeing the implementation of that Agreement.

[85] VCLT, May 23, 1969, art. 31, § 3(b), 8 I.L.M. 679, 691-2 (1969)

[86] Humphrey Waldock, *Sixth Report on the Law of Treaties*, 2 INT'L LAWCOMM'N 51, 99 (1996)

circumstances in which it was formulated, specific wording, subject matter, and the degree of support.[87] Where vast majority of States signify their acceptance to a declaration, this can be equivalent to codification of customary international law.[88] Not a single WTO member dissented from or abstained from voting for the Doha Declaration. Even if a country concluded that the Doha Declaration is not legally binding, it still constitutes soft law with substantial hortatory authority that puts political pressure on governments and international institutions to comply.[89]

2.2. The Interpretation of the TRIPS According to the Doha Declaration

If the in Doha Declaration has interpretive weight according to some scholars assert, its influence on TRIPS can be explained as follow: The Doha Declaration on the TRIPS Agreement, adopted on 14 November 2001, explicitly underscored that it is necessary for the TRIPS Agreement to address issues in respect of health problems which afflicted developing countries and least-developed countries. It calls upon attentions for placing the needs and interest in those countries at heart of application of TRIPS provisions. Declaring that members should make positive efforts designed to deal with the issues.

---

[87] *See* IAN BROWNLIE, PRINCPLES OF PUBLIC INTERNATIONAL LAW 15 (4th ed. 1990); Bruno Simma& Philip Alston, *The Sources of Human Rights Law: Custom, Jus Congens, and General Principles*, 12 Austl. Y. B. Int'l L. 82 (1992); OSCARSCHACHTER, INTERNATIONAL LAW IN THEORY AND PRACTICE 85 (1991); ANTHONY AUST, MODERN TREATY LAW AND PRACTICE 26-46 (2000).

[88] Abbott Frederick M., *The TRIPS Agreement, Access to Medicine and the WTO Ministerial Declaration*, 5 J. WORLD INTELL. PROP. 15, 612 (2002).

[89] RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW OF THE UNITED STATES, § 103 cmt. c (1987); *see also* James T. Gathii, *Good government as a Counter Insurgency Agenda to Oppositional and Transformative Social Projects in International Law*, 5 BUFF. HUM. RTS. L. REV. 65, 117-20 (1990).

The declaration plays an important role in connecting the application of intellectual property rights stipulated by TRIPS and the crucial problems of public health facing less-developed countries. It officially recognize the gravity of health problems in these countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, pointing out that TRIPS should be "interpreted an implemented in a manner supportive of WTO members' right to protect public health and in particular, to promote medicine for all"[90] It acknowledged that ensuring respect of intellectual property rights protection is an essential way to incentivize the development and research of new drugs. At the same time, it also recognized the concerns expressed by developing countries about the effect of patent protection on the price of drugs. Thus, by giving weight of effectiveness to the declaration interpreting TRIPS, the facilitation of use of compulsory license was a main focus as a means dealing with the access to medicines.

By examining the context of the declaration, much effort was put in establishing a mechanism useful for issuance of compulsory license by which developing countries can make use of in order to provide access to drugs for the diseases-stricken portion of their populations. As elucidated in Paragraph 5, it states that "each [WTO] member has the right to determine what constitute a national emergency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency." In addition, Paragraph 5 further provides that

[90] The Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/Dec/2 (Nov. 14, 2001).

compulsory licenses can be granted under domestic law without prior negotiation without patent owners.[91]

The Doha Declaration allows nations additional flexibility under TRIPS with regard to granting compulsory licenses, defining national emergencies. To the extent these options under the Declaration are utilized by WTO members, they help constitute subsequent practice that can be used in interpreting the TRIPS agreement.

Moreover, a mechanism was establish to permit countries with incapacity and insufficiency of manufacturing generic drugs to solicit importation of generic versions of patented drugs under compulsory licenses to third party countries. It is a notable design considering that, before Doha, only countries such as India and Brazil had considerably large pharmaceutical manufacturing capacities, making them able to take advantage of the compulsory licensing provision. The manufacturing capacity in generic versions of medicine was crucial under circumstances that multinational companies with forfeited patents refused to continue production or supplying the country with these medicines.

In conclusion, the Doha Declaration on TRIPS and Public Health

[91] Paragraph 5 of the Doha Declaration on TRIPS and Public Health states: "Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.
b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."

clarifies the reference in TRIPS Article 31 to emergencies and remuneration that justify the issuance of compulsory licenses. However, one commentator has argued that this approach "leaves the door wide open for abuses by allowing WTO members absolute subjective power in determining whether to issue a compulsory license."[92]

3. The Cases of Compulsory Licenses in Certain Countries

The most significant influence of a compulsory license is to give patented products wider use than the patent owner would presumably allow in ordinary scenario. Under compulsory licensing, the binds of private ownership are unleashed, permitting the generic version goods to enter into the market without infringement of patent. In addition, the act of granting compulsory licensing is usually retrospective in nature. Such measures are generally imposed only after considering property that already exist[93] (but not always the case),and then reallocating ownership rights by nationalizing them. Although the incentive to invent with respect to the licensed invention cannot be changed (since invention has already taken place), innovation policy advocates argue that the incentive to create future inventions is decidedly reduced.[94]

Generally speaking, compulsory licenses are usually resorted to under the following situations. First, to increase access to the new inventions is often the motive. For instance, when a patent owner simply refuses to practice an invention,

[92] Jamie Feldman, Note, *Compulsory Licenses: The Dangers behind the Current Practice*, 8 J. INT'L BUS. & L. 137, 163 (2009).
[93] Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, 1295 (1996).
[94] Colleen Chien, *Cheap Drugs at What Priceto Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 856 (2003)

depriving one or more countries of application of such technology, it becomes an obstacle of technology accessibility.[95] According to good business judgment, it implies that this kind of act may be an unusual occurrence for the reason that it would be economically irrational to withhold a product which could produce some profit over marginal costs in the markets. But in respect of pharmaceuticals, it is very possible to envision that under certain situations such denial of patent application might occur. To elaborate, a company may wish to hold on to tight control over distribution and pricing of its patented products in several markets[96]. One market's refusal to limit redistribution into other markets may be faced with this scheme, compelling a company to simply reduce or eliminate sales in the offending country to patent owner.[97]

Secondly, it is not unusual that a company is in favor of one patented product over another by simply precluding the sale of the unwanted patented product through its conferred patent rights.[98] In either the first or second case, supposed the technology in question is relevant to an essential drug, the withholding of such patent or the precluding of the unwanted products would result in a very negative impact on the public.

Aside from the consideration of access, the other situation of potential compulsory license is that, a person might seek to apply for compulsory licensing in order to redefine a patent owner's market influencing power. The most typical case occurs as countermeasure for the purpose of modifying the patent right's

---

[95] Gianna Julian-Arnold, International Compulsory Licensing: The Rationales and the Reality, 33 IDEA 349, 349-55 (1993).

[96] *See* Patricia Danzon& Michael Furukawa, *Prices and Availability of Pharmaceuticals: Evidence from Nine Countries*, HEALTH AFFAIRS, at http://healthnewsdaily.elsevierbi.com/~/media/Images/Publications/Archive/The%20Pink%20Sheet/65/044/00650440021/031103_health_affairs_rx_pricing.pdf

[97] *See* Daniel R. Cahoy, *Patent Fences and Constitutional Fence Posts: Property Barriers to Pharmaceutical Importation*, 15 FORDHAM INTELL. PROP., MEDIA & ENG.L.J. 623, 701-02 (2005).

[98] Kurt M. Saunders, *Patent Nonuse and the Role of Public Interest as a deterrent to Technology Suppression*, 15 HARV. J.L. & TECH. 389 (2002).

effect on prices from a public policy perspective. Theoretically, if there is no similar substitute for the patented goods or service, this would result in the monopoly of the patent holder and enable the patentee to control supply as well as price.[99] In aspect of intellectual property rights, limiting the patent right of exclusivity has the effect of canceling part of this monopoly, allowing other competitors to enter into the market. If their marginal costs are lower than the monopolist's prices, the price could be expected to come down (absent any payment back to the monopolist).[100] Developing countries use this approach to drive down the price by introducing generic version products into the market, in the negotiating process prior to compulsory license, such method is a powerful leverage commonly maneuvered by the Brazilian government to win a price reduction from multinational pharmaceutical companies. More detailed would be expounded in the following sections.

There are a plenty of global experiences with compulsory licenses, especially in pharmaceutical aspect. The following cases were selected for reference due to its large scale of licensing or controversial essence.

3.1. Compulsory Licenses in Thailand

Thailand has a national mandate to provide universal medicines to all its citizens pursuant to the National Health Security Act of 2002 and access to anti retroviral for all AIDS patients since 2003.[101] For the purpose to achieve the mandate, after years of negotiations with patent owners that failed to yield significant price reduction, Thailand issued compulsory

[99] Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 CHI. J. INT'L L. 47, 57 (2002).
[100] *Id*. at 56.
[101] Thai National Health Security Act B.E. 2245; *see also* Thai Constitution B.E. 2250, § 51.

licenses on essential patented drugs, including anti-retroviral drugs that cannot otherwise be provided despite increases in the public health budget.[102]The licenses were issued only to cover Thai citizens who are supported by government funded insurance and not the small percent of Thai citizens who can afford the premium patent prices for the drugs. In this way, the patent owners of the compulsory licenses can receive both compulsory license royalties for drugs provided for low-income citizens as well as revenue from premium of patented medicines in the market of wealthy Thai citizens.

At the end of 2006, the government of Thailand further proclaimed that it intended to issue several compulsory licenses for patents related to AIDS and heart medications.[103] The act was directed to reduce the price of branded drugs, and the license set compensation to patent owners at a mere 0.5% royalty on generic sales.[104]

On November 29, 2006, compulsory license was issue on Merck's patented drug Efavirenzz. Thailand's license stated that it was for non-commercial purpose and for the public interest to help achieve its policy of universal access to antiretrovirals for the 500,000 Thai citizens that need them for long-term use. The compulsory license also stated that the high costs Efavirenz (an effective first line treatment for AIDS that has fewer adverse side effects) without a license resulted in many Thai patients having inadequate access. The act was expected to halve the treatment cost

[102] Ho, *supra* note 1, at 412.
[103] *See* Announcement of the Dep't of Disease Control, Ministry of Pub. Health, Thai. On the Pub. Use of Patent for Pharmaceutical Products (Nov. 29, 2006), *available at* http://www.wcl.american.edu/pijip/documents/ThailandCLAnnouncement.doc
[104] Ministry of Pub. Health Announcement Regarding Exploiatation od Patents on Drugs and Medical Supplies for Clopidogrel (Jan. 25, 2007), *available at* http://www.wcl.american.edu/pijip/documents/thaicl-plavix.pdf?rd=1

so that more patients could be covered with the goal of having all new patients treated with Efavirenz as patients are treated in developed countries.[105]

In 2007, A Thai compulsory license on the AIDS drug Kaletra was issued. The government of Thailand estimated that about ten percent of patients required second-line treatments such as Kaletra within the first few years, or else such patients will die. Prior to the compulsory license, Kaletra was priced at $2200 per patient per year by patent owner Abbott, a cost that is close to the yearly income of a Thai citizen.[106] At the same time, Bristol Myers' antiplatelet drug Plavix, which was useful for treating heart disease, also was compulsory licensed.

After the three compulsory licenses, Thailand issued a ninety-paper white paper, entitled "Facts and Evidence on the Ten Burning Issues Relating to the Government Use of Patent in Thailand," disclosing supporting documents to defend its acts. The paper explained its health needs and why its acts were consistent with the TRIPS provisions. However, the paper raised international concerns because of asserting that issuing compulsory license without prior negotiations is generally more effective. Additionally, the document went beyond its original intent by considering

---

[105] Each license stated "member countries have a right to issue a safeguard measure to protect public health, especially universal access to essential medicines using compulsory licensing on the patent of pharmaceutical products." Notification of the Department of Disease Control, Ministry of Public Health, Re: Exercising of Right Under Drugs and Pharmaceuticals Products Patent (Nov. 29, 2006), reprinted in Ten Burning Issues--Government Use of Patents, supra note 10, at 39 [hereinafter Efavirenz License]; Notification of the Department of Disease Control, Ministry of Public Health Re: Exercising of Right under Drugs and Pharmaceuticals Products Patent for Combined Formulation of Lopinavir and Ritonavir (January 24, 2007), reprinted in Ten Burning Issues--Government Use of Patents, supra note 10, at 43 [hereinafter Kaletra License]; Notification of the Ministry of Public Health Re: Exercising of Right under Drugs and Pharmaceuticals Products Patent for Clopidogrel (Jan. 25, 2007), reprinted in Ten Burning Issues--Government Use of Patents, supra note 10, at 45 [hereinafter Plavix License].

[106] See, e.g., Robert Weissman, Cakewalk Ken Adelman Returns to the Stage, Multin'l Monitor, Mar. 1, 2007, *available at* http:// www.multinationalmonitor.org/mm2007/032007/weissman.html.

issuing more licenses up to fifteen percent of patented drugs not only for epidemics but also when the market price was considered too high to achieve Thailand's universal access to essential drugs.

Thailand went on issuing licenses for four cancer drugs in January 2008, on the eve of a change in government administration,[107] asserting they were necessary because cancer is currently the number one cause of death in Thailand but most effective cancer treatments are patented without cover on the Thai List of Essential Drugs due to their high costs, and thereby inaccessible to the citizens. The government contended that cancer is no less serious than HIV/AIDS, accounting for 30,000 deaths a year with 100,000 new cases diagnosed each year.[108]

The implementations of the signed licenses were delayed in order to continue further negotiations. One case was successfully revoked on the deal of patent owner Novartis agreed to provide its drugs Glivec at no cost to Thai citizens meeting certain income requirements. As for the other three cases, Thailand was not satisfied with the prices of their patented drugs. Although other patentees had offered discounts for up to one third the original price, the government asserted that it would still impose

[107] On January 4, 2008, licenses were issued on Letrozole, a breast cancer medicine made by Novartis AG, Docetaxel, the breast and lung cancer drug by Sanofi-Aventis; Erlotinib, a drug for treating, lung, pancreatic, and ovarian cancer by Roche; and Imitinab, a cancer drug patented and sold by Novartis as Glivec. Notification of the Ministry of Public Health Re: Exercising of Right on Pharmaceuticals Products Patent for Docetaxel (Jan. 4, 2008) [hereinafter Docataxel License]; Notification of the Ministry of Public Health Re: Exercising of Right on Pharmaceutical Products Patent for Letrozole (Jan. 4, 2008), reprinted in Ten Burning Questions on Cancer Drugs [hereinafter Letrozole License]; Notification of the Ministry of Public Health Re: Exercising of Right on Pharmaceutical Products Patent for Erlotinib (Jan. 4, 2008), reprinted in Ten Burning Questions on Cancer Drugs [hereinafter Erlotinib License]; Notification of the Ministry of Public Health Re: Exercising of Right under Drugs and Pharmaceuticals Products Patent for Imatinib (Jan. 25, 2008), reprinted in Ten Burning Questions on Cancer Drugs [hereinafter Imatinib License].

[108] Thai National Health Security Office, The Ten Burning Questions on the Government Use of Patents on the Four Anti-Cancer Drugs in Thailand 4 (Feb. 2008), *available at* http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_ CL_%5BEN%5D.pdf [hereinafter Ten Burning Questions on Cancer Drugs].

compulsory licenses unless the prices of patented products reduced to no more than five percent higher than those offered by generic competitors.[109]

Although facing great pressure from the multinational pharmaceutical companies' threatening impact on Thailand's international trade, Thailand ultimately decided not to revoke any of the compulsory licenses.[110] A number of health advocates made public statements to encourage continuation of the compulsory licenses. In fact, a WHO group confirmed that the use of TRIPS flexibilities, such as compulsory license, were permissible means of cost containment in providing essential medicines that were not otherwise affordable.[111]

The criticism of the Thailand's compulsory license barely subsided. The critics suggested that TRIPS licenses should be limited in scope of very exceptional circumstances. For example, Switzerland's public statement pointed out that TRIPS Article 31 (c) requires licenses be limited in scope and duration, which made the Thai licensing inadequately limited in these respect.[112] Moreover, some implied that while Thailand may not explicitly

[109] Letter from Ira Magaziner, Chairman, Clinton Foundation, to Mongkol Na Gonkhla, Minister of Public Health (Feb. 16, 2007), reprinted in Thai Ministry of Public Health and Thai National Health Security Office, Facts and Evidences on the Ten Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand 96 (Dr. Vichai Chokevivat ed., Sangsue Co., Ltd., Thailand, 2007), *available at* http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf

[110] *See*, e.g., Pongphon Sarnsamak, No Cancellation of CL for Cancer Drugs, Nation, Mar. 4, 2008, *available at* http:// www.nationmultimedia.com/2008/03/03/national/national_30067110.php; Nicholas Zamiska, Thai Ministry to Recommend Ignoring Patents on Cancer Drugs, Wall St. J. Online, March 11, 2008, http:// online.wsj.com/article/SB120515886199824251.html.

[111] World Health Organization, Improving Access to Medicines in Thailand: The Use of TRIPS Flexibilities (2008), *available at* http://www.moph.go.th/hot/THAIMissionReport%20FINAL15feb08.pdf

[112] The United States has placed Thailand on the "priority watch list" of countries, which may lead to unilaterally imposed economic sanctions. Office of the U.S. Trade Representatives, Special 301 Report 27 (2007); Office of the U.S. Trade Representatives, Special 301 Report 36-37 (2008).
In addition, although no other country has taken action towards retaliation, Switzerland and the E.U. Trade Commissioner have publicly suggested that Thailand's licenses were inappropriate. Aide Memoire: Compulsory Licenses in Thailand on Pharmaceuticals Under Patent Protection (Feb. 25, 2008), *available at* http://www.keionline.org/misc-docs/1/swiss2thailand_cl.pdf; Letter from Peter Mandelson, E.U. Trade Comm'r to Krirk-kraiJirapaet, Thai; Minister of Commerce (July 10, 2007), *available at* http://www.wcl.american.edu/pijip_static/documents/mandelson07102007.pdf?rd =1

violate any explicit provision of TRIPS, its action were nonetheless impermissible, or at least suspect. Although that TRIPS does not list specific causes for which governments can grant compulsory licenses, which is regrettably vague, Thailand's action still clearly breached "the spirit, if not the letter" of the relevant provisions.[113] Others suggested that the clarifying statements in the Doha Declaration are of dubious value, and Thailand's intention to characterize the Declaration as prompted by activists trying to alter TRIPS. The Doha Declaration was intended to be limited to health emergencies, not budgetary shortfalls.[114]

3.2. Compulsory Licenses in Brazil.

Among the developing countries with insufficient innovations in pharmaceuticals, Brazil is one of the few countries that has the capacity to use the compulsory licensing mechanism successfully for the purpose of price reduction in medicines. In fact, the Brazilian government has utilized the compulsory licensing mechanism for negotiation in price reduction aspects, and successfully reduced the price of drugs up to seventy percent of the original price.[115]

Brazil has joined the ally of protecting intellectual property rights for a long history. As a matter of fact, Brail was one of the original contracting parties to the Paris Convention back in 1883. However, the nation's policy

[113] Commentary, Lonely Thailand, WALL ST. J., May 23, 2007, at 11.
[114] Letter from Lila Feisee, Managing Dir., Biotechnology Indus. Org., to Jennifer Choe Groves, Dir. for Intell. Prop. and Innovation and Chair of the Special 301 Comm., at 3-4 (Feb. 11, 2008), *available at* http://www.pharmalot.com/wp-content/uploads/2008/02/bio-letter-to-ustr.pdf; PhARMA Special 301 Submission 2007 2 (2007); *see also* Phusadee Arunmas, Thai Traders Urge 'Extreme Caution' on CL, Bangkok Post, Feb. 14, 2008, *available at* http://www.biothai.org/cgi-bin/content/news/show.pl?0527
[115] Background Document for Third Commission Meeting, *Brazil: Commision on Intellectual Property Rights, Innovation and Public Health* (2005), *at http://www.who.int/intellectualproperty/events/BackgroundPaper.pdf*

shifted to the protection of public health in mid-1940's and excluded pharmaceuticals from patent protection. The policy was later ratified in 1969 and authorities concerned made a commitment to provide universal access to drugs and treatment to all citizens in the country's constitution, which states that" health care is the rights of all citizens and the duty of the State."[116]

It was predictable that Brazil's membership into the WTO would obstruct the viability and sustainability of its public health system functioning. And the reason for Brazilian's government early decision to comply with the TRIPS Agreement had much to do with its concerns of suffering retaliation by the developed countries, especially the United States. The strong pharmaceutical industry in Brazil had posed a threat to U.S. owned international corporations, which is conflicting with the U.S. ratification of series of policies designed to protect its export markets against foreign generic manufacturing. Thus, by 1989 Brazil was one of the U.S. "Special 301"[117] The U.S. imposed 100% tariffs on $39 million imports from Brazil when Brazil refused to abide by the U.S. demand on the protection of intellectual property rights. In 1996, Brazil finally succumbed to the great pressure from the U.S. and amended its patent legislation. Nevertheless, in compliance with the TRIPS Agreement, the new enactment

[116] Brazilian Constitution, Article 196.

[117] USTR."1989 Special 301 Report", 1989, *available at* http://keionline.org/sites/default/files/ustr_special301_1989.pdf.The Special 301 Report is prepared annually by the Office of the United States Trade Representative (USTR) under Section 301 as amended of the Trade Act of 1974. The reports identify trade barriers to US companies and products due to the intellectual property laws, such as copyright, patents and trademarks, in other countries. Each year the USTR must identify countries which do not provide "adequate and effective" protection of intellectual property rights or "fair and equitable market access to United States persons that rely upon intellectual property rights". Under the Special 301 provisions, amended into Section 301 of the Trade Act of 1974 by the Omnibus Trade and Competitiveness Act of 1988, the USTR must also undertake annual surveys of foreign countries' intellectual property laws and policies.

of the patent laws included the right to issue compulsory license under circumstances such as the patent system's failure to protect against abuse of IPR, abuse of economic power, dependent patent behavior, or in case of national emergency or public interest.[118]

Later on, the Brazilian government realized the high pricing medicines had put its public health system, especially the AIDS/HIV program in jeopardy. Moreover, it was in conflict with its policy to provide universal access to treatment for all citizens. In response to the crisis, the authorities concerned put together a committee for the purpose of negotiations with the multinational corporations operating within its country in respect of the price reduction in essential medicines. Also, a study of thorough research was conducted by the government, which is focused on the price of manufacturing of drugs under consideration to estimate the impact on budget and cost on state-owned pharmaceuticals.[119]

Months before the Doha Declaration, Brazil became the first countries announcing its intent to issue compulsory licenses mechanism for some of Merck's and Roche's patented drugs as a means of price reduction. In response, the United States filed a trade dispute under the WTO's DSU against Brazil in 2000.[120] The complaint involved a Brazilian law that empowered the Brazilian government to grant compulsory licenses for failure to work patent it had granted.[121] Specifically, the complaint claimed that Brazilian Industry Property Law was in violation of the TRIPS

[118] DUNCAN MATTHEWS, GLOBALIZING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT 24, (2002).
[119] Ten Burning Issues, *supra* note 109.
[120] Press Release, Office of the United States Trade Representative, U.S. and Brazil to cooperate on HIV/AIDS and WTO Patent Dispute(June 25, 2001), *at* http://usinfo.state.gov/topical/econ/ipr/ipr-braziltrips.htm.
[121] WTO Notification of Mutually Agreed Solution, Brazil-Measures Affecting Patent Protection, WT/DS199/3 (Jan. 9, 2001)

Agreement, particularly Article 68, which is known as the "local working" provision. The provision permits compulsory licenses in cases where patent owners fail to produce the products locally within three years of granting of the patent. According to the claims of the U.S., such legislation discriminated against imports and was in direct violation of Articles 27 and 28 of the TRIPS Agreement.[122]

Brazil contended that Article 68 did not violate the TRIPS Agreement because it is consistent with the purpose of promotion of objectives explicitly addressed in TRIPS, which is to protect public health in terms of pharmaceutical patent. The dispute between Brazil and the United States brought about a great deal of controversial issues among health activists worldwide and an enormous upheaval forcing the U.S. to withdraw its file on June 25, 2001. However, both parties entered into an agreement that "Brazil would henceforth…hold prior talks with the United States with sufficient advance notice to permit constructive discussions in the context of a special session of the US – Brazil Consultative Mechanism, should Brazil deem it necessary to apply Article 68 to grant a compulsory license on patents held by the U.S. companies."[123]

At the same time of the complaint filed, the Brazilian government continued its negotiation with Merck and Roche. The local pharmaceutical producing capacity was actually the most important leverage for Brazil to pave the way for successful negotiation. Also, the government established a domestic laboratory, evaluating the cost of local production. The public-run laboratory estimated that production could be achieved at 60% of the cost.

[122] *Supra* note 113.
[123] Ten Burning Issues, *supra* note 109.

This served to set the standard in negotiation and was ultimately the discount rate agreed with Roche. The extensive preparation as well as the visibility of the Brazilian AIDS/HIV program, combining with considerable domestic pharmaceutical manufacturing capacity to produce generic version of patented drugs, contributed to the successful negotiations with the multinational companies. Brazilian fully utilized the advantages of a well-established history of public health perspective-based models as well as public pressure, standing against the pharmaceutical giants such as Merck and Roche.[124]

Compulsory licenses became the most important means for Brazil to eliminate the barrier to medicine accessibility and allowing the generic version of patented products to break into the exclusive markets. By using it tactically, the Brazilian government realized its commitment to provide essential medicines for all its citizens through the negotiations with major pharmaceuticals companies in respect of price reduction. During 1996 to 2003, the authorities concerned in Brazil successful reduced the price on imported drugs by 47 % of the cost in average. In 2003 alone, the price reduction was 68% for AVRs (medicine for AIDS treatment) through negotiations with Merck, Abbott, Bristol-Myers Squibb, Gilead and Roche.[125]

It is notable that, although compulsory license has been Brazilian government's tactical instrument for promoting access for drugs, it was until 2007 that the authorities concerned issued its first compulsory license for two patented HIV/AIDS medicine, with a 1.5% return afforded to the patent

[124] ARACHU CASTRO & MICHAEL WESTERHAUS, ACCESS TO GENERIC ANTIRETROVIRALS: INEQUITY, INTELLECTUAL PROPERTY LAW, AND INTERNATIONAL TRADE AGREEMENTS 85-89 (2007).
[125] *Supra* note 107; *see also*Ten Burning Issues, *supra* note 109.

holders as remuneration. Since 2006, the annual cost of Merck's Efavirenz (medicine for AIDS treatment) for the Brazilian government was $42 million, at $1.59 per pill. Brazil's Health Ministry claimed that they could import a generic version of the drug from India at a price of $0.45 per pill. After rejecting Merck's offer of $1.10 per pill, on April 25, 2007, the Brazilian government took its final step in issuing a compulsory license on the generic version of the patented drugs imported from India. As for Merck, it received royalties of 1.5%. In justification, the Brazilian government claimed that this act has saved them $30 million annually, and the president of Brazil stated that public health should not be sacrificed for the sake of world trade.[126]

Aside from compulsory license, the Brazilian government has also invested considerable funds in the domestic research and development capacity. In 2001, the investment was approximately $212 million on health research alone. By 2003, the funds were doubled.

Brazil has a three-pronged approach in order to protect its compulsory license. (1) Brazil has the capacity to manufacture locally any HIV medicines that are not subject to patent protection due to its predate legal protection. (2) If the needed drugs are patented, the Brazilian government seeks price reductions through negotiations with patent owners, reaching to the price which is lower enough for the government to provide its citizens with essential drugs for free. (3) Only when the negotiations all failed, does Brazil threaten to issue a compulsory license for the targeted drugs. The Brazilian has successfully used the threat as powerful leverage to secure

[126] Vera Zolotaryova, Note, *Are we There Yet? Taking "TRIPS" to Brazil and Expanding Access to HIV/AIDS Medication*, 33 BROOK. J. INT'L L. 1099, 1110-12 (2008).

affordable price for needed drugs.[127]

3.3. Compulsory Licenses in Canada

The compulsory licenses in Canada discussed here was distinct because they were granted for export instead of domestic supply. Article 31 (f) of the TRIPS Agreement is a controversial clause, which stipulates that the uses under a compulsory licenses must be "predominantly for the supply of domestic market." For countries with little or no local pharmaceuticals manufacturing capacity, typically developing and least developed countries, the declaration of national health emergency, for example, in response to wide spread HIV/ADIS infections has little practical benefits. These countries are lacking of the capacity of producing generic version of patented medicines. To exacerbate this situation, the terms of Article 31(f) largely prohibit supply from another country in which a compulsory license has been granted.[128]

To solve this problem, paragraph 6 of the Doha Declaration directed the TRIPS Council to remedy the controversy and to facilitate export of generic drugs to developing countries and least developed countries with limited or no capacity of pharmaceutical manufacturing. In 2003, the Council adopted the 30 August Decision waiving the domestic use requirement for compulsory licenses. The waiver was subject, however, to several complex procedures and notification rules applicable to both exporting and importing WTO member countries. Both the countries have

[127] Robert Bird & Daniel R. Cathoy, *The Impact of Compulsory licensing on Foreign Direct investment: A Collective Bargaining Approach*, 45 AM. BUS. L. J. 283, 309-12, 315-16 (2008).
[128] Helfler, *supra* note 22, at 123.

to issue a compulsory license to give the remedy a go.[129] Furthermore, the Council agreed to make such waiver of Article 31(f) permanent by adopting a formal amendment to TRIPS 31 *bis*.[130]

After the implementation of the 30 August Decision, which allows compulsory license for export to developing countries and least developed countries, Canada amended its patent law in response to pressures by Canadian civil organizations and the UN Special Envoy on HIV/AIDS in Africa by committing in May 2004. It became one of the first member nations to follow the WTO decision. The enactment of the legislation was codified in Canada's Access to Medicines Regimes (CAMR), which sets forth the process or obtaining a compulsory license for export. According to

---

[129] Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 326-48 (2005).

[130] Article 31 *bis* :

"1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f)."

the CAMR, the concerned rules are applied under government by therapeutic products directorate of Health Canada, the agency to which a manufacturer file applications for export authorization under CAMR.[131]

In July 17, 2007, Rwanda became the first country to notify the WTO of its intention to take advantage of the compulsory licensing provisions of the 30 August Decision, paragraph 6 of the Doha Declaration, and Article 31 of the TRIPS Agreement by importing the generic version of HIV/AIDS cocktail drug Apo TriAvir from Canada. Such production and export of this kind of drug was the first and currently the only use of CAMR legislation since its adoption in 2004.[132]

Before taking the advantage of compulsory licenses, Rwanda has been and is currently stricken by HIV/ AIDS epidemic. An estimated 200,000 are infected with HIV or AIDS among its total population of approximately 9.3 million citizens. However, only about 44,000 patients received effective antiviral treatment. The high infection rate, coupled with the country's insufficient medical supplies and doctors, cycle of poverty, as well as history of civil war, all make the need for sufficient and effective treatment to fight HIV/AIDS extreme urgent.[133]

In December 2004, a Canadian generic pharmaceutical manufacturer, Apotexmade, committed itself to develop a "fix-dosed" combination of the HIV/AIDS antiviral drugs: zidovudine, lamivudine, nevirapine. These mentioned medicines were still under patent protection in Canada. Apotex's new "cocktail" drugs – Apo TriAvir – cost about 40 cents per pill, compared

[131] *Supra* note 129.
[132] George Tsai, Note, *Canada's Access to Medicine Regime: Lessons for Compulsory licensing schemes under the WTO Doha Declaration*, 49 VA. J. INT'L L. 1063, 1075-79 (2009).
[133] *Id*.

to roughly $20 for the patented version. The plan of exporting Apotex was up to 260,000 packages of Apo TriAvir, which is enough to treat 21,000 HIV/AIDS infected patients for a year.[134]

However, Apotex faced with many obstacles at the time obtaining compulsory license for Apo TriAvir. The first one is that the patented medicines Apotex proposed in 2004 were not included in Schedule 1 of the Patent Act, the exhaustive list of all of the pharmaceutical products that qualified for generic manufacture under CAMR. The schedule then was thus amended in 2005, including the three patented drugs: zidovudine, lamivudine, and nevirpine. As a result, Apotex received a manufacturing authorization from Health Canada in August 2006 to begin producing its "cocltail" drugs.[135]

The other obstacle following the approval from Health Canada was in negotiations with the patented drugs' owner in respect of voluntary licenses. Section 21.04(3)(c) of CAMR requires an applicant to demonstrate that it has "sought from the patentee… a license to manufacture and sell the pharmaceutical products for export to the country or WTO member named in the application on reasonable terms and conditions and that such efforts have not been successful." Specific standards for this kind of negotiations under CAMR requirement were not stipulated. In the end, the negotiations between Apotex and the three patent holders came to a standstill. To acquire a voluntary licensing from the patentees failed.[136]

The last problem facing Apotex was the transaction in Rwanda. After clearing all hurdles domestically, the final step was to win a Rwandan

[134] *Id.*
[135] *Id.*
[136] *Id.*

government's tender for purchasing Apotex's generic products. In July, 2007, Rwanda notified the WTO of its planning to import Apo TriAvir from Apotex under CAMR. The Canadian government then granted compulsory licenses on the three patented medicines on September 20, 2007. About a month later, Canada notified the WTO of the grant of compulsory licenses and its intention to export Apo TriAvir into Rwanda. Although Apotex never received Rwanda's tender actually, the first and only package of Apo TriAvir was shipped into Rwanda on September 23, 2008 in the end.[137]

3.4. Compulsory Licenses in the United States

The aforementioned cases are all in the realm of health care. As for other circumstances of granting compulsory licenses, the United States remains probably the most active, including wide-ranging fields such as government uses, anticompetitive, special programs etc.

3.4.1. Government Use

According to 28 U.S.C. § 1498 (a), the U.S. government does not have to seek a license or negotiate for use of a patent or copyright when the use is by or for the government. Any federal employee can use or authorize the use of a patent or a copyright. The right owner is entitled to compensation, but cannot enjoin the government or a third party authorized by the government, to prevent the use. The provision stipulates: "the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and

[137] *Id.*

manufacture. Reasonable and entire compensation shall include the owner's reasonable costs…" Any contractor, subcontractor, person, firm, or corporation who receives authorization from the federal government to use patents or copyrights is construed as use by the federal government, and cannot be sued for infringement.[138] The relevant cases involved (including but not limited to):

(1) Crater Corporation v. Lucent Technologies

The decision was made by the US Court of Appeals for the Federal Circuit in the case Crater Corporation v. Lucent Technologies on June 6, 2001. Lucent argued that it was not liable for patent infringement because any work it performed with respect to the Crater coupler was done under a government project and was authorized by the United States. Pursuant to 28 U.S.C. § 1498 (a), a private party cannot be held liable for infringement for any goods "used or manufactured by or for the United States." The court upheld the lower court's ruling that Lucent was not liable for infringement. As a result, the only remedy for the right holder was to seek compensation under 28 U.S.C. § 1498 (a) in a compulsory license manner.[139]

(2) Hughes Aircraft and the Williams patent.

The decision was made by the US Court of Appeals for the Federal Circuit, in Hughes Aircraft Company v. The

[138] 28 U.S.C. § 1498 (a)

[139] Crater Corporation v. Lucent Technologies, 255 F.3d 1361 (Fed. Cir. 2001).

United States on June 19, 1996.[140] Kenneth Starr represented Hughes in an unsuccessful appeal, where Hughes was seeking a higher royalty rate on a compulsory license of US Patent No. 3,758,051 (the Williams Patent). The Williams patent "relates to an apparatus for controlling the orientation of the spin axis of spin-stabilized space vehicles such as satellites positioned in orbit around the earth." The US Court of Federal Claims set a royalty rate of 1 percent in a 1994 decision[141]. It is notable that the appeals court observed that "Because recovery is based on eminent domain, the proper measure is 'what the owner has lost, not what the taker has gained.'"[142]

(3) Brunswick Corporation and the 606 patent.

The case was decided by the US Court of Appeals for the Federal Circuit in Brunswick Corporation v. the United States. The government's purchase of camouflage screens, involving US patent 3,733,606 (the 606 patent), were held to infringe on the 606 patent. Brunswick appealed an earlier US Federal Court of Claims case setting compensation for a compulsory license of the 606 patent. Brunswick sought "lost profits" for its license, while the court awarded a "reasonable royalty." In its decision, the court indicated that the US Congress directed the Army to "expand its industrial

[140] Hughes Aircraft Co. v. United States, 86 F.3d 1566 (C.A.Fed.1996).
[141] Hughes Aircraft Co. v. United States, 31 Fed.Cl. 481 (1994).
[142] Leesona Corp. v. United States, 599 F. 2d 958, 969 (Ct. Cl. 1979).

base for the production of camouflage screens in order to maintain a reliable industrial mobilization capacity," and noted that "This type of outside policy making and political influence is peculiar to the federal government and is properly taken into account when considering whether a reasonable royalty would adequately compensate an aggrieved patentee." The court further indicated that the number of units purchased by the government was greater than would have been the case in the absence of the compulsory license, and that this supported a lower amount of compensation than that sought by Brunswick.[143]

(4) Gargoyles patent for protective eyewear.

The case was decided in May 20, 1997 by the United States Court of Appeals for the Federal Circuit, in Gargoyles, Inc. and Pro-Tec, Inc. v. the United States[144]. This is another case where the private plaintiff sought "lost profits" rather than a "reasonable royalty" as compensation. The royalty set by the Court of Federal Claims was 10 percent. The government considered this excessive and sought a reduction (of half or more). The dispute involves US patent 4.741,611 (the 611 patent), for protective eyewear. Gargoyles, a company that sells commercial eyewear, was seeking compensation for a compulsory license of the patent, which

[143] Brunswick. Corporation v. United States, 36 Fed. Cl. 204 (1996).
[144] Gargoyles, Inc. v. U.S., 113 F.3d 1572 (1997).

had been used by American Optical to provide the US Army with several thousand pairs of ballistic/laser protective spectacles. The Appeals court upheld the lower court decision. Again, the court quoted the ruling of *Leesona*, "Because recovery is based on eminent domain, the proper measure is 'what the owner has lost, not what the taker has gained.'[145]"

3.4.2. Anti-Competitive

Article 31 (k) of the TRIPS Agreement allows nations to adopt compulsory licenses as remedies against patent misuse, such as anti-competitive. In the U.S., one of the compulsory licenses sought remedies to anticompetitive was the Microsoft cases. Microsoft was ordered to provide non-discriminatory licensing of certain protocol technologies. In the first attempt to satisfy this order, Microsoft issued licensing terms which were criticized as unreasonable afterwards. The US Department of Justice forced Microsoft to lower its royalties and amend some other terms. On August 1, 2003, Microsoft then issued the statement:[146]

REDMOND, Wash., Aug. 1, 2003 — Microsoft Corporation today announced that improvements to its Communications Protocol Licensing Program are now available to existing and prospective licensees. In response to industry and government

[145] Leesona, 599 F.2d at 969.
[146] Microsoft Announces Additional Improvements To Protocol Licensing Program, *at* http://www.microsoft.com/en-us/news/press/2003/aug03/08-01protocollicensingprogrampr.aspx

feedback, Microsoft has established a simplified, low-cost royalty structure and adopted new licensing terms that are more favorable to prospective licensees.

A new royalty structure, calculated as a simple percentage of the licensee's revenues from products incorporating Microsoft's protocol technology. Depending on the functions they wish to enable, licensees can elect to license some or all of the protocols supported in Windows 2000 Professional and later client operating systems. For many functions, royalties are set at 1 percent of the licensee's revenues from the software product incorporating the protocol technology. All of the more than 100 protocols available under the MCPP can be licensed at a royalty of 5 percent of the licensed product revenues. Royalty rates on Microsoft protocol technology used in embedded hardware products range from 0.5 percent to 2.5 percent. All royalty rates are subject to minimum and maximum fees per licensed unit, except certain embedded products, which are not subject to a minimum fee.

The Microsoft’s royalties setting of the cap on stacked royalties 5 percent for the MCPP is exactly the same as the voluntary cap on stacked royalties from IBM, and a common goal for voluntary patent pools.

In another case, FTC (Federal Trade Commission) ordered an antitrust remedy compelling memory chipmaker Rambus to license its

patented technology on certain specific terms and limited the maximum royalty which Rambus can receive for use of its patents to 0.25 percent for SDRAM products; 0.5 percent for DDR SDRAM products, and SDRAM memory or other non-memory chip components; and 1 percent for DDR SDRAM memory controllers, or other non-memory chip components. For these patents, the royalty rates would be zero percent after 3 years.[147]

3.4.3. Special Programs

The United States has several circumstances for granting compulsory licenses in special programs.

(1) Bayh-Dole Act

According to the Bayh-Dole Act, a federal agency that funds research which leads to patent protection may issue "March-in Rights" to the invention. The issuance allows third parties to use such invention on terms of reasonable circumstances.[148]

(2) Clean Air Act

The Act provides mandatory licensing of air pollution prevention inventions under 42 USC §7608. Administrator of Environmental Protection Agency (EPA) may ask for compulsory licenses when a patented invention is necessary to comply with the Clean Air Act.[149]

(3) Civilian Nuclear Energy

[147] Opinion of the commission on remedy, at http://www.ftc.gov/os/adjpro/d9302/070205opinion.pdf
[148] 35 U.S.C § 203
[149] 42 U.S.C § 7608

There are two provisions provided for compulsory license in respect of civilian nuclear energy programs. According to 42 U.S.C. § 2183, the U.S. government can "declare any patent to be affected with the public interest" if the invention discovery covered by patent is "of primary importance in the production or utilization of special nuclear material or atomic energy."

Another statute relates to 42 U.S.C. §2188, concerning "monopolistic use of patent". "Whenever the owner of any patent… is found …to have intentionally used such patent in a manner so as to violate any antitrust law… there may be included in the judgment of the court, in its discretion and in addition to any other lawful sanctions, a requirement that such owner license such patent to any other licensee of the Commission who demonstrate a need therefore."[150]

(4) The Proposed Public Health Emergency Medicines Act

The United States was threatened by an attack using anthrax in 2001. The U.S. government lacked for an adequate stockpile of ciprofloxacin to treat a larger population, in the event a new and broader attack was launched using a strain of anthrax that could not be treated with other antibiotics.[151] Ciproloxacin was patented in the United States by Bayer, and the price was $1.77 per pill. Bayer was unable to produce enough ciprofloxacin to supply the U.S. market timely.

[150] 42 U.S.C.A. § 2188

[151] Elizabeth Bumiller, *Public Health or Public Relation*, New York Times, October 21, 2001.

Pressured by domestic public health groups and the members of Congress, the U.S. Secretary of Health Thommy Thompson intended to override the Bayer patent and purchase generic version products unless Bayer lowered its price. In response, Bayer then lowered its price to $0.95 per pill. Due to concerns that current U.S. laws on government use of patented inventions did not give the United States sufficient leverage issuing compulsory licenses under such circumstances, Public Health Emergency Medicines Act was proposed to solve this problem, amending Federal patent law to grant the Secretary of Health and Human Services, in the case of any health care invention, the right to authorize use of the subject matter of the patent without authorization of the patent holder or any licensees (compulsory licensing) if the Secretary determines that the invention is needed to address a public health emergency.[152]

4. Concluding Remarks

The primary reason for granting patents is permitting inventors to earn a return on their inventions, which can provide incentive for technology innovations. However, patents themselves come at a significant societal cost.[153] The cost of patent protection is allowing the patentees to exercise monopoly power over the

[152] *Id.*
[153] ROBERT P. MERGES ET AL., INTELLECTUAL PROPERTY IN THE NEWTECHNOLOGICAL AGE 15 (2d ed. 2000).

markets for the new technology. It prevents the benefits of the new products being enjoyed optimally by consumers. The locking down of information which can be essential in improving the public welfare is troublesome.[154] Thus, some has said that the patent protection was limited to a certain period of time in order to achieve a desirable balance between incentives to invent and gains to consumers from products after they have been invented.

Compulsory licenses, as a negotiating tool against patent protection, serve to address the public interests issues timely. As the cases mentioned above, how powerful this tool depends on the ability of countries to bargain with patent holders. The vague languages of Article 31 of the TRIPS Agreement leaves the grounds to issue compulsory licenses wide open to debate. After the Doha Declaration, it seems to provide clarifications on the level of nations' discretion of issuing compulsory licenses. However, the legal status of the declaration was still under debate. The controversy is rooted in the unitary nature of international intellectual property law. In order to adjust to different domestic situations each WTO member nation facing, it can be inferred that this vagueness and ambiguity regarding the granting of compulsory licenses were meant to be so initially when it was designed by the original signing parties. The TRIPS agreement creates only baseline requirements for all members, and important limitations like compulsory licenses are available equally. Such flexibility has some benefits in permitting countries to adapt intellectual property law to their local political environment. However, it is particularly inadequate in addressing the needs and obligations of different actors under emergent conditions.

Among the developing countries seeking to improve their access to

[154] *See* Hans V. Hogerzeil, et al., *Is Access to Essential Medicines as Part of the Fulfillment of the Right to Health Enforceable Through the Courts?*, 368 LANCET, 305,308 (2006).

technology, the Brazilian experience is a model of what can be achieved by political commitments. Despite its negotiating advantages in terms of technological and R&D infrastructure and capabilities, compulsory license was not used frequently in Brazil as mentioned above. Instead, the Brazilian government utilized their leverage tactically to lower the price of patented products by conferring on the best way to win-win situation with patent holders.

Indeed, compulsory licensing mechanism was used within a package of political policies designed to strengthen negotiating capacity to ensure access and reasonable prices for essential patented products, which ultimately leads to enhancement of domestic technological capacities. However, it is in conflict with patent protection in essence. That is the reason that TRISP sets a series of requirements of the issuing process, intending to ensure the granting of compulsory license to be run in an equitable manner.

Although compulsory licenses may be deemed as the last resort, a sounded and well-designed system of issuing compulsory licenses may facilitate the prior negotiations and enhance the willingness of voluntary licenses from patentees. Remuneration setting could be the one of the most important factors to complete the compulsory licensing system considering the core of patent licensing revolved around royalties issues. The TRIPS Agreement also requires “adequate remuneration” in the required process if granting a non-voluntary license. Thus, in the next chapter, the thesis would expound an in-depth analysis on the compensation setting systems worldwide.

Chapter IV *Remuneration for non-voluntary use of a patent under TRIPS provisions*

Most of the global health care came from private resources,[155] which means that we all relied on sufficient incentives to drive private entities to pour capital into the investment in R&D of medicine innovation. Obviously, the most important incentive is the potential to profit from products and services resulting from the initial investment.[156] Nevertheless, the disclosure of technical information might limit the investment companies' willingness to invest, which leads to the existence of a legal mechanism to reduce competition.[157] Therefore, patent rights are intended to restore the exclusivity that provides stimuli to invest.

But strong patent protection has to make concession to public interests occasionally, especially in cases of human health. Compulsory licensing mechanism was established for the purpose of preservation of public welfare. Considering the economic advantages of patents, there is great concern about the impact of such licenses on innovation. Unfortunately, the understanding of how innovation effects occur or what licensing rules best addressing them is tenuous at best.

So far, the compulsory license controversy has centered on the grounds a country may rely on for imposing such a license.[158] On the patent owner's side, concerns that licenses may be too easily invoked absent of the threat of an emergent health crisis or

---

[155] Peter J. Neumann & Eileen A. Sandberg, *Trends in Health Care R&D and Technology Innovation*, 17 HEALTH AFF. 111, 115 (1998).

[156] *See* Patrice Trouiller, et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 LANCET 2188, 2191 (2002).

[157] Keith E. Maskus& Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods, in* KEITH E. MASKUS &JEROME H. REICHMAN, INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY 8 (2005).

[158] Peggy B. Sherman & Ellwood F. Oakley, *Pandemics and Panaceas:The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 AM. BUS. L.J. 353, 369-72 (2004).

other national emergencies has led to fear that the profit needed to fund innovation would be eroded.[159] On the public interest's side, "concerns that unrealistic rules could lead to underutilization of such important negotiating tool has channeled efforts toward a more easily implemented system that would be widely available at each government's discretion."[160]

One of the basic elements of patent protection is to ensure the patentee commercial benefits from the markets. Given that the context of a patent right is primarily composed of economic significance,[161] the impact on the patent owner's wealth is more central to the question of innovation effects.[162] Compared to tangible property rights such as real estate that carry along with them the concept of a basic "dignity" of ownership,[163] patents provide their owners with a tool for creating monetary profits only.[164] It is not abstract ownership of the right that is important in this relationship, but rather what that right can do for its owner. The possibility of monopoly rents induces invention that otherwise might not exist.[165]

In ordinary patent infringement cases, the economic foundation of patents infringement lay in the right of commercial benefits in terms of monetary loss. Even the right to exclude through injunctive relief, commonly considered a remedy disparate from monetary compensation,[166] injunctive relief could still be viewed as

---

[159] Sykes, *supra* note 99, at 60-62

[160] Peter K. Yu, *The International Enclosure Movement*, MSU Legal Stud. Res. Paper No. 03-22, 36-37 (2006).

[161] *See* Kenneth W. Dam, *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247, 250–51 (1994).

[162] *See* Cahoy, *supra* note 97 , at 683-84.

[163] The common law generally protected a man's house as "his castle of defense and asylum." 3 W. BLACKSTONE, COMMENTARIES 288 (1765).

[164] Mark A. Lemley, *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031 (2005)

[165] FED. TRADE COMM'N, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY, ch. 3, at 9-12 (2003).

[166] *See* H.H. Robertson Co. v. United Steel Deck, Inc., 820 F.2d 384, 390 (Fed.Cir. 1987) ("The nature of the patent grant thus weighs against holding that monetary damages will always suffice to make the patentee whole, for the principal value of a patent is its statutory right to exclude."), *abrogated on other grounds*, Markman v.Westview Instruments, Inc., 52 F.3d 967, 977 (Fed. Cir. 1995) (en banc).

merely a means to extract additional profits by controlling access to the invention.[167] In practice, it has an economic value. Therefore, the impact of any elimination or impairment of patent rights can be quantified, and more importantly, *any* loss of patent property rights can theoretically be remedied with compensation. In other words, it should always be possible to compensate a patent owner with money to make up for any reduction of her/his rights.

The crucial role of economic returns essentially frames the debates on compulsory licensing. The core question is not under what circumstances they will be imposed, but rather what the economic consequences of any imposition will be. Whether the license adequately accounts for economic losses suffered by the patent owner says everything significant about the impact of the license. By considering the problem from the perspective of compensation or remuneration, as long as there is economic balance between the public uses and the private owner's rights, the benefits concerning access to use of patent might exceed the innovation impacts.

The TRIPS Agreement barely mentioned the standards of setting royalty rates, leaving nations the authorities of determining the amount of remuneration. Moreover, recent revisions to international intellectual property agreements are even more likely to make compulsory license remuneration the critical factor in the future.[168]

1. Regulation Concerning Remuneration under TRIPS

The provision in regard of remuneration under compulsory license is stipulated in Article 31 (h) of the TRIPS Agreement:

[167]Patent Law Reform: Injunctions and Damages: *Hearing Before the Subcomm. on Intellectual Prop. of the S. Comm. on the Judiciary*, 109[th]Cong. (2005) (comments of Mark A. Lemley)
[168] Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, 42 GA. L. REV. 131, 138 (2007).

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

The notion of compulsory license is in conflict with the TRIPS Agreement fundamental objective of protecting intellectual property rights as private property rights. Therefore the patent owners under compulsory licenses shall always be entitled to an "adequate compensation in the circumstances of each case, taking into account the economic value of the authorization".[169]

Art. 31(h) provides two elements for said interpretation[170]: firstly, the "adequate remuneration" is assessed according to the circumstances of each case. To determine the due compensation, the circumstances of the licensee and of the country where the patented invention operates, and the purpose of compulsory license should be taken into account. Secondly, "the economic value of the authorization" is necessary to be considered, but not as the sole or determining factor. The value will significantly depend on the size of market to be supplied, the newness or maturity of the technology, and its rate of obsolescence, the degree of competition by substitute products, and the coverage of the patent.[171]

To give the meaning of "adequate" more precise guidance to national judicial and administrative authorities, there are two possible understanding. On the one hand, it simply means the licensor should be able to receive remuneration in accordance with the amount what he would have obtained in a voluntary arm's-length transaction. On the other hand, several factors may also influence the decision, such as the subsidies or other contributions that the title-holder received

[169] Correa, *supra* note 64, at 322.
[170] *Id*.
[171] *Id*.

to develop the invention, the degree to which development costs have been amortized and the R&D commitment of the patent owner.[172]

Moreover, the TRIPS itself also provides for one element that may help clarify what "adequate compensation" means, which can be found in Art.44.2. It reads:

"Notwithstanding the other provisions of this Part and provided that provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are compiled with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Artcle 31.[…]."[173]

Considering that Article 44 deals with injunction, in cases when the patent is infringed by a government or by a third party authorized by a government, WTO Members may provide that injunctions shall not be available. The only remedy in such case will be the payment of remuneration under Article 31(h), replacing the provision about payment for damages in Article 45. Since the judicial authorities have the duty and power to order the payment of adequate damages, the same criteria to assess adequate damages can be applied to gauge the adequate remuneration for compulsory license.[174] In that sense; the conjunction of Art. 31(h) and 44.2 leads to the conclusion the price that compulsory licensee must pay should correspond, Like damage, to the amount of money the licensor would make if he were commercially exploiting the patented invention in the market of licensee. In other words, the average or uniform fee that is paid in the same sector or industry must be taken into account. Therefore, the payment should be

[172] *Id.*
[173] *Id.*
[174] *Id.*

calculated based on actual or potential financial gains that the licensee may extract from the market.[175]

These interpretations of the provision would apply, in principle, to any kind of compulsory license.[176] However; in the case of licenses to remedy anti-competitive practices, the needs to correct them may be taken into account in determining the amount of remuneration (Article 31(k)). The objective being to restore a healthy competition, this provision would allow for a reduced remuneration.[177]

The TRIPS Agreement rules on compensation embody substantial flexibility as a consequence of using the terms "in the circumstances of each case", indicating that factors relating to the underlying reasons for the grant of the license may be taken into account in establishing the level of remuneration. Granting authorities are instructed to "take into account the economic value of the authorization", but not required to base the royalty payable to the patent holder on that value.[178]

To conclude, there may be several approaches to decide which would be the adequate compensation based on the above reasoning[179]:

1.1. The Market Rate

On Approach to determine the remuneration is simply resorting to the commercial compensation that the patentee would have to pay in ordinary

[175] *Id*.
[176] Carvahol, supra note 4, at 366.
[177] C Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries*, Trade-Related Agenda, Development and Equity, Working Papers (1999: Geneva, South Centre), at http://southcentre.org/index.php?option=com_content&view=article&id=75%3Aintellectual-property-rights-and-the-use-of-compulsory-licenses-options-for-developing-countries&catid=41%3Ainnovation-technology-and-patent-policy&Itemid=1&lang=en
[178] *Supra* note 64, at 475.
[179] *Id*. at 476.

circumstances. Assuming that there is a market for licenses regarding the type of technology involved in the particular case, the market rate would have provided an indication at least to what patent holders might expect from licensing their technology. This method came from the notion that compulsory licenses basically break the patent owner's power to impose monopoly pricing which TRIPS guarantees.[180]

Nevertheless, this approach could be misleading and difficult to settle the due price from two aspects.[181] One is that the market features specific kind of technology might be limited to a certain amount of patent holders, which may lead to higher rates than those in an efficiently functioning market. The other problem is most of the patent licenses are granted among members of the same enterprise group. As a result, the royalties may be overcharged considering the group's interest in order to reduce tax burden. Besides, it is hard to break down available data so as to establish what market rates would look like without the information from intra-group licenses.[182] In such cases, the joint venture interests involved might cripple the objectivity of the presumption of the normal market-rate transactions and make the determination of a market price substantially arbitrary process. A possible solution to this would be to require the patent owner to justify any market losses.[183]

1.2. Royalty Request by Patent Holder

Another feasible way is requiring the licensor to provide detailed information regarding its development costs and research as reference of determination in

[180] *Id.*
[181] *Id.*
[182] *Id.*
[183] Grain Processing Corp. V. Am, Maize-Prods. Co., 185 F. 3d 1341, 1349 (Fed. Cir. 1999).

respect of royalty level.[184] The data given by the patent holder may include whether it received or made use of any government subsidies developing its inventions, its total global market for the patented innovation, the percentage of the global market represented by the country granting the compulsory license, the average rate of return on its patented products. These factors presenting the patent holder's interests may help the granting authorities to adjudicate the adequate sum of remuneration.[185]

However, this approach misses an important point of drug discovery, research and development spending and returns are not completely segregated by drug. A company's overall research and development investment may involve several drugs. Thus, to trace down a single costs of certain drug may be difficult. Besides, a company may plan to sell a drug at a lower price below its costs using the support of another high-priced medicine.[186] In that sense, a fair royalties of given drugs would require the company's overall portfolio, which is rather complex for the government administrators to cope with under compulsory license.

Contrary to the method is user-based analysis, which depends on the effectiveness of the treatment and the degree of advancement over existing alternatives.[187] Such valuation may close the gap between the patented product's real value and the exaggeration of the property right's value claimed.

1.3. Royalty Guidelines Made by International Organization

The international organizations can provide a royalty guidance of

[184] *Supra* note 64, at 477.
[185] *Id.*
[186] Cahoy, *supra* note 168, at 166.
[187] *See* Austl'n Productivity Comm'n, International Pharmaceutical Price Differences 25-26 (2001).

compulsory license for the national concerned authorities to adjudicate in each case.[188] The licensee's royalty obligation may be calculated as a percentage of its income from sales of the licensed product. The income may be represented, for example, by its wholesales, and may be net of tax liabilities. However, a unitary system for remuneration is barely practical. There are a variety of perspectives and no single approach is optimal in any condition, every method comes with its ambiguity in its overall impact. Therefore, even under international standards, any workable system requires compromise from each party involved.[189]

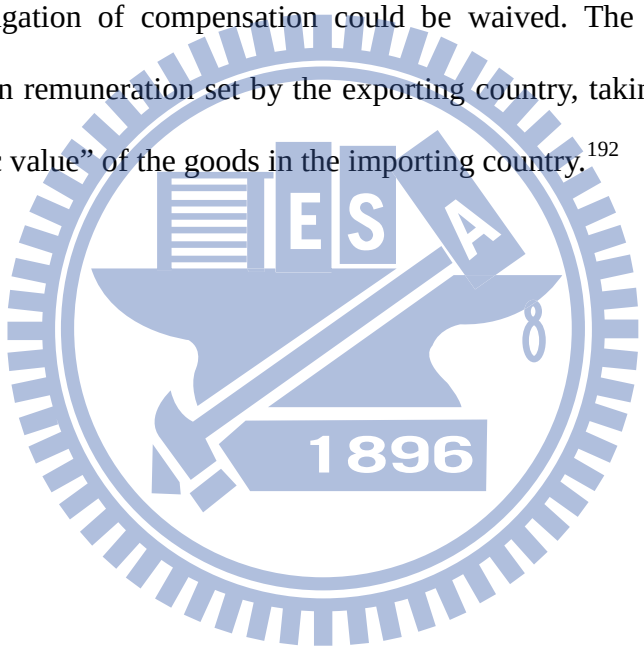
2. Remuneration Provision under The Doha Declaration

The WTO adopted the Doha Declaration on TRIPS and Public Health on November 14, 2002.[190] In the Doha Declaration, paragraph 4, it stipulates:" 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 interpreted and implemented in a manner supportive of WTO Member's right to protect health and, in particular, to promote medicines for all." In short, the paragraph calls upon WTO members to implement their domestic laws in the manner of promoting access to medicine for all.

In paragraph 6 of the Doha declaration, it requires the council for TRIPS to

[188] *Supra* note 184.
[189] Jerome H. Reichman& Catherine Hasenzahl, *Non-Voluntary Liceinsing of Patented Inventions*, UNCTAD-ICTSD Issue Paper No. 5, at p. 10 (2004), *at* http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf
[190] Ministerial Conference, Forth Session, Doha, 9-14 November 2001, WT/MIN(01)/DEC/2,20 November 2001

solve the problem of the limitations of exports of medicines manufactured under compulsory licenses. The problem lay in paragraph 6 was the provision of the TRIPS, Article 31(f), which limits exports to less than half of production when goods are manufactured under compulsory license. In 2003, the WTO concurred with additional flexibility for exports under a limited waiver of Article 31(f).[191] The decision requires the exporting country to provide "adequate" remuneration to right holders, in accordance with Article 31(h) of the TRIPS, "taking into account the economic value to the importing Member." In that sense, the importing country's obligation of compensation could be waived. The right holders are eligible to gain remuneration set by the exporting country, taking into account of the "economic value" of the goods in the importing country.[192]



[191] Decision of the General Council of 30 August 2003, WT/L/540, 1 September 2003, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health.
[192] James Love, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, Health Economics and Drugs TCM Series No. 18,at 13(2005), at http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf.

3. Summary of TRIPS Provisions and the Doha Declaration Relating to Remuneration

To give consideration to both of the public and private interests, the exceptions of patent protection must follow the requirements listed in the TIPRS provisions and the Doha Declaration. For general compulsory license, adequate remuneration must take into account the economic value of the authorization. Without more elaboration on the term “adequate”, the specific amount of compensation is open to each government’s discretion for the intended flexibility that can be adjusted to various situations. Commercial non-emergency authorizations not for the purpose of anticompetitive practices shall go through the procedural requirement of prior negotiation on reasonable commercial terms. Since compulsory license is the last resort to restrict patent right, voluntary licensing should be the first priority if it is possible.

Under the circumstances that compulsory license is permitted to correct anticompetitive practices, the authorities concerned can adjust the remuneration by evaluating the punitive elements. And for the situation where a patent cannot be exploited without infringing another patent, the owner of the first patent must offer a cross license on reasonable terms when obtaining a compulsory license to use a dependent patent.

In Pharmaceutical compulsory license, considering the main goal of promoting access to medicine for all revealed by the Doha Declaration, the cases applies to the situations involving public health problems. Thus, adequate remuneration must take into account to both the severity of the epidemic in the country and the nation’s financial ability. Additionally, cases of exporting generic version of medicines under the system established by the August 30, 2003

decision of the General Assembly, implementing paragraph 6 of the Doha Declaration, the adequate remuneration is based upon the economic value of the authorization in the importing country.

The requirements set by the TRIPS agreement and the Doha Declaration were sorted out as the following table made by the researcher James Love: [193]

Term	TRIPS Provision	Situation
Do not unreasonably prejudice the legitimate interests of the patent owner	Article 30	Applies to cases where a compulsory license is implemented under the general exceptions provision (rather than Article 31)
Prior negotiation on reasonable commercial terms	Article 31(b)	Applies to commercial non-emergency authorizations that are not remedies to anticompetitive practices
Adequate remuneration . . . taking into account the economic value of the authoriztion	Article 31(h)	Applies to all authorizations, but the need to correct anti-competitive practices may be taken into account in determining the amount of remuneration. In some competition cases, the remuneration is set to zero.
The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration	Article 31(k)	Where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.
Reasonable terms	Article 31(l)	The owner of the first patent must offer a cross license on reasonable terms when obtaining a compulsory license to use a dependent patent
Promote access to medicine for all	Doha Declaration, Paragraph 4	Applies to cases involving public health problems
Adequate remuneration . . . taking into account the economic value of the authorization in the importing country	Doha Declaration, Paragraph 6	Applies when exports are authorized under the system established by the August 30, 2003 decision of the General Assembly, implementing paragraph 6 of the Doha Declaration

[193] *Id*. at 14.

Chapter V *International Practices of Setting Remuneration*

The flexibilities of the TRIPS Agreement on the setting of "adequate remuneration" open up a wide door for numerous methods to fill in the blank left by ambiguity. Neither "adequate remuneration" nor "economic value" is defined in the agreement. As a result, there are a variety of experiences of royalties setting worldwide for the long history of compulsory licensing implementation. Different licensing regimes and various notions of fair pricing and reasonable returns on R&D spending have been thrown into the debate to argue for a variety of divergent remuneration models that supposedly treat everyone equitably.

Before the discussion of the royalties setting experiences worldwide, there is something should be borne in mind. Under compulsory license, the sales of the patentee's products will be made by a third party. Thus, profits of the patentee will be eliminated.[194] To the extent that the lost profits are replaced by a remuneration mechanism compensates for the impact on the patent owner, the innovation incentives remain uninfluenced. Since the entire amount lost is replaced, a rational pharmaceutical company should be indifferent, notwithstanding often or how long such a license is imposed.[195] However, if the remuneration makes up for only a small fraction of the lost profits, the company would suffer, and such impositions have negative impact on the patent owners.

When it comes to access to medicine, it is a rather complex story. A fair

[194] This assumes that the patentee prices optimally with respect to marginal revenue and costs.

[195] *See* Wendy J. Gordon, Toward a Jurisprudence of Benefits: *The Norms of Copyright and Problem of Private Censorship*, 57 U. CHI. L. REV. 1009, 1042-43 (1990).

remuneration relies not only on the lost profits of a patent owner but subjects to the affordability of a needed nation. The tension between patent rights as innovation incentives and the needs of developing nations is especially intense in the aspect of public health. To the extent that patent rights can be meaningfully relaxed in the cases of crisis, such concessions seem not only reasonable, but eminently noble. Nevertheless, to some level, a company's loses could reduce revenue below that projected income which is a stimuli to optimally invest funding in research and development, thus, it ensues changes in behavior with respect to future investment.[196]

To establish an equitable remuneration, nations with different level of development should account for varied burden of health care expenses. For example, industrial nations may afford higher compensation of licenses. Developing countries pay for a development-sensible royalty. And for least developed countries, the least or even zero royalty might be suitable.[197] However, such three-level system may be controversial in respect of the patent owner's right of their property. The public policy debates can be distilled into to a relatively straightforward issue: how much of the burden of providing for developing nations should be shouldered by private companies? Is it appropriate to place any obligation on pharmaceutical companies to bridge public health gaps that governments will not, or should governments be required to step in? International intellectual property law researchers attempted to grapple these difficult questions; however, no satisfying result was able to cater to everyone's need.[198] Maybe just like the other ambiguity left by international agreements intended to adjust to various situations facing WTO member nations, the

[196] *See* F.M. SCHERER, THE ECONOMIC EFFECTS OF COMPULSORY PATENTLICENSES 59-62 (1977). A 1973 study by Taylor and Silberston purported to quantify this effect through the use of surveys. Dramatically, it found that 64% of R&D in the pharmaceutical field would be displaced if patents were replaced with automatic reasonably royalty mechanisms, as opposed to a weighted average of 8% in all industries.

[197] Cahoy, supra note 168, at 181.

[198] *Id*. at 149.

practical and reasonable judgments are open to negotiations and debates in every single case.

1. Different Perspectives Between Developing and Developed Countries

Developed countries, whose citizens presently derive the greatest economic benefit from IPR and the inventions they possess, have pushed for vigorous international protection of IPR.[199] That ensures a patentee a limited monopoly in a new application of art or science, particularly in a commercially useful manner.[200] The protection of IPR serves the dual purposes of promoting and rewarding innovation (by granting some form of monopoly rights in the invention) and facilitating public access to inventions (by requiring disclosure and/or use).[201] On the opposite, developing countries generally support greater access to intellectual property to address compelling human needs and to facilitate socioeconomic development.[202]

As a result, developing countries usually view developed countries' calling for intense IPR protection as unacceptable interference with their proper roles as sovereigns addressing the needs of their citizens.[203] Thus, international regulation of IPR presents a general conflict between developed countries seeking to expand IPR protection for economic benefit and developing countries seeking to assert their sovereign rights to acquire and apply new information to address their

[199] Duane Nash, *South Africa's Medicines and Related Substances Control Amendment Act of 1997*, 15 Berkeley Tech L. J. 485, 485 (2000).
[200] Susan Vastno Vaughan, *Compulsory Licensing of Pharmaceuticals under TRIPS: What Standard f Compensation?*, 25 HASTINGS INT'L & COMP. L. REV. 87, 90 (2001).
[201] Ruth L. Gana, *Prospects for Developing Countries Under the TRIPS Agreement*, 29 Vand. J. Transnat'l L. 735, 742 (1996).
[202] *Id*., at 736.
[203] Nash, *supra* note 199, at 485.

citizens' pressing needs.[204]

1.1. Developing Countries Look for Minimal Compensation

As a threshold matter, due to the limited financial affordability, developing nations tend to interpret "adequate remuneration" under Article 31 (h) in accord with their insufficient budgets.[205] Basically, developing countries or least developed countries are overwhelmingly financially limited and unable to afford full market prices for patented products such as pharmaceuticals. Therefore, compulsory license, as the most important leverage, can be granted in cases of emergency threatening the citizens' health or other public interest.

Under such conditions, developing nations might already deplete their resources in order to dealing with the crisis. Therefore, the price of the patented products may be beyond the government's reach. Moreover, even developing nations are able to meet the requirement of issuing compulsory license under the TRIPS Agreement Article 31(a), the inadequate financial budget could also leave the public crises unsolved because of the expensive payment.[206]

Although proponents of restrictive protection over IPR argue that insufficient patent-system will inhibit investment from foreign countries and compulsory licensing would impede innovation, empirical studies indicate differently.[207] Empirical evidence proves that compulsory license will weaken

[204] Gana, *supra* note 201, at 771-72.
[205] Robert Weissman, *A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. Pa. J. Int'l Econ. L. 1069, 1114 (1996).
[206] *Id*.
[207] Richard T. Rapp & Richard P. Rozek, *Benefits and Costs of Intellectual Property Protection in Developing Countries*, Journal of World Trade, Oct. 1990, at 75, 81-87.

the incentive of innovation is somehow questionable. For instance, elimination of patent protection for pharmaceuticals in Brazil in 1969 was followed by a near six-fold increase in foreign investment in the local pharmaceuticals industry.[208] In Turkey, "abolishing patents has not adversely influenced the flow of direct foreign investment and the transfer of technology into the country."[209] Furthermore, a global survey and regression analysis conducted by J. Davidson Frame shows that the third world countries adopting less stronger IPR protections present better capacities in science and technology than other third world countries.[210]

Also, the protection in innovation does not always stand as paramount objective even in developed countries. In the U.S., the law[211] prevents holders of patents in medical procedures from suing doctors for infringement.[212] This section effectively grants compulsory license with no compensation to the most likely users of medical procedure patents-doctors.[213] The enactment of the law indicates the U.S. Congress put human needs for access to medical procedure prior to the patent holders' interests. Thus, the policy reflects the recognition of denial of that innovation will be improperly stifled by government action that provides reasonable access to important inventions.

Developing countries contend that controlled compulsory licensing with

---

[208] *See* Gary Gereffi, The Global Pharmaceutical Industry and its Impact in Latin America, in PROFIT, PROGRESS AND POVERTY: CASE STUDIES OF INTERNATIONAL INDUSTRY IN LATIN AMERICA 277-78 (Richard S. Newfarmer ed.) (1985).

[209] Arman S. Kirim, Reconsidering Patents and Economic Development: A Case Study of the Turkish Pharmaceutical Industry, 13 WORLD DEV. 219, 220 (1985).

[210] *See* J. Davidson Frame, *National Commitment to Intellectual Property Protection: An Empirical Investigation*, 2 J.L. & TECH. 209, 215 (1987).

[211] 35 U.S.C. § 287(c)

[212] Trevor Cook, Catherine Doyole&Jabbari, Pharmaceuticals Biotechnology & the Law 73, 89 (Stockton Press 1991); Bernd Hansen &Fritjoff Hirsch, Protecting Inventions in Chemistry: Commentary on Chemical Case Law under the European Patent Convention and the German Patent Law 113 (VCH 1997).

[213] Cynthis M. Ho, Patents, *Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. Davis L. Rev. 601, 669-70 (2000).

minimal compensation will promote, not stifle, innovation for the following reason. The thesis that the innovation deficiency is due to the lack of IPR protection in developing countries is unconvincing considering the insufficient infrastructure in those nations.[214] It is notable that, even though developed countries provide strong patent protection today, in virtually all cases, those protection can only extended when the nation have developed sufficient technological strength. Before equipped with greater economic power and science advance, strategies based on imitation or copying were typical to apply in develop certain industries.[215] Therefore, only after developing countries achieve greater accomplishment in economy and science, will the strict protection be feasible to promote innovation. In other words, convenient access to IPR, including access to patents through compulsory licensing, serves as vital means in economic development in developing countries. Such development will enhance the level of global innovation, which can further the ultimate goal of generating innovative capacities in both domestic and international markets.[216]

As for the remuneration to patent holders, full compensation for lost cost and profit is not defensible for licensors who suffer no injury by temporary compulsory license in developing country. Developing countries are usually not part of the pharmaceutical investment markets. The manufacturers do not develop drugs to cure diseases in developing countries in the first place, their direct investment is in developed nations. As a result, the return of investment is not impacted by compulsory license to addressing urgent health needs in developing countries. Therefore, patent holders are not entitled to the lost

[214] *Id*. at 775.
[215] *Id*.
[216] *Id*.

profit from sales of drugs in these countries.[217] The same reasoning can be found in the case in the United States, in Leesona Corporation v United States, a federal court of appeals held that compensation should be based on "what the patent holder has lost, not what the taker has gained."[218]

1.2. Developed Countries Look for Maximal Compensation

Developed countries, which are on behalf of most of the significant patent holders, contend that the denial of full remuneration of compulsory license obstructs the policy of promoting innovation embedded in IPR protection.

From the point of macroeconomic view,[219] reduced profits will yield reduced innovation. The cost of capital is low when investors perceive a predictable profit stream, so their return is commensurate with their risk. When that same profit stream is diminished, as through price controls, the cost of capital will rise not only to reflect the diminished return, but will rise an additional quantum to reflect the uncertainty in future earnings predictability. This is based on investors' beliefs, not necessarily the resulting objective outcome.[220] For example, the CEO of Genzyme Corp, a major U.S. biotech company, commented on his company's ability to raise capital during the time President Clinton was trying to advance his Health Security Act in 1993:

"We raised $100 million for our new gene therapy product last year. If we

[217] Judy Rein, *International Governance Through Trade Aggreements: Patent Protection for Essential Medicines*, 21 J. INT'L L. BUS.379, 404-05 (2001).
[218] Leesona, 599 F.2d at 970.
[219] It is a branch of economics that studies the behavior of how the individual modern household and firms make decisions to allocate limited resources. Typically, it applies to markets where goods or services are being bought and sold. Microeconomics examines how these decisions and behaviors affect the supply and demand for goods and services, which determines prices, and how prices, in turn, determine the quantity supplied and quantity demanded of goods and services.
[220] Jerry Stanton, *Comment, Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 COMM. J. INT'L L. 149, 168 (2000).

tried to hold an offering today we couldn't do it. The threat of price controls has done more to damage the biotechnology industry than anything else that has happened in the industry's history."[221]

The same effect was seen on market capitalization of biotech stocks on March 13, 2000. After a significant run-up over the previous quarter, the sector lost 11% of its value in a single day.[222] These evidences suggest that price controls apparently have chilling effect on technology innovation.[223]

The chairman of German pharmaceutical giant Bayer pointed out that "the research based pharmaceutical industry no longer has much of a future [in Germany]" if its innovation is dried up through price erosion.[224] Therefore, remuneration for compulsory license below the average of fair market value is very possible to have the same damaging effect on incentive of innovation and investment.[225]

It takes immense investment and research to develop new technology and innovation. Take pharmaceutical industry for example, given the fact that it is where the most of cases of compulsory licensing granted, to develop new drug costs millions of dollars and that only very few drugs are ultimately successful enough to recover that costs. On average, it costs $500 million to bring a new drug to market.[226] The timeframe is also quite significant. Both investors and inventors must wait for years before they receive a return, or realize a loss, on their investment. However, once the drugs come to a success in patent, the profits would be substantial. The temptation of the profit from exclusive sales

[221] *See* Robert M. Goldberg, *Pharmaceutical Price Controls: Saving Money Today or Lives Tomorrow?* (1993) Inst. for Policy Innovation (introduction by Robert Dresing) ,*at* http://www.ipi.org.
[222] Dow Jones U.S. Industry Groups, WALL ST. J., Mar. 15, 2000, at C9.
[223] *Supra* note 168, at 171.
[224] Stephen D. Moore, *European State Funded Health Systems Come Under Fire for Skyrocketing Costs*, Wall St. J., May 4, 1993, at A14.
[225] *Id*.
[226] *Supra* note 168, at 155.

of a single drug offers rich return and thus attracts some of the world's brightest mind and deepest pockets.[227]

As a result, developed countries with the most significant patent holders underscore the importance of stimulating ideas and encouraging investment by supporting fair market value compensation for compulsory license. For example, in the United States, 28 U.S.C. § 1498 allows compulsory license for public use but requires compensation for a taking. The standard for compensation of a taking is "just compensation", such that "the owner is put in the same position monetarily as he would have occupied if his property had not been taken."[228] The requirement has been further clarified as compensation at full market value.[229] Compulsory license in Switzerland is deemed as expropriation.[230] According to the North American Free Trade Agreement, the standard for compensation for expropriation is "it be paid without delay and be fully realizable". Moreover, "adequate" compensation for expropriation is defined as "fair market value", including going concern value and asset value before expropriation took place.[231] To conclude, developed countries contend that "adequate compensation" under the TRIPS Agreement should be interpreted as "fair market value", including the costs of both development and lost profit.[232]

2. Methods and Examples of Royalty Setting in General

[227] *Supra* note 200. at 109.
[228] United States v. Reynolds, 397 U.S. 14, 16 (1970).
[229] United States v. 564.54 Acres of Land, More or Less, 441 U.s. 506, 510-17 (1979).
[230] James Love, *Compulsory Licensing: Models For State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord* (Jan. 21, 2001) (paper prepared for the United Nations Development Programme, version 1.0), *at* http://www.cptech.org/ip/health/cl/recommendedstatepractice.html (last visited Dec. 19, 2011).
[231] *See*, e.g., North American Free Trade Agreement, Dec. 8, 1993, art. 1110(2)(3). 107 Stat. 2057
[232] *Supra* note 195, at 1055.

Compulsory Licenses

"Market rates" is one of the approaches discussed in the previous chapter which provides reference for compensation royalties under general compulsory licenses. Therefore, an introduction to an appropriate royalty rate to charge for voluntary licensing helps to clarify the issues of the setting of royalties for remuneration in non-voluntary cases. One approach in determining such "reasonable royalty" is to approximate the outcome of a transaction between a willing seller and buyer. There are 15 relevant factors for estimating the compensation which can be obtained from a hypothetical negotiation between parties.[233] Besides, there are also three primary methods used in assessment by

[233] Georgia-Pacific Corp. v. U.S. Plywood-Champion Papers, 318 F. Supp. 1116, 166 USPQ 235 (S.D.N.Y. 1970, modified, 446 F.2d 295, 170 USPQ 369 (2d Cir.), cert. denied, 404 U.S. 870 (1971). The fifteen factors were:
1. The royalties received by the patentee for the licensing of the patent in suit, proving or tending to prove an established royalty.
2. The rates paid by the licensee for the use of other patents comparable to the patent in suit.
3. The nature and scope of the license, as exclusive or non-exclusive; or as restricted or non-restricted in terms of territory or with respect to whom the manufactured product may be sold.
4. The licensor's established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by gaining licenses under special conditions designed to preserve that monopoly.
5. The commercial relationship between the licensor and the licensee, such as, whether they are competitors in the same territory in the same line of business; or whether they are inventor and promoter.
6.The effect of selling the patented specialty in promoting sales of other products of the licensee; the existing value of the invention to the licensor as a generator of sales of his non-patented items; and the extent of such derivative or convoyed sales.
7. The duration of the patent and the term of the license.
8. The established profitability of the product made under the patent; its commercial success; and its current popularity.
9. The utility and advantage of the patent property over the old modes or devices, if any, that had been used for working out similar results.
10. The nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.
11. The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.
12. The portion of the profit or selling price that may be customary in the particular business to allow for the use of the invention or analogous inventions.
13. The portion of the realizable profit that should be credited to the invention as distinguished from non-patented elements, the manufacturing process, business risks, or significant features or improvements added by the infringer.
14. The opinion testimony of qualified experts.
15. The amount that a licensor (such as the patentee) and a licensee (such as the infringer) would have agreed upon (at the time the infringement began) if both had been reasonably and voluntarily trying to

licensing experts to assess the value of intangible property, which are the "Cost Method", "Market Method" and "Income Method".[234] To apply these methods, sufficient data assists to decide the appropriate benchmark.[235] In industry, such as software, which can generate high profits, the royalties are thus higher. Usually, such industry applies for "the 25% Rule". For example, if the contracting parties anticipated the profit margins would be 80%, the royalty payment for licensor would be in the range of 20-30% of net revenues pre-taxed.

However, in the fields where the marginal profits are lower, 'the 5% Rule applies". For instance, in fields of medical devices or electronics and food, negotiations frequently result in a royalty of 5-6 of net revenues. A recent study shows that the median royalty rate across all industries was 4.5 %, which ranged from a low of 2.8% in the Food industries to a high of 8% in Media and Entertainment.[236]

2.1. Methods of Royalty Setting

The royalties setting principles of intangible assets, such as intellectual properties, are different in various fields. In history, according to empirical studies, a large percentage of royalty negotiations arrived at a royalty rate that equaled approximately one-quarter to one-third of the licensee's anticipated pre-tax profits derived from the technology.[237] However, nowadays, most royalties are calculated against the net revenues rather than licensee profits in

---

reach an agreement; that is, the amount which a prudent licensee - who desires, as a business proposition, to obtain a license to manufacture and sell a particular article embodying the patented invention - would have been willing to pay as a royalty and yet be able to make a reasonable profit and which amount would have been acceptable by a prudent patentee who was willing to grant a license.

[234] *See* ROBERT F. REILLY &SCHWEIHS, VALUING INTANGIBLE ASSESTS (1999).

[235] Howard G. Zaharoff, *Setting Values and Royalty Rates for Medical and Life Science Businesses*, J. BIOLAW& BUS., Vol. 7, No. 4, 2004, *at* http://www.mbbp.com/resources/iptech/royalty_rates.html

[236] Jennifer L. Knabb& Michael J. Jeffords, *Trends in Patent Infringement Damages*, 21 IPL NEWSLETTER 22, 27(2003) .

[237] *See* Robert Goldscheider, John Jarosz& Carla Mulhern, *Use of the 25 Per Cent Rule in Valuing IP*, 37 LESNOUVELLES 123, 124 (2002).

fact, so this rule must be used to yield a rate that will be applied against revenues.[238]

2.1.1. Cost Method (also called the "look back" approach)

The royalties applying this approach result from value of developing or purchasing the technology or intellectual property. The cost of development sets a ceiling on the licensee's purchase price. In fact, selling for below development cost is often the only reasonable way. As a result of changing markets or new information, the technology you developed may not have an expected value of the original investment. Importantly, the amount of revenue the technology can produce would be the main focus, which leads to the Income Method discussed below. Usually, there are few licensees would pay more for intellectual property than it would cost to develop such invention of equal desirability and usefulness. The licensor may use this approach to ask for a particular price.[239]

2.1.2. Income Method (also called the "Look Ahead" approach)

The method estimates the revenues the innovation is likely to produce, and savings it is likely to generate, and compare this to the anticipated cost to generate the same revenues or savings from other sources.[240] When using this method, it is often applied according to the discounted cash flow expected from using the appraised technology to the discounted cash flow expected from the next best alternatives.[241]

---

[238] Zaharoff, *supra* note 235.
[239] *Id*.
[240] *See* Charles T. Hardy, *Quantitative Deal Valuation and Optimization in the Biotechnology and Pharmaceutical Industries: Introduction and Modern Tools of Quantitative Deal Structuring and Decision Analysis*, J. BIOLAW& BUS., Vol. 7, No 1, 2004.
[241] Zaharoff, *supra* note 235.

2.1.3. Market Method (Also called the "Look around" approach)

Such Approach is to determine the value by learning the comparable technologies or businesses that have been sold recently. To apply this method, two elements complete the outcome: the determination of comparable transaction and reliable current data.[242]

2.2. Examples of Royalty Setting in Compulsory Licensing Cases

The royalty rates differ from country to country. The following statistics show a wide-ranging variety of remuneration under compulsory licenses in the United States

The United States permits compulsory licenses through various programs and laws, ranging from government use of patent to remedy anti-competitive practices. The remuneration of compulsory licenses for government use have come at 6%[243], and the royalties are lower in some critical cases. However, the rates have moved higher in recent years. After the courts stated to apply Georgia Pacific factors,[244] there has been an upward trend in the rates applied. For example, according to the an UNDP report conducted by James Love: in 1997, the court upheld a royalty rate of 10 per cent on the bulk of the infringing articles and 50% on a small portion of a government contract covering the development phase.[245] In 1999, the Court of Federal Claims awarded a 16.31% royalty,[246] and in 2000, it approved an award of 15 % of the benefit conferred by use of the

[242] *Id*.
[243] DeGraffenried v. United States, 25 Ct. Cl. 209 (1992).
[244] *Supra* note 233.
[245] Gargoyles, Inc. v. United States, 113 F.3d 1572 (1997).
[246] Standard Manufacturing Co. v. United States, 42 Fed. Cl. 748 (1999).

patent in view of the importance of the patent itself.[247] This award was subsequently challenged by the Federal Circuit.[248] The highest known percentage rate appears to have been awarded in Brunswick Corp. v. United States,[249] where the plaintiff obtained 17 % of the total cost of procurement.

As for remedy to anti-competitive practice, the royalties are typically low, sometimes arrived at 0%.[250] For instance, a remedial order to memory chipmaker Rambus set the royalties from 0.25-0.5%.[251]

In 2006, the U.S. Supreme Court established new standards for compulsory licensing for certain patentees, particularly those who do not commercialize their patents.[252] After the decision, a court granted Direct TV a compulsory license to use the Finisar patent on integrated receiver decoders (satellite set top boxes), for a royalty of $1.60 per device. Also, in 2006, a court granted Toyota a compulsory license in three Paice patents for hybrid transmissions, for a royalty of $25 per mobile.[253]

2.3. Approach of Determining the Compensation Used by Courts of the U.S.

The following cases elaborate the reasoning by the courts of determining the compensation of compulsory licenses:

2.3.1. Penda Corp. v. United States

[247] Dow Chemical Co. v. United States, 36 Fed. Cl. 15 (1996), rev'd in part on other grounds, 226 F.3d1334 (Fed. Cir. 2000).
[248] Dow Chemical Co. v. United States, 226 F.3d 1334, 1348 (2000).
[249] Brunswick. Corporation v. United States, 36 Fed. Cl. 204 (1996).
[250] Love, *supra* note 192, at 15.
[251] James Packard Love, *Recent Examples of the Use of Compulsory Licenses in Patents*, Knowledge Ecology Int'l, 31 March 2007, *available at*http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf
[252] eBay Inc. v. MercExchange, L.L.C., 547 U.S. 288 (2006).
[253] Love, *supra* note 251.

In *Penda corp. v. United States*,[254] Manufacturer of plastic pallets brought action against United States for unauthorized use of invention described in the '306 patent owned by Penda corporation. The court put that "The government may take a license in any United States patent, the patentee's sole remedy is a suit in this court for its 'reasonable and entire compensation' under section 1498."[255] To determine the "reasonable and entire compensation" owed the patent holder, the basic principle of is referring to an established royalty in the market. "Where the evidence establishes a royalty rate by the patentee in commercial licensing, the court will use that reasonable royalty as the basic for an award of compensation… If an established royalty rate is shown to exist, it is usually adopted as the best measure of reasonable and entire compensation." [256] This method is sometimes referred to as the "comparative royalty technique," because it employs a comparison of royalties charged others by the injured party of rights in the same or similar patents.

If there was no established commercial licensing rate, the court concluded that the best method of computing compensation would be applying the "willing buyer/willing seller" method, drawing on the fifteen factors listed in *Gerogia-Pacific*. Although the *Gerogia-Pacific* factors were postulated in the context of a private infringement action, it can still be applied in an analysis under section 1498. "It should be remembered that the entire hypothetical negotiation is a legal fiction, and that the 'whole notion of a reasonable royalty is a device in aid of justice, by which

[254] Penda Corp. v. United States, 29 Fed. Cl. 533 (1993).
[255] *Id*, at 573.
[256] *Id*

that which is really incalculable shall be approximated.'" [257]

The court then applied the fifteen factors and held that the reasonable and entire compensation to patentee was $1.85 per pallet.

2.3.2. Gargoyales, Inc. v. United States

Patentees, Gargoyales and Pro-Tech Incorporation, brought action against government, seeking compensation under section 28 U.S.C. §1498. The infringed patent was plaintiff's '611 patent. The Army of United States went into a contract with American Optical (AO), a manufacturer in the eyewear market, procuring eyewear using the '611 patent regarding the Ballistic Laser Protective System (B/LPS) owned by Gargoyles. Since the eyewear involved the B/LPS was manufactured for the United States Army by AO, the patentee was entitled to reasonable and entire compensation paid by the government.[258]

To determine the compensation, the court resorted to the fifteen factors set out in *Gerogia-Pacific*, and came to the conclusion of 10%.[259]

Factors	Evaluation in present case	Effect on royalty rate
#3 The nature and scope of the license	Government use was non-exclusive	lower
#4 The licensor's	Gargoyles was never willing to license the	higher

[257] *Id*. at 575
[258] *Supra* note 144.
[259] *Id*.

established policy and marketing program to maintain his patent monopoly by not licensing others to use the invention or by gaining licenses under special conditions designed to preserve that monopoly.	'611 patent because it is "the core and heart" of the company	
#5 The commercial relationship between the licensor and the licensee	Gargoyles and AO are both manufactures in the eyewear market. By procuring the B/LPS, the government has essentially set up AO as a direct competitor with Gargoyales and placed AO in an excellent position from which to directly challenge Gargoyles.	higher
#8 The established profitability of the	The Gargoyles eyewear was a commercial success.	higher

product made under the patent; its commercial success; and its current popularity.		
others	Previous royalty rate set by the court	
Total royalty rate		10%

(table by author)

2.3.3. Standard Manufacturing Corp. c. United States

Standard Manufacturing corporation brought action against the United States seeking compensation under section 1498. The patent infringement arose from the procurement of weapons trailers by the Air Force of the United States. MHU-173/E trailers were used by the Air Force for loading both rotary launchers and pylon adapters into the bomb bay and onto the wing stations of a B-52 bomber. Aircraft Armaments Incorporated (AAI) went into a contract with the Air Force and designed, developed and manufactured the trailer MHU-173/E. However, the MHU-173/E had problems from the time of their initial use. They were expensive, overly complex and considerably more difficult to operate and maintain than existing trailers.[260]

Standard conceived the solution to the old MHU-173/E loaders and patented the invention in the '548 patent. At the same time, Standard presented the invention and prototype to the Air Force personnel in order

[260] *Supra* note 246.

to win a contract with the Air Force. AAI had become aware of Standard's design and obtained a copy of Standard's unsolicited proposal and started to designed and manufactured the new MHU-196/M and MHU-204/M trailers by infringing the '548 patent owned by Standard. Subsequently, AAI was awarded the sole source contract by the Air Force.[261]

In determining the compensation, the court first applied the 25% rule for the basic royalty rate then adjusted it drawing on the fifteen factors in *Gerogia-Pacific*, the outcome of reasonable royalty rate was 16.31%.[262]

Expected profit of AAI	25% rule(expected profit*25%)	Basic rate
17.26	17.26%*25%	4.31%
The fifteen Factors	Evaluation in the present case	Effect on the royalty rate
#3 The nature and scope of the license	Non-exclusive	-1%
#5 The commercial relationship between the licensor and the licensee, such as, whether they are competitors in the same territory in the	AAI's status as the licensee would have strongly influenced Standard at the hypothetical negotiation	+2%

[261] *Id.*
[262] *Id.*

same line of business; or whether they are inventor and promoter.		
#8 The established profitability of the product made under the patent; its commercial success; and its current popularity.	The commercial success and current popularity concerns favor Standard	+2%
#9 The utility and advantage of the patent property over the old modes or devices, if any, that had been used for working out similar results.	Standard Improved and solved the problems of the invention MHU-173/E	+2%
#10 The nature of the patented invention; the character of the	The patent at issue have influenced the Air Force to place a high value on obtaining	+2%

commercial embodiment of it as owned and produced by the licensor; and the benefits to those who have used the invention.	other license	
#11 The extent to which the infringer has made use of the invention; and any evidence probative of the value of that use.	The Air Force could have reasonably expected to achieve cost savings near $100 million over the useful life of the infringing trailers.	+4%
others	The government did not attempt to use non-infringing alternatives at the time of the negotiation.	+1%
subtotal		+12%
Total royalty rate (+4.31%)		16.31%

(table by author)

3. Compensation Royalty Guidelines in Pharmaceutical Compulsory Licenses

There were several approaches proposed in order to setting out systematic guidelines of remuneration under compulsory license. Given the fact that the TRIPS Agreement leave a considerable room for members to determine what constitute "adequate" remuneration, each country retains broad authority to set royalties according to system of their choosing. With their discretion, different nations may be in favor of varied approaches to compensation, based upon administrative capacity, resource constrains and policy objectives concerning access and innovation, among other factors. However, when determining appropriate policies and practices for reasonable remuneration under compulsory license, there are some considerations must be thought of in establishing the system of royalty guidelines.[263]

First, the objective of setting royalty guidelines is to provide an increased transparency and predictability for both adjudicators and patent owners. As a result, complexity and bureaucracy should be eliminated in order to facilitate the governmental management over the system. Well-adopting royalty guidelines may save administrative costs and speed up the prior negotiations of compulsory license.[264]

Second, the royalty guidelines should be aware of the needs of various patent holders in products with multiple patents. Each patentee is entitled to receive divided royalty payment. In these cases, the remuneration among various patent owners may be determined by the relative importance of each patent or simply on

[263] Love, *supra* note 192, at 62.
[264] *Id*.

an equal basis. The policy makers can balance the interest between those patentees according to the needs of different situations.[265]

Third, the amount the remuneration should not become a barrier for access to medicine. To be consistent of the TRIPS Agreement and the Doha Declaration, in the cases of compulsory license issued on the medicine, the policy goal would give priority to public health comparing to private interests. In this sense, the remuneration will be lower than other situations to assist the purpose of improving medicine access for all.[266]

Additionally, there are a range of appropriate factors may be considered: therapeutic value of the medicine, including the extent to which it represents an advance over other available products; the ability of the public to pay for the medicine; actual, documented expenditures on the development of the medicine; the extent to which the invention benefited from publicly funded research; the need to respond to public health exigencies; the importance of the patented invention to the final product; cumulative global revenues and profitability of the invention; and the need to remedy anti-competitive practice.[267]

Germany adopted various forms of royalty guidelines as Japan. Japan has used rates ranging from 2% to 4% for certain purposes. For pharmaceutical products, Germany used a range of royalty rates from 2% to 10%. After the WHO's 30 August 2003 decision on the export of medicines to countries which lack sufficient manufacturing capacity, the European Commission set out several requirements and conditions from implementing such decision: The Regulation of The European Parliament and of the council of 17 May 2006 on Compulsory Licensing of Patents Relating to the Manufacturing of Pharmaceutical Products

[265] *Id.*
[266] *Id.*
[267] *Id.*

for Export to Countries with Public Health Problems.[268]

The Regulation established a maximum of royalty rate at 4%. In Paragraph 3 of the regulation, it states "Prior negotiation with right owners is waived 'in situation of national emergency or other circumstances of extreme urgency or in cases of public non-commercial.' In these cases, 'the remuneration shall be a maximum of 4 % of the total price to be paid by the importing country.' In other cases, remuneration may consider 'humanitarian or noncommercial circumstances relating to the issue of the license.'"[269]

The royalty rates regarding compulsory licenses in Canada varied according to the facts. Examples include a per piece royalty of 10 cents on watch bracelets; 5 % of cost on a machine and its component parts; between 6 % and 10 % on parts for a machine with a two cent per piece minimum; and 3.5 % of the net selling price of an article. In pharmaceuticals, Canada, cited by WHO and the UK Commission on Intellectual Property Rights as an example of a country with the most comprehensive program on compulsory licensing and compensation-setting, had set a more or less universal royalty rate of 4%.[270]

The following approaches are recommended by the UNDP report, conducted by James Love, as reasonable and appropriate methods of setting remuneration[271]:

3.1. 2001UNDP/HDR Guidelines

The 2001 UNDP Human Development Report proposed a system of

[268] *Id.*
[269] *Id.*
[270] ROGER HUGHES & JOHN WOODLEY, HUGHES AND WOODLEY ON PATENTS §66 (2001).
[271] *Id.* at 63.

royalty guidelines setting the base of royalty rate is 4 percent of the price of the generic products. The basic rate can be increased or decreased by 2 percent in accordance with the varied factors involved, such as public funds and the degree of innovation. The approach provides greater transparency and predictability royalty rate for a range of 2 to 6 percent. The benefits of this method are its simplicity, ease of administration and ability to incorporate certain factors particularly to a certain patented product.[272]

However, the Guidelines fail to accommodate all factors considered by a country when setting their royalties. For example, it ignores the budgets of different nations to pay, resulting in the same royalty outcome between rich and poor countries. The royalty payments under the guidelines are simply according to the price of generic product, without reflecting countries' income and adjustment to their financial ability. Besides, in pharmaceutical area, the royalty calculation based upon the price of generic products leads to variation of remuneration circumscribed by the cost of manufacture of products instead of the therapeutic value of medicine.[273]

To illustrate, the approach applied to three important AIDS drugs can create the following outcome:[274]

Application of UNDP guidelines to AZT, 3TC, and NVP

	Standard Rate	Therapeutic Value	Government Support	Total
AZT	.04	.02	-.02	.04
3TC	.04	.02	-.01	.05

[272] *Id.*
[273] *Id.*
[274] Love, *supra* note 192, at 52.

NVP	.04	.02	-.01	.05

(info from *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*)

3.2. 1998/Japanese Patent Office

Article 93 of the Japan Patent Act requires the Japan Patent Office should determine the amount of consideration concerning the compulsory license for public interests.[275] The Japanese Patent Office established guidelines for royalty setting on government-owned-patents in 1998. The guidelines set a normal royalty of 2 to 4 percent of the price of generic product, which can be adjusted upward or downward as much as 2 percent, for a range of 0 to 6 percent.

The difference between the Japanese Patent Office Guideline and the UNDP guidelines is the former one added "utilization factor" of 0-100 percent. The factor is used to allocate royalty payment among patent holders when the patented products contain multiple patents. This is particularly useful to determine the fixed dose of each patentee's compensation.[276]

Compared to the UNDP guidelines, the Japan Patent Office (JPO) Guidelines offer more effectiveness and elaboration on relevant factors, but at the cost of administrative complexity. In this way, it would be more difficult for the authorities to manage the royalty rates with additional flexibility.

This guideline is set by the following formula:[277]

Royalty rate=value*utilization*increased/decreased factors*exploration

[275] Japan Patent Act § 93, 86 (2006).
[276] *Supra* note 192.
[277] *Id*.

Each of the factors are calculated based on the responding number of percent Given by the following tables:[278]

3.2.1. JPO VALUE OF WORKING VARIABLE

The value of working variable can be categorized into three groups: [279]

High	4 percent (expected profit 30 %)
Medium	3 percent (expected profit 20%)
Low	2 percent (expected profit 10%)

(info from *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*)

3.2.2. JPO UTILIZATION RATIO

The "utilization ration" is determined by the importance of the invention relative to the product. If the invention is the product, the ratio is 100 percent. On the other hand, the ratio represents the fractional value of the part compared to the whole invention.[280]

3.2.3. JPO INCREASED OR DECREASED FACTORS

The increased or decreased ratio goes from 50-150 percent, applying to the following cases:[281]

a. The working of the patent is particularly necessary for public interest.

b. A royalty fee is particularly high or low.

c. The patent is not particularly novel, and other similar inventions exist.

---

278 *Id.*
279 *Id.*
280 *Id.*
281 *Id.*

d. There are other special conditions.

3.2.4. JPO EXPLORATION RATION

The ratio goes from 50-100 percent.[282] The lower ratio is used when

a. A large sum is required to conduct research for the industrialization of an invention.

b. A large sum is required to advertise and promote a product employing an invention.

3.2.5. ADDITIONAL GUIDANCE FOR USE OF JPO ROYALTY GUIDELINES FOR PHARMACEUTICALS

3.2.5.1. Additional Guidance for Value Variable

The criteria include:[283]

a. Two percent for a product that does not represent a significant advance in therapeutic benefits.

b. Three to four percent for a patented product that provides a significant advance in therapeutic benefits.

3.2.5.2. Additional Guidance for the Increased or Decreased variable

The variable contains:[284]

a. The degree to which the invention benefited from publicly funded research,

b. Evidence of particularly high therapeutic value (best in class),

c. Evidence the product was particularly innovative (first in class),

d. Evidence the private cost of development was relatively high or

[282] *Id.*
[283] *Id.*
[284] *Id.*

low,

e. Evidence that Manufacturing costs are particularly low(increased royalty for products that are particularly inexpensive to manufacture),

f. The extent to which the investment in research and development was directed at developing countries, or conducted in a country.

g. Evidence that the patent owner engages in R&D and technology transfer activities,

h. The need to correct anti-competitive practice,

i. Public health needs, including the benefits of increased access to medicines,

j. The need to respond to crises or emergency conditions, such as environmental disasters or epidemic threatening public health, and

k. Other public interest considerations.

3.2.5.3. Illustration of 1998 JPO Royalty Guidelines for Pharmaceutical Drugs

The royalty guidelines are applied to the three patented AIDS medicines in accordance with the flowing factual conclusions:[285]

a. AZT received a large sum of funding by government support in its development and research of the drug. AZT was first in its therapeutic class. The private cost of development through approval was low. As a consequence, AZT was given an *increased/decreased value* of 50 percent due to its abundant

[285] *Id.*

funding supported by the government (including the discovery of the molecule) and the relatively low private cost for research and development.

b. 3TC also benefited from some government aids. It was forth in its therapeutic class. In this way, 3TC was given 100 percent for *increased/decreased value* because of a *decreased value* in government support but an *increased value* for the therapeutic benefit.

c. NVP (Nevirapine) gained some governmental supplies in trials on product's approval. NVP was the first in its therapeutic class, and second in market share currently in its therapeutic class in the U.S. Besides, NVP is the least expensive to manufacture" third drug" in HAART therapy. Accordingly, NVP was given 150 percent for an *increased/decreased value*, considering the decrease with the governmental research and development offset by innovative nature of the product (1st in class) and low cost of producing NVP(compared to other "3rd drug" in HAART treatment).

3.2.5.4. Stand-alone Royalties

Considering all three drugs are successful sold in the market, the "exploration factor" is set at the maximum of 100. The outcomes of calculation are showed in the following table:[286]

Patents	Value	Utilization	Increased/Decreased	Exploration	Total

[286] *Id*. at 54.

AZT	.04	100%	50%	100%	.02
3TC	.04	100%	100%	100%	.04
NVP	.04	100%	150%	100%	.06

(info from *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*)

3.2.5.5. Fixed Dose Combination (FDC) ATC+3TC+NVP-Everything Patented

The percentage of each patented drug in the fixed dose combination (AZT+3TC+NVP) can be analyzed as the following table: [287]

Patents	Value	Utilization	Increased/Decreased	Exploration	Total
AZT+3TC+NVP					.04
AZT+3TC	.04	10%	100%	100%	.06
AZT	.04	30%	50%	100%	.012
3TC	.04	30%	100%	100%	.018
NVP	.04	30%	150%	100%	.04

(info from *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*)

3.3. Canadian Export Guidelines

The government of Canada adopted royalty guidelines in 2005 for compulsory license of patents for export to countries lacking capacity to manufacture drugs. In 2004, following intensive campaigning by civil society groups, the Parliament of Canada unanimously passed the Jean Chrétien Pledge to Africa Act to implement the WTO decision. The Act and related

[287] *Id.*

regulations came into force in May 2005. The relevant provision is set out in section 21.8.[288]

The Canadian Export guidelines, pursuant to section 21.08 of the Canadian Patent Act, present a sliding scale of 2 to 4 percent of the price of the generic product, in accordance with the country's raking in the UNNP Human Development Index (HDI). For most of the developing countries, the royalty rate on average is less than 3 percent. As for least-developed countries in Africa, the rate is less than 1 percent.

The most useful advantage provide by the guidelines is to adjust royalty rates based on the countries' ability to pay, resolving the insufficiency problem constraining those countries facing sever limited resources in promoting medicines for their citizens. Further, the rate is simple calculation. However, the Canadian Export Guidelines is lacking of considerations such as therapeutic value of the medicine or any other characteristic of the drugs.[289] Besides, the royalty rates are determined by the price of generic products. In this way, the remuneration would always be low even though the approach adjusts for countries' development status. The top rate is only 4 percent of the generic sales price, and the lowest rate was .02 percent for Sierra Leone. Weighted by global population, the average rate is 1.9 percent. Weighted by global rates of HIV infection, the average rate is 1 percent. It may be well helpful for less developed countries indeed, but not less feasible for industrial nations that are able to pay higher remuneration.

With 177 countries currently in the HDI index, the royalty rate under the Canadian Royal Guidelines can be formulated as:

[288] Canada Patent Act §21 (2005).
[289] Love, *supra* note 192, at 64.

Royalty Rate = .04*[(178)-(rank of the importing country)]/177[290]

The following are a fractional part of the royalty rates based upon the 2004 UNDP HDI raking:[291]

Country	2004 HDI Rank	Royalty Rate
Norway	1	4.0
United States	8	3.8
Chile	43	3.1
Brazil	72	2.4
Philippines	83	2.2
Indonesia	111	1.5
India	127	1.2
Swaziland	131	.9
Zambia	164	.3
Mozimbique	171	.2
Sierra Leone	177	.02

(info from *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*)

3.4. Tired Royalty Methods

The specialty of the approach is that, the royalty is based on the price of the patented product in the high-income country instead of the price of the generic product. Therefore, it is a completely different method comparing to the 2001/UNDP, 1998/JPO or 2005/Canadian methods. The approach serves as a role to strike a balance between the factors of countries' income and disease burden. Tiered Royalty method (TRM)is in relevance to proxies for therapeutic value (the high income price) and nations' capacity to pay. The base rate of royalty is 4 percent of the high-income country price. To calculate the royalty rates, first thing is relying on a determination of price in high-income countries, and then an adjustment based on the ratio of

[290] *Id*. at 55.
[291] *Id*.

high-income country income to licensing country income (or a similar adjustment if incidence of diseases is to be taken into account).[292]

To be more specific, the TRM is composed of two steps:[293]

1. A base royalty is calculated from the price of the product in the U.S. or European market (where prices are assumed to be both affordable and related to the therapeutic benefits of the product), and a standard royalty rate. In the testing of the approach, a four percent royalty was used, a rate that approximates the average royalty payments for pharmaceutical products in the U.S. market.
2. The base royalty is adjusted for each country, according to the relative capacity to pay. The proxy for the relative capacity to pay is either the relative per-capita income, or where there is an unusually high incidence of a disease, the relative national income per person needing treatment.

As a consequence, the results vary directly with the therapeutic benefits and the affordability.[294]

The benefit of the method is it provides a more rational framework by giving importance to the sharing of the cost of research and development (R&D). As a result, for industrial countries, it is more acceptable and sustainable speaking of sharing of R&D costs. Under this method, highest-income countries with lower burdens of disease pay much higher royalties. On the contrary, lowest-income countries with higher burdens of disease only afford the lowest royalties. When it comes to global or regional patent pools that serve countries with disparate conditions in aspect of income and disease burdens, the approach particularly remains the most appropriate

[292] Love, *supra* note 192, at 64.
[293] *Id*.
[294] *Id*.

method to calculate compensation.[295]

3.5. Comparison of Different Remuneration Methods

The following table shows the differences among the varied approaches mentioned above: [296]

Annual Royalties in USD for AIDS drug Kaletra/LPV+RTV, with high income price of $7,766 and generic price of $500

			2001/UNDP – 1998 JPO Methods @ 4 percent	2004 Canadian Export Method	Tiered Royalty Method
Country	2002 GDP/POP	HIV+/POP	LPV+RTV@$500	LPV+RTV@$500	LPV+RTV@$7766
United States	36,123	.31%	20.00	19.21	224.81
Germany	23,956	.05%	20.00	17.97	277.31
Chile	4,118	.13%	20.00	15.25	47.45
Brazil	2,593	.35%	20.00	11.98	14.45
Thailand	2,052	1.1%	20.00	11.57	3.69
Philippines	964	.01%	20.00	10.73	11.24
Indonesia	817	.06%	20.00	7.57	9.42
India	491	.38%	20.00	5.76	2.50
Swaziland	1,082	15.63%	20.00	4.63	.14
Zambia	352	11.47%	20.00	1.58	.06
Mozambique	213	5.97%	20.00	.79	.06

(info from *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*)

4. Concluding Remarks

There has been a wide discussion about the detrimental effects to patent holders in cases of compulsory licenses, which would lead to impediment to innovative activities. And it became the strongest supporting argument for

[295] *Id.*
[296] *Id.* at 57.

proponents of strict patent protections. However, less research was put into the assessment of "what constitutes 'adequate remuneration' set out in Article 31 of TRIPS". Some comments imply that "reasonable compensation" is inherently inadequate given the fact that the essence of compulsory license is to deprive patent owner of the right of pricing through a voluntary licensing process. Thus, even the remuneration is satisfactory it can never be "adequate" since compulsory licenses leave right holders with far less than a reasonable economic return.[297]

Nevertheless, it is important to recognize that compulsory license is a compromise between public interests and private benefits essentially. As a result, although market rates can be regarded as reference when granting non-voluntary licenses, TRIPS never stipulated that compulsory license should compensate patent owners with royalty according to market rate. The critical issue is whether the royalty rates satisfy the requirement set out in Article 31(h) that the amount be "adequate…taking into account the economic value of the authorization." In other words, flexibilities are open to nation's discretion in order to adjust different situations. For industry with less concern of public emergency and more with technological policy, the royalty rates may be closer to market rates in voluntary licensing scenario. In respect of public health, the royalty rates can be various depending on the financial affordability as well as the severity of epidemics or diseases in granting country. For less developed countries lacking of medical treatment and resources, charging of market-rate compensation would contravene the objective and purpose of TRIPS seeking preservation of public interest.

Additionally, in countries with abundant resources, it would still be unreasonable to pay for higher remuneration when it comes to compulsory licenses for export to needed countries. To use compulsory licenses as

[297] See Ronald Cass, *Drug Patent Piracy*, WALL ST. J., May 7,2007, at 15.

anti-competitive remedies, the punitive elements should be considered when determining the royalty rates since patent holder misuses the right in previously. This is the reason that in some anti-competitive remedies, the compensation could be as low as zero.

The “adequate” compensation varies in cases, but there is one thing for sure: a transparent and efficient system for royalty setting in compulsory license would facilitate the prior negotiations of voluntary licensing as well as the later process of non-voluntary licensing.

Concrete guidelines of remuneration provide predictability for the licensor to evaluate the strategies of licensing price and give administrative officials clues and leverage in negotiating with patent holders. If being used tactically, compulsory licensing mechanism is a powerful means for less developed countries to stand against multinational corporations. Take Brazil for example, it successfully utilizes the mechanism to achieve the objective of price reduction of high-pricing drugs. As for patent holders, compulsory license is not an evil in every aspect. By receiving royalties of licensee’s net sale, it somehow makes up for the lost profits. Furthermore, in countries without the supply of patented drugs, generic products can broaden the markets for more business.

In short, the decision of the amount remuneration is a result of compromise taking into account of a variety of political policies and market considerations. And it needs more reliable guidance and specific research among nations to bring better predictability to future compulsory licensing implementation.

Chapter VI *Experiences of Compulsory License in Taiwan*

1. Cases of Compulsory License in Taiwan

In Taiwan, there are two compulsory licensing cases so far. In July, 2004, the Taiwan Intellectual Property Office issued compulsory license to Gigastore for 5 patents related to CD-R of Philips. And In November 2005, Taiwan granted a compulsory license for patents needed to manufacture and sell generic versions of Tamiflu.

1.1. Compulsory Licenses for Philips' CD-R Patents

Koninklijke Philips Electronics N. V. (hereinafter Philips) owned the patents to the Orange Book recordable compact disc (CD-R) standard for about 20 years. In 1999, Philips entered into contracts of package licensing agreement with three companies, Gigastorage Corp. (Gigastorage), Princo Corp. and Linberg Enterprise Inc. The Royalties set in the agreement was either at 3% of the net selling price or ￥10 per disc, which ever was higher. In fact, Philips has licensed the patents to Taiwanese companies since early 1990's and Taiwanese manufacturers supplied approximately 80% of the world's CD-R market by 2003. However, the wholesale price of CD-R had fallen to $0.50 in 2000, compared to $7 per disc in 1996. Thus, ￥10 came to represent approximately 30% of an off-the-shelf CD-R's price, which was unproportionate to the original agreement. Consequently, all three licensees stopped paying royalties to Philips. Philip thus terminated the license to Gigastorage for its non-reporting and under-reporting sales and failure to pay

royalties. However, Gigastorage went on manufacturing CD-R with the patented standard. And both parties were unable to reach a new agreement regarding to a satisfying royalty.[298]

In July, 2002, the Intellectual Property Office of Taiwan (TIPO) issued compulsory licenses to the 5 patents related to CD-R possessed by Philips in response to Gigastorage's application. The granting ground supporting the TIPO's decision was that Gigastorage had made several attempts to negotiate with Philips but in vain. According to the earlier finds of The Taiwan Fair Trade Commission (FTC), Philips had abused its patent right by requiring unfairly high royalty. Pursuant to Article 76 (1) of Taiwan's Patent Act, which allows the granting of compulsory license when a patent owner has failed to offer a voluntary license on "reasonable commercial terms and conditions"[299], TIPO granted compulsory licenses to the 5 patents at issue.[300]

On appeal, the Committee of Appeal of the Ministry of Economic Affairs (MOEA) affirmed TIPO's decision. As a result, Philips continued to seek redress and file a complaint against Taiwan for granting compulsory licenses to CD-R invoking Article 28 and 31 of the TRIPS Agreement. The EC circulated the case to Trade Barrier Regulation Investigation Report to Member State and made public on 30 January 2008. In the report, it concluded that Article 76 of the Taiwanese Patent Act and the compulsory licenses to

---

[298] *See* Report to the Trade Barriers Regulation Committee, *Examination Procedure Concerning an Obstacle to Trade, within the Meaning of Council Regulation (EC) No 3286/94, Consisting of Measures Adopted by the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu Affecting Patent Protection in Respect of Recordable Compact Discs* (Jan. 30, 2008) , *available at* http://trade.ec.europa.eu/doclib/docs/2008/january/ tradoc_137633.pdf [hereinafter the EC TBR Report]. For an Executive Summary, see http://trade.ec.europa.eu/doclib/docs/2008/january/ tradoc_137632.pdf

[299] The provision specifying "patent owner's failure to offer a voluntary license on reasonable terms and conditions constitutes ground of compulsory license "has been eliminated in the new draft of Taiwan's Patent Act since the authorities concerned had faced with pressure from the European Commission after the issuance of compulsory licenses to Philips.

[300] *Supra* note 298

Philips were in violation with the TRIPS Agreement. Furthermore, the EC pressured Taiwan to amend the Patent Act and invalidate the grant of compulsory licenses within 2 months. If the concrete steps were not taken, it would file a WTO complaint against Taiwan. Afterwards, the Taipei High Administrative Court revoked the controversial decision on 13 March, 2008.TIPO did not appeal.[301]

1.2. Compulsory License for Tamiflu

On 25 November, 2005, the Department of Health (DOH) in Taiwan announced that the Taiwanese government would issue compulsory license on Roche's patented drugs of "Tamiflu" for local production, which was regarded as the most promising treatment for avian influenza. According to TIPO's Director of International Affairs, stockpile of Tamiflu was only enough to treat 1% of the population, well below the WHO recommended stockpile of 10% of the population. When the negotiations with Roche were still ongoing, a decision to grant a compulsory license was granted to DOH by TIPO. TIPO issued a conditional license for the generic version of Tamiflu valid until December 2007 or until a licensing agreement is concluded between Taiwan and Roche. TIPO's announcement stated that the locally produced versions would be solely for domestic use and would be used only in the event that supplies of Roche-produced Tamiflu were exhausted.[302]

During the negotiations between Taiwan's DOH and Swiss drug-manufacturer Roche over supply of avian influenza treatment Tamiflu, Roche's spokesman claimed that Roche would be able to provide Taiwan with

[301] *Id*.
[302] ICTSD, *Taiwan Issues Compulsory License for Tamiflu*, *at* http://ictsd.org/i/ip/39838/

the necessary supply, and promised to offer Taiwan with 2.3 million doses (10% of the population in Taiwan) by June 2006. However, Taiwan health officials were concerned about the timely supply of Tamiflu. According to the DOH Bureau of Pharmaceutical Affairs Director General' announcement, the most dangerous period for avain influenza infections was likely to be between January and March of 2006. Therefore, considering the global demand for Tamiflu, it was doubted that Roche would be able to meet its commitment to supply Taiwan necessary amount of stockpile.[303]

As a result, TIPO invoked Article 31 of the TRIPS Agreement and limited the locally produced generic versions of Tamiflu to domestic use under the control of DHO, justifying its issuance of compulsory license for Tamiflu.[304]

2. Analysis of Possible Methods for Appliance in Taiwan

2.1. The Outcome of Possible Methods

After the comparison of different experiences and guidelines in other countries, this part elaborates how the approaches and practice adopted and used by other nations can be applied in Taiwan. The application may be seen as reference when administrative authorities have to determine the compensation of compulsory licenses.

2.1.1. General Compulsory License

In General cases, the remuneration amount can take into account the fifteen factors listed in *Gerogia-Pacific* case used by the courts in

[303] *Id.*
[304] *Id.*

the U.S. However, considering the legislative backgrounds of Taiwan and America are different in respect of compulsory license. This approach needs some adjustment in order to fit it the domestic situation.

In the U.S., the government is able to take any protected patent in the country, and the right owner can only seek for just compensation under section 1498. This is the reason that the infringement of the government is altered to compulsory license since the U.S. cannot be held as infringer. Sometimes the compulsory license is for no public interests.

Nevertheless, in Taiwan, compulsory license must go through the requiring prerequisites set out in the Patent Act, usually involving public interests. As a result, the hypothetical negotiation method in *Gerogia-Pacific* case is not perfectly applicable in domestic situation. For example, the issuance of compulsory license might be the means of addressing national emergency, public interests, technological application and anti-competitive. When the grounds for compulsory license involves non-commercial usage and public welfare or anti-competitive considerations, the remuneration should be adjusted downward comparing to the hypothetical negotiation, or even much downward due to the punitive elements. Besides, the remuneration decided by the courts in the U.S. mentioned above are basically too high for the situations in Taiwan considering the royalty payer in the introduced American cases is the U.S. government instead of private corporations.

Article 87 specified the grounds for compulsory license:

” In response to national emergency or other major emergencies, the Patent Authority may, through an urgent order or upon notice from the central government authorities in charge, grant compulsory licensing of a patent as needed, and notify the patentee of the same as soon as possible.

Under any of the following circumstances, for which a compulsory patent licensing is needed, the Patent Authority may, upon request, grant compulsory licensing of a patent:

1. Where a non-profit-seeking practice of the patent is sought for enhancement of public welfare;

2. Where the practice of a later invention or utility model patent may inevitably infringe on an earlier invention or utility model patent, and where the later invention or utility model patent offers significant technical improvement with considerable economic significance over the prior invention or utility model patent.

3. Where a patentee has committed act(s) restricting competition or has committed unfair competition acts, which have been confirmed via a judgment issued by a court or a decision issued by the Fair Trade Commission of the Executive Yuan.”

In conclusion, while applying the fifteen factors to determine the compensation, compulsory licenses without public welfare are more likely to fully utilize the *Gerogia-Pacific* case in order to protect the patent holders. But in the situations where public interests are involved , the hypothetical negotiation may concede the evaluation of

public policy.

2.1.2. Pharmaceutical Compulsory License for Domestic Use

Since the compulsory licensing cases in Taiwan are not sufficient enough to make the authorities concerned adopt concrete guidelines to determine compensation, a more specific guidelines might be suitable for the administrative process. Due to the lack of experiences, the UNDP report may be to simple and with less value for the Intellectual Property Office referring to.

As for the tiered royalty method, it was brought out by scholar and with no practices in real world. Therefore, considering the fact that Taiwan have not dealt with plentiful compulsory licensing cases, the approach can be too ambiguous and abstract for Taiwan Patent Office to put into practice.

However, the approach proposed and used by the Japan Patent Office is more applicable to Taiwan Intellectual Property Office. Aside from the more similar cultural background, the approach set out much more specific considerations and its relevant royalty rates for the official to operate. With the elaborate and careful evaluation guidelines regarding the administrative discretion, it provides useful guidance for the Taiwan Patent Office the clues and facilitate the determining process.

3. Interview with the official of Taiwan Intellectual Property

Office

In order to conduct the empirical study of the remuneration issue for compulsory license, the thesis includes an interview with the section chief of First Patent Division, Shin-Ling Wu, in the Intellectual Property Office in Taiwan. The complete interviewing verbatim can be found in the appendix.

The main goal to do this interview is to understand the stance that the government takes in compulsory licensing compensation, and how the officials interpret “adequate” remuneration in non-voluntary licensing. Besides, by interviewing the administrative official in respect of remuneration, we can explore how they undertake the negotiating process of compulsory license and the background of the two compulsory licensing cases in Taiwan.

According to the official, the interpretations of “adequate” differ between the situations of compulsory license. In pharmaceutical aspect, Article 91 in the new Amendment of Patent Act takes into account of the Decision of the General Council of 30 August 2003, and incorporates the requirement of the Decision considering “the economic value to the importing Member”. Also, when there is still confusion, the authorities concerned shall refer to the human resource development index issued by the United Nations. As for ordinary compulsory license, it is difficult for the administrative authorities to make a concrete legislation.

General compulsory licenses are for the purpose of redressing the wrongs of patent right abuses that result in unfair competitions in the market. Therefore, the major object of ordinary compulsory license is to force the parties to enter into a contract in reasonable terms. In this part, the section chief interviewed thinks the remuneration under such circumstances would vary case by case. “For example, I

remembered there was a case in America considering twelve elements to determine the compensation, including the factors of the markets, the change of the whole industry, these are all possible considerations taken into account. Also, aside from the domestic factors, we evaluate the international markets as well. Like in the case of CD-R, the prevalence of the product and the supply-demand in the market are all elements should be considered."[305]

Under the present articles of the Patent Act, the remuneration is decided by the concerned parties first. The administrative authorities step in when the negotiations between the parties fail. The responsible institution is Intellectual property Office. Therefore, there are two steps in determining the compensation. However, this process would be time-consuming and sacrifice the interests of the patent holder. After the amendment of the Patent Act, Article 88 stipulates that "a decision on an application for compulsory licensing shall be made in writing, and shall indicate the reasons, scope, time period, and the required compensation." In order to balance the benefits of both parties, the compensation should be determined by the government as soon as the decision is made.

There were no ensuing negotiations for compensation in the both cases of compulsory license in Taiwan. For Tamiflu case, the decision of compulsory license is valid for two years. In the two years, the Department of Health did not file any application. As a result, the decision had no executive force after the period. In fact, at the time, the Department of Health lacked of the capability to produce Tamiflu on a large scale. This was the main reason why the Department of Health did not file the application. According to the section chief, Wu, "Although the capability of producing generic pharmaceuticals in Taiwan is above the international average, Tamiflu was not one of the dugs that Taiwan could produce

[305] Verbatim, at 144.

in mass. Besides, Roche had provided sufficient amount of medicine for domestic market in the end."[306]

When it comes to setting royalty guidelines in compulsory license, it would be no easy task in ordinary cases; however, in pharmaceutical cases, due to its humanitarian considerations, it is easier to reach a consensus between the governments and the right owners worldwide. In this way, looking into the legislations in other countries, only the calculation of remuneration under compulsory license in medicine can be specifically enacted or adopted in their laws. Section chief Wu comments "For mandatory contracting, if there is such a specific guideline, everyone can establish a measurement strategy. I think it can provide reference for all the industries. So when I'm making a contract with you, I knew how the authorities concerned think of the compensation. In this range, the risk of compulsory licensing is decreased (which can encourage voluntary licensing between the parties). But the question is: among all these industries, which one should be chosen? The documents of royalties for private licensing are usually commercial secrets, which cannot be obtained by the government easily."[307]

"As a result, we have not thought of setting specific guidelines for general compulsory license yet. But in the CD-R case, we referred to the foreign cases and asked for opinions from scholars and experts about a proper rate for the industry. There should be a formula for this, I cannot remember it right now. It should be something like 25% of the net sales, which the industry deems appropriate.... I think when the Intellectual Property Office decides to set the guidelines, it will go back to the issue of the appropriate rates for the industry…. As for the

[306] Verbatim, at 145.
[307] Verbatim, at 146-47

pharmaceutical cases, we have already adopted an approach in the amendment of the Patent Act. 'The amount of compensation shall be decided by the Patent Authority according to the economic value of the patent covering the required pharmaceuticals in the importing country with reference to the human resource development index issued by the United Nations.'"[308]

In the New Amendment of the Patent Act, "reasonable commercial terms" has become the requirement of negotiating process instead of issuing ground for compulsory license as stipulated in Article 76 of the present Patent Act. The CD-R case was initially decided by the Intellectual Property Office using the ground of "both parties failed to reach a consensus in reasonable commercial terms in a period of time." But the court later on revoked the decision and ruled that the evaluation of reasonable commercial terms by the office was too reckless and vague. However, in Wu' opinion, she puts "Basically, in the previous CD-R case, I think the court step in the issue improperly. I think this is an 'uncertain legal concept', which belongs to administrative institution's discretion that the court should show respect…. In the CD-R case, it should be dealt with a violation of fair competition, but that would be a road with endless waiting for the companies. As a result, we used the ground of reasonable commercial terms. However, the main purpose was to urge the parties concerned to have more negotiations."[309]

As for whether the royalty is the indication of reasonable commercial terms, Wu provides that "remuneration for compulsory license should go back to situation of the general reasonable royalty in private licensing. If the similar case comes up in the future, the previous case must be the indication of the next, taking into account of other factors regarding different backgrounds in the cases.

[308] Verbatim, at 147.
[309] Verbatim, at 148.

Therefore, if the industries are similar, the previous compensation determined would be the indication for the next."[310]

4. Concluding Remarks

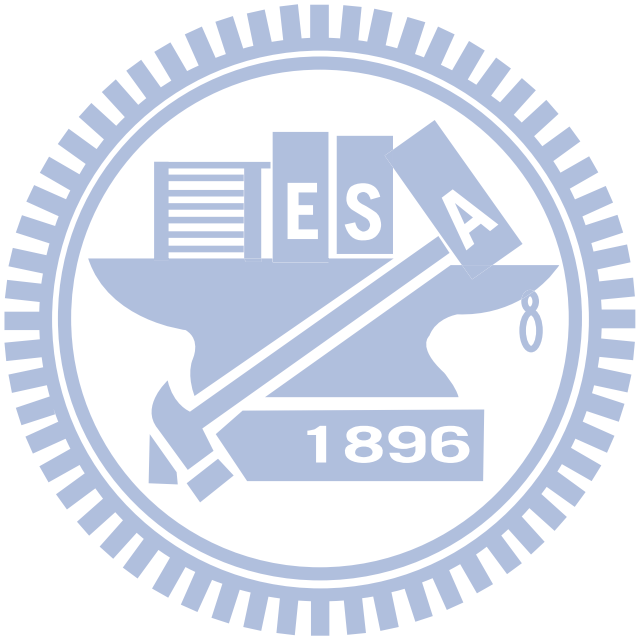
In sight of the interview with the official of Taiwan Patent Office, it is obvious that there are limited research and studies made by the administrative office concerning the remuneration of compulsory license. Part of the reason is that the Patent Office have only dealt with two cases so far, and the other reason may be that compulsory license is the last thing that the authorities concerned would like to face with in the future. The CD-R case was effort, time consuming to the Patent Office for not only the pressure from the EU but also the policy concerns of the Taiwanese government.

However, a thorough study of the royalty rates adopted by the market in different industries and the guidelines of remuneration used in certain countries can help the officials make the decisions on the issuance of compulsory license and the remuneration. In general compulsory licensing cases, market rate is a deciding factor of determining the compensation. In pharmaceutical cases, humanitarian concerns make the standard of royalty setting more specific and predictable.

Therefore, to make the next compulsory license case with less controversy and more predictable, the remuneration guidelines disclosed by the government may let the licensor and licensee know the scope of reasonable royalty rates and lower the risk of compulsory license. Besides, if there is an unavoidable case, then

[310] *Id.*

the process of determining the compensation can be transparent and justifiable by referring to the guidelines, saving the arguments about the ambiguity and reckless decision-making process.



Chapter VII *Conclusions*

After the adoption of the TRIPS Agreement in 1995, the global standard of patent protection was set up. Compulsory license, as leverage against patent right abuse, is stipulated in Article 31 of the TRIPS agreement. However, compulsory license means to take the patent without right owner's voluntary authorization, depriving the patentee of the right of the freedom of licensing. As a result, in TRIPS, an adequate remuneration paid to the patentee is required for balancing the private and public interests.

As a WTO member, the Taiwanese Patent Act has incorporated the compulsory licensing clause into its contents. The Taiwanese New Patent Act stipulates the Patent Office shall specify the amount of compensation for compulsory license within the decision in written form. However, the provision does not set out the approach and method of how to determine the remuneration.

The thesis makes a study of the academic interpretations and practices in reality regarding "adequate remuneration" in compulsory licenses and intends to provide some useful future references for the administrative office to fill in the room left by the legal contexts. As mentioned above, the determining of adequate remuneration can be discussed with two tiers, which is the general compulsory licensing and pharmaceutical compulsory licensing.

Compensation for compulsory licensing in general cases should consider the existing market rates and the environment of the industry. For example, the nature of the patented invention; the character of the commercial embodiment of it as owned and produced by the licensor; the benefits to those who have used the invention; the established profitability of the patent, etc. The fifteen factors listed in the Gerogia-Pacific case can be taken into account. But it should be born in mind that

under the circumstances where there are public interests involved, the royalty rates should be adjusted downward public policy concerns. To facilitate the process of administrative work, the government may do some research on the existing royalty payment in the market according to various industries in case there is a need. Besides, the demonstration on the existing royalty rates can also make the remuneration decisions more acceptable.

The pharmaceutical part is much easier to formulize with clear computing methods due to its humanitarian considerations. That is the reason why it can be standardized into different methods and used in some countries. For Taiwan, the approach of Japan Patent Office provides more guidelines for application and thus is more suitable for the administrative office with less experience about deciding the compensation. But considering the interests of patent holders, the question is: to what extent the pharmaceutical patentee should shoulder the burden of public health

Lastly, royalty setting guidelines can provide future references for voluntary licensing between in the free market. Although the provision concerning the granting ground of “reasonable commercial conditions and terms” was crossed out in the new draft Amendment of Taiwanese Patent Act and became a procedural requirement, it is still obvious that there is no concrete guideline for reasonable commercial conditions and terms for the administrative reference. By looking at the history of the CD-R case, the cause of the controversy was both parties could not reach a consensus on the royalties. Royalty is usually the first concern when it comes to commercial terms. Additionally, one of the approaches to determine remuneration in compulsory license is referring to market rates. Thus, a royalty setting system in regard of compensation in non-voluntary licensing can not only provide reference for what constitutes “reasonable commercial terms and conditions” but also make the process of compulsory license more transparent and predictable.

Appendix

The Verbatim of the interview with Section Chief of First Patent division in Taiwan Intellectual Property Office

1. 請問對於 TRIPS 所規定「應予被強制授權人適當補償金」之規定，如何解釋「適當」須考量之因素?

「適當」這個部分我想還是要分成兩個部分來談，一個是屬於一般的強制授權、一個是屬於公共衛生這個部分。這兩個不一樣，像 TRIPS 的規定是一般強制授權這個部分嘛，那醫藥強制授權是由這個總理事會的部分，現在修法也還沒有通過，那醫藥強制授權這個部分，我記得度哈宣言還有總理事會的決定是說要參考進口國的狀況嘛，所以我們在修法的部份也把他訂進去啊。這是新修正的專利法第 91 條嘛(原草案第 93 條)，今年十一月二十九號會施行。所以在這個 public health 的部分呢，我們是參照總理事會的宣言內容，以進口國的計算價值以及聯合國 UNDP 的計算標準、立法指標核定之,，所以這個部份在 public health 我們是有訂到這個標準的。至於一般強制授權的部分，因為一般強制授權這個就沒有訂到，因為很難訂嘛。而且其實強制授權主要糾正的是什麼?那是糾正專利權人一個不當實施的情況，你不實施，或是沒有合理理由不實施的情況下啟動所謂的一般強制授權。所以這兩個的性質是不一樣的，在我個人認知裡面，我認為醫藥強制授權比較像是這個徵收的狀況，那至於一般的強制授權比較是在強制締約的狀況。所以兩個會是有些不同的，那這個 public health 也是目前只有針對藥品的部份嘛，而且它是基於一個人道的考量，所以這個補償金的部分是有辦法去做一些衡量的；那至於一般的強制授權，我們應該是不希望有一般強制授權的狀況，一般強制授權最主要是希望能糾正一般專利權人這個壟斷的狀況下造成的一個不公平的狀態，所以這個一般強制授權，它最主要是要促使雙方去締約，而且是在一

個合理的狀況下去締約，所以這個部分，所謂的適當補償金我覺得要衡量的因素就很多了，我記得美國有一個 case 有衡量到十二種的這個補償金的狀態，包括市場的因素啊等等，整個產業的變動，這個都是它可能去衡量的因素，所以這個我認為是說要看各案的情況。所以 TRIPS 第 31 條的第一款也說到應就各案的情況去做判斷，因此我覺得還是要看各案上它所要去考量的因素是什麼。

那強制授權有規定說是主要供應國內市場需求嘛，所以除了看國內市場外，我們也有去衡量些國際的市場。像是在 CD－R 的這個案子，在整個市場上的普及率多少，那個市場供應價格的情況是怎麼樣?其實都會去衡量啦，所以就算是主要供應國內市場的這個部份，我覺得在一般強制授權的狀況下，國內外的因素應該是都會一起去考量。

2. 我國強制授權補償金之決定機關及程序為何?

在現行的法條是說由雙方去協議，協議不成在由主管機關訂之。這邊指的主管機關是智慧局。那當然大家對這個補償金的內容還有爭議的時候，原來的第 76 條，應該是在第 3 項，特許實施權人應給與專利權人適當之補償金，有爭執時，由專利專責機關核定之。診本的專立法裡面都沒有提到經濟部智慧局，都是用專利專責機關，這就是指智慧財產局。因為主管機關是經濟部，經濟部會指定專利專責機關，你看第 3 條，本法主管機關為經濟部，專利業務由經濟部指定專利專責機關辦理。所以目前專利專責機關指的就是經濟部智慧財產局。

我們目前的組織分工裡面，智慧財產局的相關組織條例是規定關於特許實施的部份是由法務是來處理啦，而不是由專利組。所以就是由法務是處理內部幕僚的問題，當然整個行文的作成，最後的處分機關是經濟部智慧財產局啊。那現在修法的話，已經有一些變革了啦，為了雙方的利益是可以衡平的，所

以權利金是在第 88 條裡面，第 3 項規定強制授權之審定應以書面為之，並載名其授權理由、範圍、期間、及應支付之補償金，所以會要求在審定的書面就會有支付補償金的一個狀況。

3. 克流感之強制授權一案，最後是否有後續補償金之協商，若有，其補償金額為?

那個(案件的強制授權)處分是確定，可是它有一個就是兩年的期限，那兩年期限到了之後，衛生署沒有做這個申請的動作，所以期限到了之後這個處分就結束了，就不會在有它的執行力了，所以就沒有後續的動作，那個案子後來就是沒有實施的，因為衛生署也有考量到它可能是做不出來，它沒有辦法量產，當然我們的學名藥製藥是很厲害，但後來針對克流的藥品，還是有考量到可能沒辦法量產，而且實際上羅氏後來有充足供應給國內，它有把藥調進來。

所以在補償金的部分，在現行法時代是由雙方去磋商，所以向我剛剛說的，在一般強制授權是一的強制締約的狀況嘛。我這個主管機關是把手伸進來，促使雙方締約，至於締約後的後續條件呢，我們在現行法的架構底下，是交由雙方協議，我告訴你應該締約，至於內容是什麼，你們再去磋商，所以補償金就會說有一個兩階段的狀況嘛，第一個是說我行政機關說要強制授權，請你跟他強制締約；後續條件你們兩個去談，談不攏的時候我來核定。

在智慧局裡面目前是沒有補償金核定標準，但我們有在研究，像是在 CD-R 的案子的時候我們有請一些專家來提供意見，那當然他們都是說補償金的計算呢，會對應到後續的部分，像是合理商業條件的部份，合理商業條件我想就是衡量什麼是合理授權金的一個內容。那當然，這個合理的補償，應該說合理的授權金是怎麼樣去衡量的，就會被運用在怎麼去衡量合理補償金的狀況。因為在一般的強制授權裡，當然是要回到一般市場的狀態去做考量，以

市場指標為準。那可能看產業類別，相關的東西在這個市場的佔有率是多少，那對於整個未來產業發展的影響是多少，或許會有這些的判斷因素會進來。

4. 我國有無建立補償金制度的參考指標之計畫?

唯一我現在可以告訴你的是在修正專利法第 91 條，公共衛生的部份我們已經訂了嘛，就是進口國的經濟價值，並且要參考聯合國 UNDP 的標準去訂。所以這個部份是有的，而且我想，各國也只敢針對 public health 的公共衛生議題這一塊去明確在法規中訂出一個計算標準，因為公共衛生議題的用意是為了去填補這些低度開發國家他們的用藥需求，我覺得這是我目前看過的各國草案中是也把這些資料寫進去的。進口國經濟標準是聯合國總理是會決議中所提到的文字，那我記得當初立法時，我們是參考加拿大的計算標準，來把它寫進去的，所以你可以看一下我們修正草案的內容，我必須強調這個部份，就是有參考到這個 UNDP 以及把它具體要參考的標準有把它概括寫進去的，就我所知只有在公共衛生議題這一塊，把它寫的這麼清楚，其他的一般強制授權，就沒有。應該還是會回到市場，或是各產業類其不同的計價標準去認定。修正草案理由的部分第八點，我們就有寫到，是基於人道立場嘛，所以呢，參考它的規定。

5. 請問如建立強制授權補償金參考標準，是否有助於促成專利權人自願授權?

但你要用什麼要的標準去訂呢?產業別那麼多的情況之下，就我所了解，目前台灣有兩個案子，一個是克流感的案子，一個是 CD-R 的案子。克流感比較是公共衛生的議題去做的。在這個狀況，目前為止，我們都沒有想到要訂這樣的一個具體權利金的比率，是沒有考慮過的。不過在 CD-R 的案子，我們有去參考國外的案子，請專家學者提供給我們說，在這個產業類別，適當的比率是什麼。應該是有一個公式啦，但確定的是什麼忘了，應該是譬如說像

淨銷售額的百分之二十五，那種等等的產業上會認為說這個是合理的一個情況，那同時你的權利金有可能是用量來計，可能是按照價來計，所以都會有各種不同的情況，那每個產業類別有它的比較適當的公式。我們那時候是沒有想說要去把它具體化，訂到說補償金是要做到多具體的程度。不過我覺得一旦智慧局決定要核定這個補償金的時候，一定還是會回到這個產業類別的適當性去判斷，像是藥品的器具，可能就不是用計次的方式，而是說你用這個器具去製造的要藥銷售了多少的百分比，去當做我授權給你的授權金。所以這計價方式產業類別會不一樣啦，一定會回去考慮各產業類別的情況。

那以強制締約的狀況來看，如果有訂這樣的一個具體標準，我想對各產業來講，大家心理會有一把尺，也就是說可以拿來當參考，向我在跟你締約的時候我就知道，大概主管機關認定的標準是怎麼樣，那在這個範圍之中，就比較不會有強制授權的風險、或是歧異啦。這是一個可能的情況，只是說這麼大的範圍，應如何訂定?

那各國提供的資料也並非去訂出一個具體標準，而是事後的蒐集。那我覺得是有幫助的啊，這麼多的情況之下，怎麼去衡量什麼合理補償金，但在這麼多產業類別下，你應該選哪個產業類別去訂?但很多產業間的授權金都是秘密，不太容易取得這樣的資料，公開資訊不見的有。

基本上，之前國碩案的部分，我認為法院對於「合理商業條件」的認定，法院的手伸的太進來了，我覺得這是一個不確定的法律概念，主管機關的判斷應該受到法院的尊重，那這個部份我不評論，也不代表智慧局的立場。只是說我們也尊重法院的一個決定。那後來飛利浦跟國碩間也談好了，那當然是最好的情況。

那補償金額它就希望回到一般合理授權金的情況下嘛，那如果說是這樣的話，那當然是這樣。那譬如說你說 CD-R 的案件再出來，那到時候原來前一個案子核定的補償金額一定是下一個案子的參考指標，那可能會在因為當時的時

空背景不同加進一些其他因素作判斷。但原來核定的金額當然會是下一個案子的指標。那它的前提當然是說它的產業類別是一樣的，類似性高的等等情況下，它會是一個參考指標。

國碩案是有一些歷史淵源的，其實剛開始 CD-R、sony 的授權標準呢，它們是用免費使用的方式，就我所知，CD-R 是碟片嘛，它把這個規格就放入它的碟機裡面，所以你要用這個碟機就醫定要用它的碟片，那這個時候它在用一個低價的方式，最早開始的時候適用銷售的百分之三或者是十日圓嘛，高的當作它的授權金額，那因為那時候市場剛開始，大家會覺得說，好啊，那就跟它去大量的取得這個授權，跟大量的製造 CD-R 的碟片，等它造成一定的市場大量使用後，它這個專利已經形成市場上的壟斷了，大家不得不使用。那大量生產的結果就變成說是價格大量下跌嘛，它的競爭就會價格下降，價格就會低，那這個時候它的百分比的部分就佔很多了。所以這些至少廠商就沒有利潤了，但時在這個情況下，我們是考量到整個市場的狀況啦，那我們不否認就是國內廠商給我們很大的壓力，就希望說促使飛利浦在跟他們去談，它是在這樣的時空背景作成的。我想這也是大多數專利權會適用的方式，我在市場還不成熟的時候，可以免費使用，等到你習慣它了之後，你要跟我要多一點的錢，我方便的話我就願意付你錢，後專利權人再把權利金抬高。

其實國碩的背後是有很多廠商的，它是代表了相關的光碟場都一起進來的，它只是一個代表出來打的公司而已，其實這個案子最主要應該是可以用違反公平競爭的部份去處理啦，但因為法條要確定啦，但對廠商而言那是一場無止盡的等待，所以才會回過頭來用合理商業條件的部份去處理，最主要是希望促成雙方能夠繼續一直去協商這樣子。

References

(1) Agreements, Treaties and Regulations

1. Agreement on Trade-related Aspects of Intellectual Property Rights, Apr. 15, 1994 Marrakesh Agreement Establishing the World Trade Organization, 33 I. L. M. 1125 (1994).
2. Canada Patent Act §21 (2005).
3. Convention Establishing the World Intellectual Property Organization, July 14, 1967, 21 U.S.T. 1749, 828 U.N.T.S 3 (as amended Sep. 28, 1979).
4. Decision of the General Council of 30 August 2003, WT/L/540, 1 September 2003, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health.
5. Japan Patent Act § 93, 86 (2006).
6. Ministerial Conference, Forth Session, Doha, 9-14 November 2001, WT/MIN(01)/DEC/2,20 November 2001
7. The Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/Dec/2 (Nov. 14, 2001).
8. United Nations, Vienna Convention on the Law of Treaties, 23 May 1969, United Nations, Treaty Series, vol. 1155, p. 331.

(2) Books

1. AUST, ANTHONY, MODERN TREATY LAW AND PRACTICE (2000).
2. AUSTL'N PRODUCTIVITY COMM'N, INTERNATIONAL PHARMACEUTICAL PRICE DIFFERENCES (2001).
3. BOEHM, KLAUS, THE BRITISH PATENT SYSTEM (Cambridge Univ Press, 1967)
4. BROWNLIE, IAN, PRINCPLES OF PUBLIC INTERNATIONAL LAW (4th ed. 1990)

5. CAMBRIDGE UNIVERSITY PRESS, RESOURCE BOOK ON TRIPS AND DEVELOPMENT (2005).
6. CARVALHO, NUNO PIRESDE, THE PATENT REGIME OF PATENT RIGHTS (2th ed. 2005).
7. CASTRO, ARACHU & MICHAEL WESTERHAUS, ACCESS TO GENERIC ANTIRETROVIRALS: INEQUITY, INTELLECTUAL PROPERTY LAW, AND INTERNATIONAL TRADE AGREEMENTS (2007).
8. CORREA, CARLOS M., TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (2007).
9. GEREDA, SHUMANI L. , THE AFTERMATH OF CANADA'S IMPLEMENTATION OF THE DOHA DECLARATION ON THE FUTURE OF PHARMACEUTICAL INNOVATION (2004)
10. GEREFFI, GARY, ,PROFIT, PROGRESS AND POVERTY: CASE STUDIES OF INTERNATIONAL INDUSTRY IN LATIN AMERICA (Richard S. Newfarmer ed.) (1985).
11. HELFER, LAURENCE R. & GRAEME W. AUSTIN, HUMAN RIGHTS AND INTELLECTUAL PROPERTY (2011).
12. HUGHES, ROGER & JOHN WOODLEY, HUGHES AND WOODLEY ON PATENTS §66 (2001).
13. MAKUS, KEITH E. &JEROME H. REICHMEN, INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY (2005).
14. MATTHEWS, DUNCAN, GLOBALIZING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT (2002).
15. MERGES, ROBERT P. ET AL., INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE (2d ed. 2000).
16. MILLER, ARTHUR R. & MICHAEL H. DAVIS, INTELLECTUAL PROPERTY – PATENTS. TRADEMARKS, AND COPYRIGHT IN A NUTSHELL (2d ed. 1990)

17. ORGANIZATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, REGIONALISM AND THE MULTILATERAL TRADING SYSTEM (2003).
18. REILLY, ROBERT F. &SCHWEIHS, VALUING INTANGIBLE ASSESTS (1999).
19. SCHACHTER, OSCAR, INTERNATIONAL LAW IN THEORY AND PRACTICE (1991)
20. SCHERER, F.M., THE ECONOMIC EFFECTS OF COMPULSORY PATENT LICENSE (1977)
21. SCHMIDT, J. & J. L. PIERRE, DROIT DE LAPROPRIETEINDUSTRIELLE (1996)
22. UGLOW, JENNY, THE LUNAR MEN – THE FRIENDS WHO MADE THE FUTURE (2002).

(3) Cases

1. Brunswick. Corporation v. United States, 36 Fed. Cl. 204 (1996).
2. *Canada – Pharmaceutical Patents: Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, adopted 7 April 2000, DSR 2000:V, 2289.[7.92].
3. Crater Corporation v. Lucent Technologies, 255 F.3d 1361 (Fed. Cir. 2001).
4. DeGraffenried v. United States, 25 Ct. Cl. 209 (1992).
5. Dow Chemical Co. v. United States, 226 F.3d 1334, 1348 (Fed. Cir. 2000).
6. eBay Inc. v. MercExchange, L.L.C., 547 U.S. 288 (2006).
7. Gargoyles, Inc. v. U.S., 113 F.3d 1572 (1997).
8. Georgia-Pacific Corp. v. U.S. Plywood-Champion Papers, 404 U.S. 870 (1971).
9. Grain Processing Corp. V. Am, Maize-Prods. Co., 185 F. 3d 1341 (Fed. Cir. 1999).
10. Hughes Aircraft Co. v. United States, 86 F.3d 1566 (C.A.Fed.1996).
11. *Japan – Alcohol*: *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, adopted 1 November 1996 [24].
12. *Japan – Taxes on Alcoholic Beverages*, WT/DS8/AB/R, WT/DS10/AB/R,

WT/DS11/AB/R, adopted 1 November 1996[14]; see also *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, adopted 6 November 1998[21.5].

13. Leesona Corp. v. United States, 599 F. 2d 958 (Ct. Cl. 1979).
14. *Mexico – Taxes on Soft Drinks: Mexico – Tax Measures on Soft Drinks and Other Beverages*, WT/DS308/AB/R, adopted 24 March 2006 [384].
15. Penda Corp. v. United States, 29 Fed. Cl. 533 (1993).
16. Standard Manufacturing Co. v. United States, 42 Fed. Cl. 748 (1999).
17. *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, adopted 20 may 1996.

(4) Internet

1. Announcement of the Dep't of Disease Control, Ministry of Pub. Health, Thai. On the Pub. Use of Patent for Pharmaceutical Products (Nov. 29, 2006), at http://www.wcl.american.edu/pijip/documents/ThailandCLAnnouncement.doc
2. Background Document for Third Commission Meeting, Brazil: Commision on Intellectual Property Rights, Innovation and Public Health (2005), at http://www.who.int/intellectualproperty/events/BackgroundPaper.pdf
3. Carlos Correa, *Implications of the Doha Declaration on TRIPS Agreement and Public Health* 45(WHO 2002), at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf
4. Controller General of Patents Designs and Trade Marks, Patents: Twenty-second Annual Report, 1993-94 (1996) (Nashik, India: Government of India Press), at http://www.ipindia.nic.in/
5. Facts and Evidences on the Ten Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand (Dr. Vichai

Chokevivat ed., Sangsue Co., Ltd., Thailand, 2007), at http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf

6. Fred Hassan, Chairman & CEO, Schering-Plough Corp., Keynote Address at U.S. Chamber of Commerce 5th Annual Intellectual Property Summit, Fueling Innovation: To Be Our Best for a Better World (Oct. 8, 2008), at http://www.phrma.org/about_phrma/ceo_voices/fueling_innovation_to_be_our_best_for_a_better_world.
7. Gillespie-White, L., What did Doha Accomplish? The Doha Declaration on Intellectual Property Rights and Access to Medicines (2001), at http://www.iipi.org/Views/Doha 1101.pdf
8. Howard G. Zaharoff, Setting Values and Royalty Rates for Medical and Life Science Businesses, J. Biolaw& Bus., Vol. 7, No. 4, 2004, at http://www.mbbp.com/resources/iptech/royalty_rates.html http://healthnewsdaily.elsevierbi.com/~/media/Images/Publications/Archive/The%20Pink%20Sheet/65/044/00650440021/031103_health_affairs_rx_pricing.pdf http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf.
9. James Love, Compulsory Licensing: Models For State Practice in Developing Countries, Access to Medicine and Compliance with the WTO TRIPS Accord (Jan. 21, 2001) (paper prepared for the United Nations Development Programme, version 1.0), at http://www.cptech.org/ip/health/cl/recommendedstatepractice.html.
10. James Love, Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies, Health Economics and Drugs TCM Series No. 18,at

13(2005), at

11. James Packard Love, Recent Examples of the Use of Compulsory Licenses in Patents, KNOWLEDGE ECOLOGY INT'L, 31 March 2007, at http://www.keionline.org/misc-docs/recent_cls_8mar07.pdf
12. Jean O. Lanjouw&IianCockcurn, Do Patent Matter? Empirical Evidence After GATT. NBER Working Paper Series 7495 (2000), at http://www.nber.org/papers/w7495.pdf
13. Jerome H. Reichman& Catherine Hasenzahl, Non-Voluntary Liceinsing of Patented Inventions, UNCTAD-ICTSD Issue Paper No. 5, at p. 10 (2004), at
14. Joint communication from the Africa Group, Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement (2003), at http://www.iatp.org/documents/taking-forward-the-review-of-article-273b-of-the-trips-agreement
15. Letter from Lila Feisee, Managing Dir., Biotechnology Indus. Org., to Jennifer Choe Groves, Dir. for Intell. Prop. and Innovation and Chair of the Special 301 Comm., at 3-4 (Feb. 11, 2008), at http://www.pharmalot.com/wp-content/uploads/2008/02/bio-letter-to-ustr.pdf
16. Martin J. Adelman, Compulsory Licensing of Drugs: TRIPS Context 1, Paper Presented at ATRIP Annual Meeting in Tokyo, Japan (Aug. 4, 2003), at http://www.atrip.org/upload/files/activities/tokyo2003/s02-Adelman_art.doc.
17. Ministry of Pub. Health Announcement Regarding Exploiatation od Patents on Drugs and Medical Supplies for Clopidogrel (Jan. 25, 2007), at http://www.wcl.american.edu/pijip/documents/thaicl-plavix.pdf?rd=1
18. Opinion of the commission on remedy, at http://www.ftc.gov/os/adjpro/d9302/070205opinion.pdf
19. Patricia Danzon& Michael Furukawa, Prices and Availability

ofPharmaceuticals: Evidence from Nine Countries, HEALTH AFFAIRS, at

20. PongphonSarnsamak, No Cancellation of CL for Cancer Drugs, Nation, Mar. 4, 2008, at http://www.nationmultimedia.com/2008/03/03/national/national_30067110.php
21. Press Release, Merck & Co., Statement on Brazilian Government's Decision to Issue Compulsory License for STOCRIN™ (May 4, 2007), at http://www.merck.com/newsroom/press_releases/corporate/2007_0504.html.
22. Press Release, Office of the United States Trade Representative, U.S. and Brazil to cooperate on HIV/AIDS and WTO Patent Dispute, (June 25, 2001), at http://usinfo.state.gov/topical/econ/ipr/ipr-braziltrips.html
23. Report to the Trade Barriers Regulation Committee, Examination Procedure Concerning an Obstacle to Trade, within the Meaning of Council Regulation (EC) No 3286/94, at http://trade.ec.europa.eu/doclib/docs/2008/january/tradoc_137633.pdf
24. Robert Weissman, Cakewalk Ken Adelman Returns to the Stage, Multin'l Monitor, Mar. 1, 2007, at http://www.multinationalmonitor.org/mm2007/032007/weissman.html.
25. S. P. Shukla, From GATT to WTO and Beyond (2002), at http://www.wider.unu.edu/publications/working-papers/previous/en_GB/wp-195/
26. Sykes, Alan O., TRIPs, Pharmaceuticals, Developing Countries, and the Doha 'Solution' (February 2002). U Chicago Law & Economics, Olin Working Paper No. 140. at http://ssrn.com/abstract=300834
27. Thai National Health Security Office, The Ten Burning Questions on the Government Use of Patents on the Four Anti-Cancer Drugs in Thailand 4 (Feb.

2008), at http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5BEN%5D.pdf.

28. USTR."1989 Special 301 Report", 1989, at http://keionline.org/sites/default/files/ustr_special301_1989.pdf.
29. Wesley M. Cohen et al.,Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or not) (2000), NBER Working Paper Series 7552, at http://www.nber.org/papers/w7552
30. WIPO, Summary of WIPO Technical Assistance for the Least Developed Countries, at http://www.wipo.int/ldcs/en/ip/tech_assistance.html.
31. World Health Organization, Improving Access to Medicines in Thailand: The Use of TRIPS Flexibilities (2008). at http://www.moph.go.th/hot/THAIMissionReport%20FINAL15feb08.pdf

(5) Articles

1. Abbott, Frederick M., *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 Vand. J. Transna'l L. 689 (1989).
2. Abbott, Frederick M., *The TRIPS Agreement, Access to Medicine and the WTO Ministerial Declaration*, 5 J. WORLD INTELL. PROP. 15 (2002).
3. Abbott, Frederick M., *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317 (2005). *An Empirical Investigation*, 2 J. L. & TECH. 209 (1987).
4. Bird, Robert & Daniel R. Cathoy, *The Impact of Compulsory licensing on Foreign Direct investment: A Collective Bargaining Approach*, 45 AM. BUS. L. J. 283, 309-12 (2008).
5. Boyle, James, *A Manifesto on WIPO and the Future of Intellecual Property*,

2004 DUKE. L. & TECH. REV. 9 (2009).

6. Boyle, John, *Patents or Premiuns*, 26 J. PAT. OFF. SOC'Y446, 450-51 (1944).
7. Bumiller, Elizabeth, *Public Health or Public Relation*, New York Times, October 21, 2001.
8. Cahoy, Daniel R., Confronting Myths and Myopia on the Road from Doha, 42 GA. L. REV. 131 (2007).
9. Cahoy, Daniel R., *Patent Fences and Constitutional Fence Posts: PropertyBarriers toPharmaceutical Importation*, 15 FORDHAM INTELL. PROP., MEDIA & ENG. L.J. 623 (2005).
10. Carcalho, NunoPires de,*The Primary Function of Patents*, 1 J. L. TECH. & POLICY 25 (2001)
11. Cass, Ronald, *Drug Patent Piracy*, WALL ST. J., May 7, 2007, at 15.
12. Chien, Colleen, *Cheap Drugs at What Priceto Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853 (2003)
13. Cordray, Monique L., CATT v. WIPO, 76 J. PAT. & TRADEMARK OFF. SOC'Y 121 (1994)
14. Correa, Carlos M., *TRIPS and Access to rugs: Towards a Solution for Developing Countries without Manufacturing Capacity*, 17 EMORY INT'L L. REV. 389 (2003).
15. Dam, Kenneth W., *The Economic Underpinnings of Patent Law*, 23 J. LEGAL STUD. 247 (1994).
16. Dorahos, Peter, *BITs and BIPs*, 4 J. WORLDINTELL. PROP. 791, (2001).
17. Emmert, Frank, *Intellectual Property in the Uruguay Round – Negotiating Strategies of the Western Industrialized Countries*, 11 MICH. J. INT'L L. 1317 (1989)

18. Feldman, Jamie, Note, *Compulsory Licenses: The Dangers behind the Current Practice*, 8 J. INT'L BUS.& L. 137 (2009).

19. Frame, J. Davidson, *National Commitment to Intellectual Property Protection:*

20. Gana, Ruth L., *Prospects for Developing Countries Under the TRIPS Agreement*, 29 VAND. J. TRANSNAT'L L. 735, 742 (1996).

21. Garcia-Castrillon, Carmen Otero, *An Approach to the WTO Ministerial Declaration on the TRIPS Agreement and Public Health*, 5 J. INT'L ECON. L., 212 (2002)

22. Gathii, James T., *Good government as a Counter Insurgency Agenda to Oppositional and Transformative Social Projects in International Law*, 5 BUFF. HUM. RTS. L. REV. 65 (1990).

23. Gathii, James, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291 (2002).

24. Goldscheider, Robert, John Jarosz& Carla Mulhern, *Use of the 25 Per Cent Rule in Valuing IP*, 37 LESNOUVELLES 123 (2002).

25. Gordon, Wendy J., Toward a Jurisprudence of Benefits: The Norms of Copyright and Problem of Private Censorship, 57 U. CHI. L. REV. 1009 (1990).

26. Hardy, Charles T., *Quantitative Deal Valuation and Optimization in the Biotechnology and Pharmaceutical Industries: Introduction and Modern Tools of Quantitative Deal Structuring and Decision Analysis*, J. BIOLAW& BUS., Vol. 7, No 1, 2004.

27. Helfler, Laurence R., *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE INT'L L. J. 1 (2004).

28. Ho, Cynthia M., *Patent Breaking or Balancing? : Separating Standards of*

Fact from Fiction under TRIPS, 34 N.C. J. INT'L L. & COM. REG. 371 (2009).

29. Ho, Cynthis M., Patents, *Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601 (2000).
30. Hogerzeil, Hans V., et al.,*Is Access to Essential Medicines as Part of the Fulfillment of the Right to Health Enforceable Through the Courts?*,368 LANCET, 305 (2006).
31. Julian-Arno,lGianna d, *International Compulsory Licensing: The Rationales and the Reality*, 33 IDEA 349 (1993).
32. Kapczyniski, Amy, *The Access to Knowledge Mobilization and the New Politics of Intellectual Prpperty*, 117 YALE L. J. 804 (2008).
33. Kirim, Arman S., *Reconsidering Patents and Economic Development: A Case Study of the Turkish Pharmaceutical Industry*, 13 WORLD DEV. 219 (1985).
34. Knabb, Jennifer L. & Michael J. Jeffords, *Trends in Patent Infringement Damages*, 21 IPL NEWSLETTER 22 (2003) .
35. Lanjouw, Jean O., *Intellecual property and the availability of pharmaceuticals in poor countries*, 3 Innovation Policy and the Economy 91 (2002).
36. Lemley, Mark A., *Property, Intellectual Property, and Free Riding*, 83 TEX. L. REV. 1031 (2005)
37. Mehrotra, N. N., *Patent Act and Technological Self-reliance: The Indian Pharmaceutical Industry*, 24 ECONOMIC AND POLITICAL WEEKLY 1059 (1989).
38. Merges, Robert P., *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293 (1996).
39. Moore, Stephen D., *European State Funded Health Systems Come Unde Fire for Skyrocketing Costs*, WALL ST. J., May 4, 1993, at A14.
40. Nash, Duane, *South Africa's Medicines nd Related Substances Control Amendment Act of 1997*, 15 BERKELEY TECH L. J. 485 (2000).

41. Neumann, Peter J. & Eileen A. Sandberg, *Trends in Health Care R&D and Technology Innovation*, 17 HEALTH AFF. 111 (1998).

42. Petersmann, Ernst-Ulrich, *Constitutionalism and International Organizations*, 17 NW. J. INT'L L. & BUS. 398 (1997)

43. Rapp, Richard T. & Richard P. Rozek, *Benefits and Costs of Intellectual Property Protection in Developing Countries*, JOURNAL OF WORLD TRADE, Oct. 1990, at 75.

44. Rein, Judy, *International Governance Through Trade Aggreements: Patent Protection for Essential Medicines*, 21 J. INT'L L. BUS. 379 (2001).

45. Rozec, Richard P., *The Effects of Compulsory Licensing on Innovation and Access to Health Care*, 3 J. WORLD INTELL. PROP. 889 (2000).

46. Saunders, Kurt M., *Patent Nonuse and the Role of Public Interestas a deterrent to Technology Suppression*, 15 HARV. J.L. & TECH. 389 (2002).

47. Sherman, Peggy B. & Ellwood F. Oakley, *Pandemics and Panaceas:The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 AM. BUS. L. J. 353 (2004).

48. Simma, Bruno & Philip Alston, *The Sources of Human Rights Law: Custom, Jus Congens, and General Principles*, 12 AUSTL. Y. B. INT'L L. 82 (1992)

49. Stanton, Jerry, *Comment, Lesson for the United States from Foreign Price Controls on Pharmaceuticals*, 16 COMM. J. INT'L L. 149 (2000).

50. Sykes, Alan O., *TRIPS, Pharmaceuticals, Developing Countries, and the Doha"Solution"*, 3 CHI. J. Int'l L. 47, 57 (2002).

51. Trouiller, Patrice, et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 LANCET 2188 (2002).

52. Tsai, George, Note, *Canada's Access to Medicine Regime: Lessons for*

Compulsory licensing schemes under the WTO Doha Declaration, 49 VA. J. INT'L L. 1063 (2009).

53. Vaughan, Susan Vastno, *Compulsory Licensing of Pharmaceuticals under TRIPS: What Standard f Compensation?*, 25 HASTINGS INT'L & COMP. L. REV. 87 (2001).

54. Waldock, Humphrey, *Sixth Report on the Law of Treaties*, 2 INT'L LAW COMM'N 51 (1996)

55. Weissman, Robert, *A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. Pa. J. Int'l Econ. L. 1069, 1114 (1996).

56. Yu, Peter K., *The International Enclosure Movement*, MSU LEGAL STUD. RES. Paper No. 03-22 (2006).

57. Zolotaryova, Vera, Note, *Are we There Yet? Taking "TRIPS" to Brazil and Expanding Access to HIV/AIDS Medication*, 33 BROOK. J. INT'L L. 1099 (2008).