

3-10-2009

# Pharmaceutical Data Protection Law and Policy and Their Effects on the Right to Medicines : a Comparative Analysis

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**Golden Gate University School of Law**

**Pharmaceutical Data Protection Law and Policy and Their Effects on  
the Right to Medicines: A Comparative Analysis**

Submitted to the Golden Gate University School of Law, Department of  
International Legal Studies, In Fulfillment of the Requirement for the  
Conferment of the degree of Scientiae Juridicae Doctor (SJD).

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By  
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San Francisco, California  
March 10, 2009

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## Abbreviations

2001 Doha Declaration	2001 Doha Declaration on the TRIPS Agreement and Public Health
2003 Decision	2003 Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health
2005 Amendment	2005 Decision on the Amendment of the TRIPS Agreement
ACHR AP	American Convention on Human Right: Additional Protocol
AfCHPR	African Chapter on Human and Peoples' Rights
ADRD	American Declaration of the Rights And Duties of Man
ANDA	Abbreviated New Drug Application
BNHI	Bureau of National Health Insurance
CAFTA(DR-CAFTA)	Central America of Free Trade Agreements
CCMP	The Committee on Chinese Medicine and Pharmacy
CRC	Convention on the Rights of the Child
CRDAW	Convention on the Elimination of All Forms of Discrimination Against Women International Covenants on Civil and Political Rights
DOH	Taiwan Department of Health
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
EDL	Essential Drug List
ESC	European Social Chapter
FDA	Food & Drug Administration

FDCA	The United States Federal Food, Drug, and Cosmetic Act
FOIA	Freedom of Information Act
FTAS	Free Trade Agreements
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economical, Social and Cultural Rights
ICH	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICH-E5	The ICH guidance E5 Ethnic Factors in the Acceptability of Foreign Clinical Data
IHR	International Health Regulation
IMS	Intercontinental Marketing Services
MRDT	Treaty on Medical Research Development
NAFTA	North American Free Trade Agreement
NDA	New Drug Application
NHI	National Health Insurance
TIPO	Taiwan Intellectual Property Office
PhRMA	Pharmaceutical Research and Manufacturers of America
WHA	World Health Assembly
WHO	World Health Organization

## 1 Introduction

The concept “*protection of pharmaceutical data*” is a result of pharmaceutical registering system or procedure;<sup>1</sup> as its language this principle implicitly calls for some kind of legal protection to the data, or at least the non-disclosure of the data. In most jurisdictions, the health agency requires that, for safety concerns, pharmaceutical companies submit preclinical and clinical test data in order to obtain a marketing approval.<sup>2</sup> For instance, in the United States, the Food and Drug Administration (FDA) requires an originator to submit pharmaceutical data, before new medicines enter the market. The submitted data should provide sufficient information to prove the safety and effectiveness of drugs. This procedure, which is established by the Federal Food, Drug and Cosmetic Act (FDCA) of 1938,<sup>3</sup> is known as New Drug Application (NDA).<sup>4</sup> The data submitted to the FDA will become a part of governmental records, even though the data is owned by the applicant. If there is no exception applied, as a part of public record, these pharmaceutical data should be disclosed to the public in accordance with Freedom of Information Act (FIOA).<sup>5</sup> However, since the data contains commercial value and secrecy on it, the question arises as to whether the FDA can disclose the pharmaceutical and have them be

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<sup>1</sup> Press Release, World Trade Organization [hereinafter WHO], *Data Exclusivity And Other “TRIPS-PLUS” Measures*, at 3, Briefing Note Access to Medicines (Mar. 2006).

<sup>2</sup> CPTECH, Pharmaceutical Test Data Protection, available at <http://www.cptech.org/ip/health/data/> (last visited Feb. 10, 2009).

<sup>3</sup> Milestones in U.S. Food and Drug Law History, FDA Backgrounder, May 3, 1999, Updated August 2005, (<http://www.fda.gov/opacom/backgrounders/miles.html>, last visited on February 17, 2007).

<sup>4</sup> Milestones in U.S. Food and Drug Law History, FDA Backgrounder, May 3, 1999, Updated August 2005, (<http://www.fda.gov/opacom/backgrounders/miles.html>, last visited on February 17, 2007).

<sup>5</sup> McGarity & Shapiro, The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies, 93 Harvard Law Review 837, at 837 (1980).

used by second entrants. In 1984 the US launched the protection of pharmaceutical data by the adoption of the Hatch-Waxman Act. One clear attempt of this Act is to advance the entry of generic medicines. Perhaps another reason is that the FDA decided to settle the issue as to whether pharmaceutical data should be disclosed to the public. The form of protection to the data since then is finalized in the US but this new form of protections of pharmaceutical innovations has not been accepted widely among the World Trade Organization (WTO) members.

The HIV-AIDS outbreaks brought the international community's attention to the issue of access to medicines. Suddenly, the protection of pharmaceutical innovation draws the attention of international community, because many developing countries argued that the implementation of intellectual property impedes the access to medicines and made the essential medicines unaffordable for them.<sup>6</sup>

Traditionally legal researchers have largely focused on the impact of pharmaceutical patents on the access to medicines, but this trend has slightly changed. It is true that the more complicated pharmaceutical registering scheme grows the safer the medicines become. Nevertheless, this also means that cost of clinical trials will skyrocket.<sup>7</sup> Inevitably, this cost will be reflected on the price of medicines. The emergence of the generic drugs industry brings cheaper medicines to consumers because generic medicines

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<sup>6</sup> Carlos M. Correa, *Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 *Chi. J. Int'l L.* 69, 70-71.

<sup>7</sup> *Globalization, TRIPS and access to pharmaceuticals*, WHO Policy Perspective on Medicine, No. 3 March 2001, World Health Organization, also available on <http://www.who.int/hiv/amds/regulations1.pdf>.

do not have the high developing cost incumbent.<sup>8</sup> This benefits all consumers. However, in the long run, generics would eat all the profits that originator can make. Most importantly, it would discourage pharmaceutical firms from investing in and developing new drugs. In a survey, pharmaceutical companies confessed that more than 60% of new drugs were not developed and more than 65% of new drugs were not introduced to market if there are no protections for pharmaceutical innovation.<sup>9</sup> Not only patent the pharmaceutical companies now also rely on data exclusivity to exclude the generic medicines out of the market in order to manipulate the industry and control the price.<sup>10</sup> Many researchers have indicated that the price of generic medicines one year after the patent expired will be 65 % lower than the average price of the brand version.<sup>11</sup> Thus, it is an unexpressed goal for research and developed oriented pharmaceutical industry to retain its profits by maintaining a monopoly status.

The globalization of international trade made it difficult to protect pharmaceutical data outside the US. In many jurisdictions, the health agencies rely on test data registered by brand-name drug firms to approve generic drugs; thus the local generic manufacturers are not required to submit the data to prove their generic medicines safe.<sup>12</sup> By doing so, these

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<sup>8</sup> Shanker A. Singham, Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry, 26 *Brook. J. Int'l L.* 363, 363 (2000).

<sup>9</sup> Ronald J. Vogel, *Pharmaceutical Economics and Public Policy*, page 59-60 (2007).

<sup>10</sup> Brook K. Baker, Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of The Doha declaration On the TRIPS Agreement And Public Health, 14 *IND. INT'L & COMP. L. REV.* 613, 708-709 (2004).

<sup>11</sup> Schweitzer, *Pharmaceutical Economics and Policy*, page 150-151 (2<sup>nd</sup> ed., 2007).

<sup>12</sup> Cecilia Oh & Sisule Musungu, The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines? Commission on Intellectual Property Rights, Innovation and Public Health

generic drug manufacturers could save costly expenditures in drug tests,<sup>13</sup> so no wonder they can provide medicines at lower price. Naturally, this price competition caused by generic drug makers led originator to lose profit; therefore, they argued that the new medicines should get a full scale of protection and should also be free from the generic competition within a period of time in order to compensate their high research and developing cost.<sup>14</sup> These objectives will reach not only accounts for the pharmaceutical patents but also the protection of data submitted for the registration of a new drug.<sup>15</sup> Consequently, they suggested that all governments, besides patent, should grant “*market exclusivity*”<sup>16</sup> or what is called “*data exclusivity*”<sup>17</sup> to stimulate pharmaceutical innovation. Developing countries, human right advocates, and even the World Health Organization (WHO) challenged such a position.<sup>18</sup> In 2001, this controversial issue has

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(CIPHI), Study 4c, vii, World Health Organization, August 2005,  
<http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf>, last visited Feb 20, 2007.

<sup>13</sup> The cost of a new drug is around 800 million. See PHARMACEUTICAL RESEARCHERS AND MANUFACTURERS OF AMERICA (PHARMA), INDUSTRY PROFILE 2003, ch. 1, at 2 (“The average cost to develop a new drug has grown from \$138 million in 1975 to \$802 million in 2000.”), at <http://www.phrma.org/publications/publications/profile02/2003%20CHAPTER%201.pdf> (last visited Feb. 15, 2007).

<sup>14</sup> Singham, *supra* note 9, at 481-483.

<sup>15</sup> *Id.*

<sup>16</sup> The terms “marketing exclusivity,” “market exclusivity,” “new drug product exclusivity,” “Hatch-Waxman exclusivity,” “sui generic protection,” “data exclusivity,” and “data protection” are all found in the U.S. and/or E.U. legal literature. See Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 FOOD & DRUG L.J. 479, nt. 2 (2004).

<sup>17</sup> *Id.* See also the report of Commission on Intellectual Property Rights, Innovation and Public Health provides a definition for Data protection: an obligation imposed on third parties to protect test data (e.g. the results of clinical trials) – usually collected in order to comply with government regulations on the safety, efficacy and quality of a broad range of products (e.g. drugs, pesticides, medical devices). For example, TRIPS provides for the protection of such data against unfair commercial use.

<sup>18</sup> Network for Monitoring the Impact of Globalization and TRIPS on Access to Medicines, Meeting Report, 19-21 February 2001, Chulalongkorn University Bangkok, Thailand, Introduction page, [http://whqlibdoc.who.int/hq/2002/WHO\\_EDM\\_PAR\\_2002.1.pdf](http://whqlibdoc.who.int/hq/2002/WHO_EDM_PAR_2002.1.pdf).

also been brought to discussion at World Trade Organization (WTO) Doha Ministerial Conference as a trade related issue, though the essence of this issue, arguably, lies with both trade law and human rights law.<sup>19</sup>

The controversy over data protection in the academic field began with a question as to whether the pharmaceutical data is a subject matter of intellectual property law. Most supporters-protectionists think protection of test data would secure profits of investors and attract them to invest in the pharmaceutical industry, thereby developing more new drugs for the good mankind.<sup>20</sup> In contrast, opinions opposed this viewpoint, are based on the underlying purpose of intellectual property. Opponents, basically, see intellectual property as a system to reward innovation and not to promote investment. Under such logic, the protection of test data cannot be rationalized on the basis of securing investments.<sup>21</sup>

Regardless of the academic confrontation between these two views, international law has recognized that the test data is protectable item. Article 39.3<sup>22</sup> of the Agreement on

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<sup>19</sup> The Ministerial Conference is the highest forum in the structure of the WTO. The Ministerial Conference is composed of representatives of all the WTO Members and meets at least once every two years. Since the establishment of the WTO, the Ministerial Conference has been held five times: Singapore (December 1996), Geneva (May 1998), Seattle (November - December 1999), Doha (November 2001), and Cancun (September 2003).

<sup>20</sup> Junod, *supra* note 14, at 481-486.

<sup>21</sup> *Id.*

<sup>22</sup> Article 39.3:Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>23</sup> recognizes that pharmaceutical data submitted for marketing approval is protectable subject matter.

However, whether the protection of this subject would be limited under the concern of public health, or human rights is still controversial issue in international law.<sup>24</sup>

To clarify the relationship between public health, human rights and intellectual property, member states scheduled a WTO ministerial conference in Doha and adopted a Declaration on the TRIPS in 2001. Paragraph 4 of the Doha declaration states:

“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 members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”<sup>25</sup>

The language in this context has expressed the flexible use in TRIPS to increase access to medicines.<sup>26</sup> It states the importance of public health and the access to medicines, but it does not clarify what is the relationship between states' obligation to protect intellectual

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<sup>23</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement], Annex 1C, Legal Instruments - Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement], available at [http://www.wto.org/english/docs\\_e/legal\\_e/27-trips.pdf](http://www.wto.org/english/docs_e/legal_e/27-trips.pdf).

<sup>24</sup> Carlos, M. Correa, Implications of the Doha Declaration on the TRIPS agreement and public health, June, 2003, WHO, (WHO/EDM/PAR/2002.3).  
[http://www.who.int/medicines/areas/policy/WHO\\_EDM\\_PAR\\_2002.3.pdf](http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf)

<sup>25</sup> WTO Ministerial Conference, Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/2 (Nov. 20, 2001), 41 I.L.M. 755 (2002) [hereinafter Doha Declaration], available at [http://www.wto.org/english/thewto\\_e/minist\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm).

<sup>26</sup> Oh & Musungu, *supra* note 10.

property and obligation to ensure the right to access medicines or the right to health. Should the right to access medicines as a fundamental human, take priority over intellectual property? The text did not answer our question. This ambiguous position created by Doha Declaration in 2001 may lead member states to adopt different positions, some of which could, somehow, inadvertently, impede access to medicines.

Pragmatically speaking, due to political and economical reasons, the use of flexibility in TRIPS has its difficulties. For example, how in a flexible way a member state can implement the TRIPS, and what kind of measures is adopted is left open to member states, so their various implementation strategies would bring different results. Therefore, issues still remained to be settled in the international system of data protection.

## **1.1 From Drug Safety to Data Protection**

### **1.1.1 The Concept of Drug Safety and NDA Procedures**

Because of the development of new drugs, many human lives have been saved from infectious diseases. However, the events of exposure to the unsafe medicines are still reported everyday.<sup>27</sup> The quality and safety of food and medicines are always a concern of public welfare for every country, especially when the incidents of adverse drug reactions occur. To deal with the sanitation crisis in the beginning of 20<sup>th</sup> Century,<sup>28</sup> the US Congress passed Pure Food and Drug Act (PFDA) in 1906.<sup>29</sup> The PFDA created the

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<sup>27</sup> *Milestones in U.S. Food and Drug Law History*, FDA Backgrounder, May 3, 1999, Updated August 2005, (<http://www.fda.gov/opacom/backgrounders/miles.html>, last visited on February 17, 2007).

<sup>28</sup> Jeffrey E. Shuren, Essay: The Modern Regulatory Administrative State: A Response to Changing Circumstances, 38 Harv. J. on Legis 291, 299-301, Summer, 2001.

<sup>29</sup> Pure Food and Drug Act of 1906, Pub. L. No. 59-384 Stat. 768 (repealed 1938).

Bureau of Chemistry in the Development of Agriculture, which was the predecessor of FDA.<sup>30</sup> Compared with today's FDA, the PFDA had different tasks. Regarding the regulation of drugs, the PFDA was mainly to intervene against the sale of fraudulent drugs, but not to protect the public health by intervening in the approval of drugs.<sup>31</sup> Latter, two drug incidents changed the US's policy regarding the regulation of drugs: one was Sulfanilamide tragedy, and the other was Thalidomide calamity.<sup>32</sup> To fill up the gaps in the regulations of drugs, Congress formed a prototype of the modern drug approval system. At first, it created the FDA and formed the drug pre-market notification system. Latter, the FDA annulled the drug pre-market notification system and fortified the function of FDA by formation of new drug regulations.<sup>33</sup>

The Sulfanilamide tragedy was a significant incident in the history of public health because it led to the formation of the FDA. In 1937, the first time Elixir Sulfanilamide was introduced to treat certain types of bacterial infections, especially in the use of sulfanilamide for streptococcal infections.<sup>34</sup> Latter, this new sulfa antimicrobial medicine, Elixir Sulfanilamide, killed 107 persons, many of whom were children, and has proved to

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<sup>30</sup> Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 Va. L. Rev 1753, 1761-1766, 1996.

<sup>31</sup> Shuren, *supra* note 26.

<sup>32</sup> Joseph P. Reid, *A Generic Drug Price Scandal: Too Bitter A Pill for the Drug Price Competition and Patent Term Restoration Act to Swallow?* 75 Notre Dam L. Rev 300, 312-313, Oct. 1999.

<sup>33</sup> Merrill, *supra* note at 28.

<sup>34</sup> Wax, Paul M., *Elixirs, Diluents, and the Passage of the 1938 Federal Food, Drug and Cosmetic Act*, *J Ann Intern Med*, V 122, N 6, p 456-461, March 15, 1995, also available on <http://www.annals.org/cgi/content/abstract/122/6/456>. See also *Taste of Raspberries, Taste of Death, The 1937 Elixir Sulfanilamide Incident*, FDA Consumer magazine, June 1981 Issue, also available on <http://www.fda.gov/oc/history/elixir.html>.

be one of the most consequential mass poisonings of the 20th century.<sup>35</sup> At the time when this incident occurred, drug safety testing before marketing was not required under the existing drug regulations. In reaction to this tragedy, Congress passed the 1938 Federal Food Drug and Cosmetic Act,<sup>36</sup> which required a New Drug Application to be filled and proved safe before marketing.<sup>37</sup>

Thalidomide tragedy<sup>38</sup> had another significant impact on the evolution of drug approving legislation in the US; it reformed pr-market notification system for drug approval. Thalidomide first went on sale in West Germany in 1956, and was marketed as a medicine to treat vomiting during pregnancy and as a tranquillizer to help sleep. After Thalidomide was widely distributed in Europe, the cases of birth defect were increasingly reported after 1959 and around four hundred and seventy-seven cases were reported in 1961.<sup>39</sup> Moreover, about 10,000 infants were harmed in all over the world in 1960s' due to the use of Thalidomide. The FDA did not approve the marketing of thalidomide, but this medicine had been distributed to more than 1,200 physicians in the US for clinical testing. This wide usage harmed a great deal of infants in the US, and as mentioned, this

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<sup>35</sup> Milestones in U.S. Food and Drug Law History, *supra* note 25.

<sup>36</sup> Federal Food, Drug, and Cosmetic Act of 1938, ch. 675, 52 Stat. 1040 (codified as amended at 21 U.S.C. §§ 301-395(2000)).

<sup>37</sup> Carolyn H. Asbury, Orphan Drugs: Medical versus Market Value, D.C. Heath and Firm/Lexington, 12-41, 1985.

<sup>38</sup> Nancy E. Pirt, Regulation of the Export of Pharmaceuticals to Developing Countries, 25 Duq. L. Rev. 255.

<sup>39</sup> *Id.*, see also ASBURY, *supra* note 35.

incident triggered the action of Congress. As a result, the amendment to the 1938 Act - also known as the Kefauver-Harris 1962 amendments- was introduced.<sup>40</sup>

The Act of 1938 put the burden of proof on the FDA; consequently, if the FDA failed to demonstrate that a drug is not safe to market 180 days after an applicant has submitted a New Drug Application, and then the new medicine is automatically approved.<sup>41</sup> This kind of approval system is also called a pre-market notification system<sup>42</sup> or automatic approval system.<sup>43</sup> In spite of the speedy and simple drug approval procedure, the pre-market notification system was debated for years after the FDA adopted it. First, the Act of 1938 did not require the FDA to take serious measures to review the data, which was submitted for drug approval.<sup>44</sup> In addition, under an automatic approval system, if the FDA cannot review or cannot provide any reason to reject the application within 180 days, an applicant can market the drugs in the US.<sup>45</sup> This system created a drug approval procedure that acted like a notification with the data submission procedure as a notice.

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<sup>40</sup> Act of Oct. 10, 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified in scattered sections of 21 U.S.C.). Senator Estes Kefauver (E-Tenn.), then chairman of the Senate subcommittee on Antitrust and Monopoly, originally began his investigation into the pharmaceutical industry in 1959 for the purpose of reviewing the alleged monopolistic pricing practices of the industry. After the thalidomide incident, drug safety was included in the Amendments. Campbell and Smith, Profitability and the Pharmaceutical Industry, in *THE PHARMACEUTICAL INDUSTRY* 105, 108-09 (C.M. Lindsay ed. 1978). The co-sponsor of the Amendments was Representative Orren Harris (E-Ark.), Chairman of the House Committee on Interstate and Foreign Commerce.

<sup>41</sup> Shuren, *supra* note 26, at 13.

<sup>42</sup> Merrill, *supra* note 28.

<sup>43</sup> ASBURY, *supra* note 35.

<sup>44</sup> Merrill, *supra* note 28.

<sup>45</sup> *Id.*

Ultimately, the Thalidomide tragedy speeded up the reform of the automatic approval system.

This Thalidomide tragedy, disclosed in 1962, precipitated the 1962 amendments of the FDCA, also known as the 1962- Kefauver-Harris Amendments (1962 Amendment). The 1962 Amendments restructured features of approving a new drug in the US.<sup>46</sup> Several significant reforms in the 1962 Amendments were included. They abolished pre-market notification system by default; provided specified labeling, package insert and advertising requirements; established certain quality control measures and record keeping measures; and required proof of efficacy for all drugs.<sup>47</sup> With regard to drug approval system, the 1962 Amendment changed the 180-day feature that a manufacturer can sell in the market if the FDA did not object to its application within 180 days.<sup>48</sup> As a result, the Amendment shifted the burden of proof from FDA to the manufacturer.<sup>49</sup> Congress noted that the structure of the modern New Drug Approval system is constructed on the basis of 1962 Amendment.

### 1.1.2 Freedom of Information Act and FDA's Disclosure Policy

The 1962 Amendment to the FDCA requires that all new drugs shall not be marketed in the US, unless an approval of an application is effectively filed with the FDA.<sup>50</sup> The

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<sup>46</sup> ASBURY, *supra* note 35, at 21.

<sup>47</sup> *Id.*, at 12-41.

<sup>48</sup> New Drug Application (NDA) Process, <http://www.fda.gov/cder/regulatory/applications/NDA.htm>

<sup>49</sup> Shuren, *supra* note 26, at 293.

<sup>50</sup> 21 U.S.C § 355 (a) (1976).

statute requires the applicant to submit substantial evidence to prove that the drug is both safe and effective. In addition, the statute requires drug sponsors or manufactures to submit to the FDA a copy of "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use."

<sup>51</sup> According to the FDA's explanation, full reports include all the records produced during each clinical trial of a drug.<sup>52</sup> Therefore, after the FDA received the applicant reports, it is clear the reports would be viewed as a part of the FDA's record, which is subject to the Federal Freedom of Information Act (FOIA) of 1966.<sup>53</sup>

The FOIA establishes a disclosure system for the government.<sup>54</sup> It requires that a federal agency must disclose records unless they are withheld pursuant to one of the nine enumerated exemptions listed in § 552(b).<sup>55</sup> The basic purpose of the FOIA is to ensure an informed citizenry, to check against corruption of government, and to hold the government accountable to the governed, all of which are vital to a functioning democratic society.<sup>56</sup> In addition, the aim of the nine exemptions is to protect some

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<sup>51</sup> § 505(b)(1)(A), 21 U.S.C. § 355 (b) (1)(A).

<sup>52</sup> Merrill, *supra* note 30, at 1783.

<sup>53</sup> 5 U.S.C.A. § 552 (2002).

<sup>54</sup> Martin E. Halstuk and Bill F. Chamberlin, *The Freedom of Information Act 1966-2006: A Retrospective on the Rise of Privacy Protection Over the Public Interest In Knowing What the Government's up to*, 11 COMM. L. & POL'Y 511, 2006.

<sup>55</sup> 5 U.S.C.A. § 552 (b) (2002). The nine exemptions of records include: 1. National defense or foreign policy matters 2. International Personnel Rules and Practices 3. Matters Specially Exempted from disclosure by Statutes 4. Trade secrets and Commercial or Financial Information 5. Inter-Agency or Intra Agency Memoranda or Letters 6. Personnel, Medical and Similar Files 7. Records of Information compiled for law enforcement purposed 8. regulation or supervision of financial institutions 9. Geological or geophysical information.

<sup>56</sup> *Westchester General Hospital, Inc. v. Department of Health, Ed. & WELFARE and Blue Cross of Florida, Inc.*, 464 F.Supp. 236

legitimate governmental and private interests from releasing certain types of information.<sup>57</sup>

Under the FOIA, the public has a right to request any record held by the FDA, if record does not fall within one of the nine exemptions of disclosure.<sup>58</sup> However, only exemption 4 of section 552 (b) is related to the disclosure of health and test data submitted by private sectors, which deal with trade secrets or confidential commercial information.<sup>59</sup>

The development of the disclosure policy of the FDA regarding the pharmaceutical data for the drug approval procedure demonstrated that not only the general requirements, but also exemptions of the FOIA have great impact on the disclosure policy. The most significant influence is that the FDA issued its FOIA procedures in 1974, which are called "Public Information Regulations."<sup>60</sup>

The purpose of the Public Information Regulations is to disclose all pharmaceutical data to the public, if the law permits, but the data for all new human use drugs is not subject to disclosure.<sup>61</sup> At this point, the FDA explained that the data should be protected under the exemption of commercial information, because the investment of obtaining the pharmaceutical data is huge and competitive harms occur when the data is released.<sup>62</sup>

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<sup>57</sup> *FBI v. Abramson*, 456 U.S. 615, 621, 102 S.Ct. 2054, 2059, 72 L.Ed.2d 376 (1982); see also *CIA v. Sims*, 471 U.S. 159, 167, 105 S.Ct. 1881, 1883, 85 L.Ed.2d 173 (1985).

<sup>58</sup> See 5 U.S.C.A. § 552 (b) (1)-(9).

<sup>59</sup> See 5 U.S.C.A. § 552 (b) (4) (2002).

<sup>60</sup> 39 Fed. Reg. 44, 602 (1974).

<sup>61</sup> Robert M. Halperin, *FDA Disclosure of Safety and Effectiveness Data: A Legal and Policy Analysis*, 11 *DUKE L. J.* 286, at 302-310, 1979.

<sup>62</sup> *Id.*

However, the FDA does not view this exemption as an absolute protection, under some circumstances, the FDA can disclose the data, such when the NDA application has been abandoned, rejected, or the new drug has been withdrawn from the market or founded not to be new.<sup>63</sup> Moreover, all early litigation history shows that the FDA's policy favored applicants to protect their data,<sup>64</sup> such as in the case of *Public Citizen Health Research Group v. FDA*.<sup>65</sup>

In *Public Citizen Health Research Group*, the Federal Court of Appeals recognized the information submitted to the FDA by a commercial entity qualifies for protection under Exemption 4, if the information is shown to be (1) commercial or financial, (2) obtained from a person, and (3) privileged or confidential.<sup>66</sup> The court did not confine the commercial information provision of Exemption 4 to records that actually reveal basic commercial operations, such as sales statistics, profits and losses, and inventories, or relate to the income-producing aspects of a business. Instead, the court construed terms "*commercial*" and "*financial*" in the Exemption should be given their ordinary meanings. Thus, the court held that a noncommercial scientist's research design was an item of commercial information, because it recognized "an individual . . . engaged in profit-oriented research . . . could conceivably be shown to have a commercial or trade interest

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<sup>63</sup> Halperin, *supra* note 59.

<sup>64</sup> James T. O'Reilly, Article: Knowledge Is Power: Legislative Control of Drug Industry Trade Secrets, 54 U. CIN. L. REV. 1, 21-22, 1985.

<sup>65</sup> See *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1291.

<sup>66</sup> *Id.* at 1291.

in his research design."<sup>67</sup> In other word, regarding the documentation of the health and safety experience of the new product will be instrumental in gaining marketing approval for new products; the manufacturers of new products have a commercial interest in the requested information. Therefore, the safety and efficacy testing information that is submitted to the FDA for approval to market falls within the scope of confidential commercial information under the FOIA's protection.<sup>68</sup> Of course, the public and consumer protection groups opposed this policy, because they think the FDA's policy infringes on consumers' right to know.<sup>69</sup>

### 1.1.3 The Arguments for and Against Disclosure

For years, the FDA's disclosure policy was disputed and some aspects continued to be debated until today.<sup>70</sup> Although the policy underlying the FOIA supports the disclosure of the data for drug approval, the FDA's policy insisted that testing data is protected under exemption 4 of section 552 (b).<sup>71</sup> This action favored the pioneer submitter, but the right of the patient holder is impaired.

The argument to support the FDA's non-disclosure is based on the idea of fostering research and innovation.<sup>72</sup> The 1962 Amendment adopted more complicated procedure to

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<sup>67</sup> *Id.* at 1290.

<sup>68</sup> O'Reilly, *supra* note 62.

<sup>69</sup> McGarity and Shapiro, *supra* note 5, 844-847 (1980).

<sup>70</sup> O'Reilly, *supra* note 62, at 14-21.

<sup>71</sup> *Id.* at 15.

<sup>72</sup> McGarity and Shapiro, *supar* note 5, at 849-856.

review the new drug application,<sup>73</sup> but this Amendment also increased the pioneer applicant's cost for developing a new drug, because more detailed testing requirements should meet and the FDA's review period has been elongated.<sup>74</sup> Obviously, the potential harms to a pioneer applicant from disclosure of testing data are well-founded. Therefore, pioneer applicants against the disclosure of testing data provided their arguments.<sup>75</sup> They argued that the testing data fall within exemption 4,<sup>76</sup> and were protected under the Trade Secret Act,<sup>77</sup> and the Confidentiality Provisions of the FDCA,<sup>78</sup> so this data should not be disclosed to the public<sup>79</sup>. In contrast, the arguments against the FDA's non-disclosure have several goals. First, data disclosure would make the FDA's decision more transparent, and achieve the goal of the FOIA; an open government makes information available to the public and outside experts. Second, data disclosure may help the FDA to make better decisions. The third argument in favor of the disclosure of test data is on the basis of cost saving, since the disclosure of data would avoid the cost of duplicating the testing. Fourth, data disclosure would stimulate competition in the marketing of generic drugs. This competition would lower prices for consumers. As a final point, investments in pharmaceutical research should be protected under the patent system, rather than a policy of trade secrecy practiced by the FDA. From the perspective of generic firms, the

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<sup>73</sup> Asbury, *supra* note 35.

<sup>74</sup> Reid, *supra* note 30.

<sup>75</sup> Halperin, *supra* note 59.

<sup>76</sup> See 5 U.S.C.A. § 552 (b) (4) (2002)

<sup>77</sup> 18 U.S.C § 1905 (1976).

<sup>78</sup> 21 U.S.C. § 331 (j) (1976).

<sup>79</sup> Halperin, *supra* note 59, at 311.

FDA should disclose all pharmaceutical data or Congress should pass law to allow them to use data without testing. Of course, if the firms can produce and sale generic drugs successfully, the price of drugs would be lowered. Yet, from the perspective of the promotion of pharmaceutical innovation, the harms of pioneer drug makers should be considered and cannot be neglected. All of these arguments were also widely discussed.<sup>80</sup>

In the early 1980's, the average price of medicine was soaring and health care costs increased,<sup>81</sup> so Congress faced the pressure from both, pioneer and generic drug makers, medical providers, and patients to lower the cost of medicines. These factors led to the passage of the Hatch-Waxman Act in 1984,<sup>82</sup> and the emergence of the data exclusivity.

#### 1.1.4 Data Exclusivity

Prior to the passage of the Hatch-Waxman Act, even though the FDA disagreed to the disclosure of test data, most scholars believed that the test data regarding approval of new drugs should be disclosed for three important reasons:<sup>83</sup> consumers' right to know, lower costs of medicine and the progress of science. In addition, these scholars recommended that, if the government decided to disclose clinical test data to the public after approving new drugs for marketing or relied on the test data, submitted by the pioneer drug makers to approve the generic copies of the pioneer drugs, then the pioneer drug makers should

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<sup>80</sup> Halperin, *supra* note 59, at 311

<sup>81</sup> Elizabeth Stotland Weiswasser & Scott D. Danzis, The Hatch-Waxman Act: History, Structure, and Legacy, 71 *Antitrust L.J.* 585, 591 (2003).

<sup>82</sup> Reid, *supra* note 30.

<sup>83</sup> McGarity and Shapiro, *supra* note 5, at 844-847 (1980).

be compensated.<sup>84</sup> At some point, Congress adopted the scholars' opinions for balancing the interests among consumers, and both the generic and pioneer drug makers.

Later, Congress added two more provisions in the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act (1984 Act).<sup>85</sup> The 1984 Act compromise the interest of pioneer and generic manufactures.<sup>86</sup> Thus, on one hand, the 1984 Act established a new application process for generic drugs, which was called as Abbreviated New Drug Approval (ANDA).<sup>87</sup> This new application procedure only required the generic drug makers to show that the ANDA drug was identical to a pioneer drug; therefore the FDA could rely on the data of pioneer drugs to approve the ANDA drug.<sup>88</sup> On the other hand, the Act of 1984 provided a limited market exclusivity to compensate the pioneer drug makers ("data exclusivity right.")<sup>89</sup> The Act grants two types of data exclusivity rights, the five years and three years period of data exclusivity.<sup>90</sup> The five years of exclusivity is for new chemical entities not previously approved by the FDA.<sup>91</sup> The three years of exclusivity is for New Drug Supplemental Application

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<sup>84</sup> *Id.*

<sup>85</sup> Hatch-Waxman Act, § 101, 21 U.S.C. § 355 (1984).

<sup>86</sup> Rebecca S. Eisenberg, Symposium, *Pharmaceutical Innovation and Cost: An American Dilemma, the Problem of New Use*, 5 YALE J. HEALTH POL'Y, L. & ETHICS, 717, 725-728.

<sup>87</sup> 21 U.S.C. § 355. (b) (2). Hatch-Waxman Act codified FDA's "paper NDA" process in § 505(b)(2) of the Act; applications filed under this section are now often referred to as "505(b)(2) applications." In addition, Section 505(b)(2) allows approval of generic drugs for which the investigations relied upon "were not conducted by or for the applicant, and for which the applicant has not obtained a right of reference or use."

<sup>88</sup> Reid, *supra* note 30.

<sup>89</sup> *Id.*

<sup>90</sup> 21 U.S.C. § 355 (b), (c), (j).

(NDAs) on previously approved products, including as new indications or other changes in a previously approved product that require conducting new clinical trials to get FDA approval.<sup>92</sup>

Prior to the 1984 Act, generic competitors could not rely on the test data of pioneer drug makers to win an approval by the FDA, so they need to create their own data for generic drugs.<sup>93</sup> However, the cost of regenerating test data for marketing is so high that generic drug firms could compete with the pioneer drug firms at lower price, even after their patents had expired.<sup>94</sup> Congress wanted to settle this question, and introduce generic copies of pioneer drugs to the market at an affordable price, and so enacted the 1984 Act. The Act, basically, benefits both generic and pioneer drug makers. First, the act provides that generic copies of pioneer drugs could file an ANDA to be approved upon a showing of bioequivalence to the pioneer drugs, thus allowing them to skip the expensive testing process.<sup>95</sup> On the other hand, the 1984 Act prohibits filling of ANDA's during the period of data exclusivity, which creates a period of market exclusivity to compensate pioneer drug makers.<sup>96</sup> These arrangements are compromise legislation for both pioneer and generic drug makers.

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<sup>91</sup> *Id.*

<sup>92</sup> 21 U.S.C. § 355(j)(5)(F)(iii).

<sup>93</sup> Eisenberg, *supra* note 84.

<sup>94</sup> *Id.*

<sup>95</sup> 21 U.S.C. § 355(j)(5)(F)(iii).

<sup>96</sup> O'Reilly, *supra* note 62, at 16.

## 1.2 World Public Health Situation and Global Demand of Pharmaceuticals

The provision of health services is limited on how many resources a country may control, own and allocate them.<sup>97</sup> As public health policy makers; plan effective national health policy, they should be aware of background health situation to improve situation. Such information includes what diseases occur in their region, and what risk factor causes them.<sup>98</sup> Acquiring both global and regional health information and providing sound global and regional health policies and priorities are challenging for domestic and international policy makers. To address the widespread demand for health information and to further establish a system for assessing health standard, since 1990, the WHO has conducted a Global Burden of Disease (GBD) project to collect information in relation to health, and disease for WHO member states and for sub-regions of the world.<sup>99</sup> Additionally, in 2002, the directors of GBD found that the impact of the spread of the HIV epidemic and the level of HIV/AIDS mortality on the global health was underestimated, so a research team reassessed this crucial factor and updated the research.<sup>100</sup> The updated GBD project of 2002 (2002 GBD study) projected the global mortality at country level and also demonstrated the results in regional and income groups. Three income groups included low-, middle-, and high-income, which were

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<sup>97</sup> Alan D. Lopez, Colin D. Mathers, Majid Ezzati, Dean T. Jamison, and Christopher J. L. Murray, "Measuring the Global Burden of Disease and Risk Factors, 1990–2001." *Global Burden of Disease and Risk Factors*, ed., 1. New York: Oxford University Press. DOI: 10.1596/978-0-8213-6262-4/Chpt-1, 2006.

<sup>98</sup> *Id.*

<sup>99</sup> About the Global Burden of Disease Project, <http://www.who.int/healthinfo/bodabout/en/index.html>. (last visited April 1, 2007).

<sup>100</sup> Mathers CD, Loncar D, *Projections of Global Mortality and Burden of Disease from 2002 to 2030*. *PLoS Med* 3(11): e442 doi:10.1371/journal.pmed.0030442, 2007, also available on <http://www.who.int/healthinfo/bodabout/en/index.html> (Last visted on April 1, 2007).

defined based on World Bank estimate of GDP per capita in 1999.<sup>101</sup> This project presented the mortality by disease and injury causes, in which three broad causes of groups are comprised: Group I (communicable, material, parental and nutritional conditions), Group II (non-communicable disease), and Group III (injuries.)<sup>102</sup> At least one of the major findings of the updated GBD study in 2001 is helpful to identify the demand of medicines in different areas, which is global and regional mortality.

The 2002 GBD study showed that more than 56 millions people died in 2001, and also one death in every three is from Group I causes in the world.<sup>103</sup> Although the death caused by most communicable disease had decreased, the deaths caused by HIV/AIDS on global health had increased from 2 percent to 14 percent from 1990 to 2001. In particular, Group I causes, including HIV/AIDS were responsible for one-third of deaths in South Asia and two-thirds of deaths in Sub-Saharan Africa. This finding showed the imminent need of HIV/AIDS medicine in South Asian and Sub-Saharan African countries, so increasing access to HIV/AIDS's medicine becomes high priority in these regions.

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<sup>101</sup> The income categories are based on the World Bank's "2003 World Development Indicators" Report (World Bank 2003). Countries are divided according to 2001 GNI per capita, calculated using the World Bank Atlas method. The groups are: low income, \$745 or less; lower middle income, \$746 - \$2,975; upper middle income, \$2,976 - \$9,205; and high income, \$9,206 or more.

<sup>102</sup> Group I included the causes of Tuberculosis, HIV/AIDS, Diarrheal diseases, Measles, Malaria, Lower respiratory infections, Perinatal conditions, Protein-energy malnutrition. Group 2 includes the causes of Stomach cancer, Colon and rectum cancers, Liver cancer, Trachea, bronchus, and lung cancers, Diabetes mellitus, Unipolar depressive disorders, Alcohol use disorders, Cataracts, Vision disorders, age-related, Hearing loss, adult onset, Hypertensive heart diseases, Ischemic heart diseases, Cerebrovascular diseases, Chronic obstructive pulmonary diseases, Nephritis and nephrosis, Osteoarthritis, Congenital anomalies, Alzheimer and other dementias. Group 3 comprises the causes of injury, which are road traffic accidents, falls, self-inflicted injuries, and violence.

<sup>103</sup> LOPEZ ET AL., *supra* note 98.

Another finding was that the epidemiological transition from infectious to chronic non-communicable diseases in low-income and middle-income countries (except for South Asian and Sub-Saharan African countries), so Group II causes (non-communicable diseases) were accounted for more than 50 percent of deaths in adults ages 15 to 59 in these countries.<sup>104</sup> In high-income countries, Group II causes (non-communicable diseases) are major causes of death, which accounted for more than 80 percent of deaths in adults age 15 to 59 in all regions.<sup>105</sup> This implies that the need of medicine and the strategy to improve the status of public health should be different in different income groups of countries.

The finding of global mortality, at least, presented a phenomenon. Although most of communicable diseases are curable or controllable in the 21<sup>st</sup> century, communicable diseases are still responsible for major causes of death in the world, in particular, in low and mid-group of countries. Thus, countries in these regions have to provide their people adequate access to communicable disease medicines.

The next section examines global medicine situation and assess whether these regions do lack the adequate access to medicines.

### **1.3 The Global Policy to Access Medicines**

To provide reliable and accessible source of information on medicines, the WHO reviewed the world medicine situation both in 1998 and 2004 (WHO 2004 Report).<sup>106</sup>

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<sup>104</sup> LOPEZ ET AL., *supra* note 98.

<sup>105</sup> *Id.*

<sup>106</sup> WHO, THE WORLD MEDICINE SITUATION [Hereinafter WHO 2004 Report ]1-2, 2004.

The WHO 2004 Report presented the available information on global production, R&D, international trade and consumption of medicines,<sup>107</sup> and supported a background analysis for many major policy issues in medicine strategy, such as intellectual property rights, or parallel trade, around which strong disputes lasts at both domestic and international level.<sup>108</sup>

According the WHO 2004 Report, the global pharmaceutical market can be separated to several submarkets, including “originator”, “copy version” (which is produced before the expiry of patents), and “generic versions of originators,” which is produced after the expiry of patent.<sup>109</sup> The originator is protected from competition in the jurisdiction of the patent before the expiry of patent. The “copy version” of medicine is copied from the patented medicine, so its legality relies on patent jurisdiction. In other words, it is perhaps not a violation, if countries did not provide patent right to protect the originator of drugs. The “generic version of originators” is a multiple source drug, which consists of “unbranded commodity generic drug” and “other brands.” Due to the complexity of the definition of generic medicines, the size of generic market cannot be calculated accurately.

The WHO 2004 Report demonstrated that world sales of medicines in 2000 were around US\$ 282.5 billion, over 89% of which was concentrated in the high-income countries, and over 95% of which was concentrated in the top 10 pharmaceutical markets: USA,

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<sup>107</sup> WHO 2004 Report, *supra* note 104.

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* at 34.

Japan, France, Germany, UK, Italy, Spain, Canada, Brazil and Mexico.<sup>110</sup> The size of generic market is hard to estimate because researchers defined generic drug market in different ways. IMS,<sup>111</sup> noted global pharmaceutical market intelligence, simple separated the global market into two markets, originator and generic drug markets. According to its estimate, the generic drug market is around US\$ 87 billion in 2000 (about 30 % of global sales).<sup>112</sup>

The sales of medicines in the top 10 therapeutic class medicines in 2001 are anti-ulcers, cholesterol and triglyceride reducers, antidepressants, non-steroidal anti-inflammatory, anti-hypertension, anti-psychotics, oral anti-diabetics, ACE inhibitors, antibiotics, and systematic antihistamines, which are almost accounted for one-third of all sales.<sup>113</sup> The data showed that nine classes of top 10 therapeutic classes are for non-communicable disease treatment, and only one class is for communicable disease treatment (which sales \$6.7 billion in 2001, around 2% in global shares).

In addition, the WHO 2004 Report found originator medicines are the biggest source of medicine in high-income countries, which accounted for two-thirds of sales and the share

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<sup>110</sup> *Id.*, at 31-40.

<sup>111</sup> IMS is the one global source for pharmaceutical market intelligence, providing critical information, analysis and services that drive decisions and shape strategies.  
[http://www.imshealth.com/ims/portal/front/indexC/0,2478,6599\\_1825,00.htm](http://www.imshealth.com/ims/portal/front/indexC/0,2478,6599_1825,00.htm) (last visited on April 1, 2007)

<sup>112</sup> Despite that the global production and consumption of medicine by volume is a sound instrument to analyze how the people in region access the medicine, it is not available. Thus, the most research reports use global sales of medicine by value to do basic analysis of pharmaceutical industry. However, this data may ignore some significant information. For example, the report indicated that India accounts for around 1% of the world's production by value, but 8% by volume (weight). It ranks thirteen in world production by value, but ranks fourth in the volume of pharmaceutical produced.

<sup>113</sup> WHO, *supra* note 104, at 8.

of these in total sales.<sup>114</sup> In contrast, in low-income countries, generic medicines are major source of medicines, which accounted for 60% of sales in the total sales of medicines.<sup>115</sup> This shows that low-income countries relied more on generic medicines than high-income countries. Also an important conclusion may be drawn from the WHO 2004 Report, which, the wide uses in low-income countries and the needs for medical insurers to lower cost stimulate the growth of generic drug markets.

However, the emergence of generic drug firms caused an intense competition between them and the brand name drug firms. It is clear that more legal protection for brand name drug would stimulate the innovation, but one the downside it may also create more barriers to access medicines; therefore reconciling innovation and access to medicines is imperative.

Meanwhile, the adequate access to medicines does not mean access to any medicine, otherwise it would depress the drug market. Therefore, the WHO created the concept of essential medicines and selected the essential medicines to lower the financial burden and legal barriers to access medicines.<sup>116</sup>

### 1.3.3 The WHO's Essential Medicines Definition and List

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<sup>114</sup> WHO, *supra* note 104, at 35-36.

<sup>115</sup> *Id.*

<sup>116</sup> Essential Medicines, WHO/ WHO Sites/ Medicines/ Services/ Essential Medicine, [http://www.who.int/medicines/services/essmedicines\\_def/en/](http://www.who.int/medicines/services/essmedicines_def/en/) (last visited on April 2, 2007).

The WHO introduced the concept, “*essential medicines*”, in 1977.<sup>117</sup> The underlying premise of the concept, some medicines are so important for human survival; therefore, human beings shall have access to them regardless of cost or price, because accessing these medicines is a human right.

Initially, in 1977, WHO has defined the concept as the medicines that [s]atisfy the needs of the majority of the population and therefore should be available at all times, in adequate amounts in appropriate dosage forms and at a price the individual and community can afford. Subsequently, the WHO expanded the definition and clarified its contents. As it stands today, the definition seems broad enough to encompass a wide range of medicines that are very crucial to all humans:

“Essential medicines are those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford. The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains a national responsibility.”<sup>118</sup>

The first WHO Model List of Essential Drugs was promulgated in 1977. It identified 208 individual medicines, which together could provide safe, effective treatment for the majority of communicable and non-communicable diseases. The List is updated several times. The current Model List of Essential Medicines, prepared by the WHO Expert

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<sup>117</sup> See Press Release, Equitable access to essential medicines: a framework for collective action, WHO Policy Perspectives on Medicines (March 2004).

<sup>118</sup> WHO/Health Topic/ Essential Medicine, [http://www.who.int/topics/essential\\_medicines/en/](http://www.who.int/topics/essential_medicines/en/) (last visited April 2, 2007)

Committee in March 2005, contains 312 individual medicines, including antiretroviral medicines for the prevention and treatment of HIV-AIDS.<sup>119</sup>

### **1.3.4 Access to Medicine: Factors, Barriers and Improvement**

WHO has recognized that access to essential medicines is a portion of medicine policy<sup>120</sup> in the Report of "WHO Medicines strategy 2004-2007: Countries at the core." WHO states that, it would provide a guidance and support for countries to improve access to essential medicines.<sup>121</sup>

According to the WHO,<sup>122</sup> the spending on drugs represents less than one-fifth of total public and private health spending in most developed countries, but it represents 15 to 30% of health spending in transitional economies and 25 to 66% in developing countries. The figures implied that [p]harmaceuticals are the largest public expenditure on health after personnel costs and the largest household health expenditure in most low-income countries.<sup>123</sup> However, the percentage of people who lack access to essential medicines in low-income countries is still higher than in high-income countries, which 39 percent, and

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<sup>119</sup> Essential Medicines, *supra* note 115.

<sup>120</sup> In the WHO official website, it declares that WHO's goal in medicines is to help save lives and improve health by ensuring the quality, efficacy, safety and rational use of medicines, including traditional medicines. Our vision is that people everywhere have access to the essential medicines they need; that the medicines are safe, effective, and of good quality; and that the medicines are prescribed and used rationally. <http://www.who.int/medicines/en/> (last visited on April 2, 2007).

<sup>121</sup> Medicines Policy and Standards, Technical Cooperation for Essential Drugs and Traditional Medicine, <http://www.who.int/medicines/en/> (last visited on April 2, 2007)

<sup>122</sup> Essential Medicines, *supra* note 115.

<sup>123</sup> *Id.*

0.3 percent respectively.<sup>124</sup> In addition, 80 percent of the total number of people (1.3 billion) in the world who lack essential medicines resided in the low-income countries.<sup>125</sup> These figures prove that people in low-income countries lack adequate access to medicines; accordingly, there is an inherent nexus between lack of access to medicines and poverty. To increase access to medicines in this group of countries, the WHO identifies all factors that effect access to essential medicines. Those factors are categorized into four groups: rational selection, affordable prices, sustainable financing, and reliable health and supply systems.<sup>126</sup>

To provide affordable prices of medicine, WHO's policy is not likely to approve the strict intellectually property protection, in particular, data exclusivity, since this position would, inevitably exclude generic drug firms from the drug market and decrease the market competition;<sup>127</sup> consequently, the high price drugs will fill up the market. This position is based on concerns of human rights law; however, if followed, regardless of its side effects this position would improve access to medicines and states would find it easy to fulfill their responsibilities under international human rights law.

### **1.3.5 Public Health, Innovation and WTO Doha Declaration**

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<sup>124</sup> WHO 2004 Report, *supra* note 104, at 61-75.

<sup>125</sup> WHO, *supra* note 104, at 61-75.

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*, at 66-71.

Globalization has a great impact on the international trade system.<sup>128</sup> Multilateral and bilateral trade agreements have increased in number and played significant role in trade disputes settlement in the recent decades. The GATT Agreement of 1944, which latter became the WTO, is the most significant international trading system.<sup>129</sup> The purpose of WTO is to liberalize trade, and to provide a forum for governments to negotiate trade agreements. In addition, it also provides a body to settle trade disputes between states. The most important function is to operate a system of trade rules. There are 18 specific agreements annexed to the Agreement establishing the WTO, five of them are with greatest relevance to the health sector: Agreement on Trade-Related Aspects of intellectual Property Rights (TRIPS) the Agreement on the Application of Sanitary and Phytosanitary measures (SPS); the Agreement on Technical Barriers to Trade (TBT); the General Agreement on Tariffs and trade (GATT); and the General Agreement on Trade on Services (GATS).<sup>130</sup> Of course, TRIPS has the greatest effect on the pharmaceutical sector, because it sets the rules that are directly applicable to the pharmaceutical industry and its intellectual production.

The harmonization of certain aspects of the protection of intellectual property in the international level is one of TRIPS Agreement greatest dedications.<sup>131</sup> The Agreement

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<sup>128</sup> Trade and Globalization, <http://www.globalization101.org/issue/trade/?PHPSESSID=f> (last visited on April 2, 2007)

<sup>129</sup> Understanding the WTO, [www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/understanding\\_e.pdf](http://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf). (last visited on April 2, 2007)

<sup>130</sup> Globalization, TRIPS, and Access to Pharmaceuticals, WHO Policy Perspectives on Medicine, No.3 March 2001, WHO, Geneva, <http://www.who.int/hiv/amds/regulations1.pdf> (last visited on April 2, 2007)

<sup>131</sup> Globalization and Access to Drugs: Perspectives on the WTO TRIPS Agreement, EDM Series No. 7, 17-19, <http://www.who.int/medicines/areas/policy/who-dap-98-9rev.pdf>. (last visited on April 2, 2007)

sets out rules to achieve two main objectives: first, the Agreement requires the WTO member states to guarantee minimum standard of protection for intellectual property rights mentioned in TRIPS;<sup>132</sup> second, according to Part III of the Agreement, member states must make available for certain procedures to enforce the intellectual property rights.<sup>133</sup> Further, the WTO member states attempt to integrate the public health concern or concept of access to medicines into TRIPS agreement recently.

In fact, immediately after the WTO was set, the World Health Assembly (WHA) adopted a resolution in 1996, because it thought that the WTO agreements would no doubt effect the health situation;<sup>134</sup> therefore, it requested the WTO to report on the impact of the WTO agreements with regard to national drug policies and essential drugs.<sup>135</sup> Latter, most of developing countries shared the WHA's views and agreed that the TRIPS Agreement would inevitably jeopardize access to medicines. To the contrary, developed countries support TRIPS to protect their pharmaceutical industry.

There are two conflicting views regarding TRIPS and access to drugs. The argument in favor of the TRIPS Agreement at stake on access to drugs, including an enlarge in the flow of technology transfer, a boost in R&D investments by domestic pharmaceutical

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<sup>132</sup> The minimum standards of protection are based on the provisions of Paris conventions (adopted in 1883) and Bern conventions (adopted in 1886). *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> Resolution WHA 49.14.

<sup>135</sup> The Forty-Ninth World Health Assembly in May 1996, adopted a resolution requesting the Director-General to "report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs. See Globalization and Access the Drug, WTO, 1997, <http://www.who.int/medicines/areas/policy/who-dap-98-9rev.pdf>, Trade, Intellectual Property rights and Access to Medicines, <http://www.who.int/medicines/areas/policy/globtrade/en/>

firms in the developing countries.<sup>136</sup> The argument against the Agreement constraints on access to drugs responded that the price of drugs would increase, strengthening the protection of patented drugs would not increase domestic pharmaceutical firms in R&D investments in the developing countries, which lack infrastructure, funds and professional specialists.<sup>137</sup> These two competing arguments do not reflect any kind of reality. The first one, if followed, would jeopardize the entire pharmaceutical industry, because it assumes the pharmaceutical firms should not have protection. The second one, if followed to its ultimate end, a monopoly of access to medicine should be assumed. Therefore, a reconcillary position between these two arguments is desirable. A position would take into account both the protection of pharmaceutical firms and facilitate access to medicines.

The Doha Declaration of 2002 aimed at settling the relationship between public health and protection of patented drugs, but whether it is a general principle to apply in any case related to drugs access is uncertain. Paragraph 4 of the Doha Declaration only emphasizes the importance of protecting public health, promoting access to medicines, and reaffirms the right of the WTO member states to use, to the full extent, the provisions in TRIPS Agreement in flexible way,<sup>138</sup> but it does not mention that member states can apply this declaration in TRIPS. Moreover, Paragraph 6 of the Doha Declaration only deals with the situation of issuing compulsory license, so it does not deal with the issue of data

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<sup>136</sup> Carlos M. Correa, Implications of the Doha Declaration on TRIPS Agreement and Public Health, Health Economics and Drugs EDM series No. 12 (WHO/EDM/PAR/2002.3), WHO, June 2002.

<sup>137</sup> *Id.*

<sup>138</sup> CORREA, *supra* note 134.

protection. However, seeking a balance point between human rights and the international trade is a new trend in international law; therefore, it is expected that the protection of pharmaceutical data is likely to follow this trend.

#### **1.4 Aims and Purpose**

This research engages several inter-related issues: rationality of protection of test data and patent, compatibility of public health and innovation. It also examines the rationale behind the protection of test data, and the effect of the right to health and the right to access medicines vis-a-vis the protection of test data or *vice versa*. Also, the possible flexible measures under the TRIPS Agreements are examined. Further, a case study from Taiwan is provided to highlight the problems associated with test data protection and its substantial impact on medicines accessibility. Indeed the thrust of this research is the legal and policy aspects of these issues; therefore, quantitative and empirical research is considered as far as it further the legal and policy outcome of this research.

#### **1.5 Scope**

Because of development in the digital production of data, there is substantial amount of data produced in any industry. Likewise, in pharmaceutical industry, there is a huge body of data produced during research, manufacturing, advertising and sales. However, this study is only concerned with data produced for developing drugs.

This study will only focus on the legal regime of the protection of pharmaceutical data, which submitted to health authorities for marketing approval. The other kind of data made by pharmaceutical firms for other business or management purpose is beyond the scope of this study.

To examine the compatibility between data protection and the right to access medicines in the current data protection regimes, this study examines the concept of data protection in current legal regimes, examine exclusive data protection regime, discusses the impact of the right to medicines on data protection regime, finally provide sound legal reform and recommendations to improve the protection of pharmaceutical data. In its entirety, this research aims at researching the protection regime of pharmaceutical data from top to bottom; therefore, this research conducts a comprehensive analysis within three dimensions of protections: first, the international dimension represented by TRIPS, second; the regional dimension represented by NAFTA, and CAFTA and other regional agreements and; third, the national dimension represented by Israel and India.

Another attempt of this research is to explore the entire exceptions of data exclusivity. The research reviews the exceptions provided under Article 39.3 of the TRIPS. In addition, the compulsory license scheme is another possible ground to exclude data exclusivity although it provides under the patent regime; therefore it also examined. The thesis will explore the three major sources of WTO documents, 2001 WTO Doha Declaration, 2003 Doha Decision and 2005 Amendment to analyze current trends and pattern of exceptions of data exclusivity, within the international as well as the national system.

This research also provides an overview of human rights instruments to justify its call for the reconciliation of the protection of pharmaceuticals data with the right to health and medicines. In the last chapter, the case of Taiwan shows how a state like Taiwan is making such reconciliation a reality.

## 2. Concept of Data Protection

### 2.1 Introduction

“The life of the law has not been logic: it has been experience. The felt necessities of the time, the prevalent moral and political theories, intuitions of public policy, avowed or unconscious, even the prejudices which judges share with their fellow-men, have had a good deal more to do than the syllogism in determining the rules by which men should be governed.”<sup>1</sup>

“Mr. Justice Holmes”

While speaking in a different context, perhaps what Justice Holmes had pronounced applies, literally, to the concept of “data protection”: it comes from necessities, modified by reality, and finally becomes a part of the international intellectual property legal system. This legal system has three dimensions: multinational, regional, and domestic dimensions. In these three dimensions, the development of the concept of Data Protection is emerging in two philosophies of intellectual property: the first is trade secrets; while the second is not yet recognized as one of intellectual property family, which we may call *sui generis* system.<sup>2</sup> It is the system of data exclusivity. This system does not fit within any of the four branches of intellectual property family. The formation of these models is largely attributable to disagreements among states; the US and the major industrial states on one hand and the rest of the world on the other hand.

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<sup>1</sup> Oliver Holmes, *The Common Law* (1881), Dover Publications edition, 1991, 1.

<sup>2</sup> Carlos Maria Correa, Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement xi, The South Center, avail at <http://archives.who.int/tbs/global/h3009ae.pdf> (Last visited on October 26, 2008).

The US is the first country to grant the data exclusive right, setting the first model for the protection of data.<sup>3</sup> In addition, the US was the first to introduce this concept in the regional level by the signing of the North American Free Trade Agreement (NAFTA)<sup>4</sup> in 1992. On the international level, the adoption of 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights, (TRIPS)<sup>5</sup> has officially marked the introduction of the concept on global level. This transformation of the issue of data protection from being a local concern to an international one, which implicates many vital international issues, including human rights, trades and the protection of innovations. But, what more urgent is how to balance all these diverse human interests without prejudicing an issue, against the other.

Although the US and the European Union have established a model for the protection of test data by granting exclusive right, TRIPS followed neither of them.<sup>6</sup> The TRIP Agreement loosely sets the conditions of protection of test data; it allows state members

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<sup>3</sup> Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., 28 U.S.C., and 35 U.S.C.); see, in particular, Hatch-Waxman Act, § 101, 21 U.S.C. § 355 (1984) [hereinafter Hatch-Waxman Act].

<sup>4</sup> North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 107 Stat. 2057, 32 I.L.M. 289 (1993) [hereinafter NAFTA].

<sup>5</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization [hereinafter WTO Agreement]; Annex 1C, art. 39.3, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

<sup>6</sup> Currently, scholars classified two types of the data exclusivity, the US model and European Model. The US model provides five years period of data exclusivity and three-year period of data exclusivity to new indication of existing drugs. The European Model provides eight years of data exclusivity and two years of marketing exclusivity. The market exclusivity means the first pharmaceutical producer has a right to monopoly the market for a period even though those products are not protected under the patent. See Meir Perez Pugath, *Intellectual Property, Data Exclusivity, Innovation and Market Access, in Negotiating Health: Intellectual Property and Access to Medicines* 97, 104-106 (Roffe, P. et al. eds., 2006).

to determine whether they shall grant the exclusive right for pharmaceutical test data owners. This flexible approach did not please the US, because it apparently provides a lesser protection than what the US wants. Consequently, the US have, attempted, bilaterally and unilaterally to circumvent the TRIPS.

Those agreements, which the US made with countries, can broadly be grouped into three models: model one represented by NAFTA, provides five years of exclusive right; model two exemplified by the second generation US-FTAs<sup>7</sup> (signed between 2003-2007) and CAFTA, which provide the data exclusivity right and link the marketing approval with patent status; model three represented by the new updated 2007 FTAs (US-Peru FTA, US-Panama FTA and US-Columbia FTA) recognizes the Doha Declarations and attempted to compromise between the protection of pharmaceuticals with the right to access medicine.

The first model provides the five year data exclusivity on the basis of Hatch-Waxman Act. It requires states to protect the submitted undisclosed test data for approving the marketing of pharmaceutical product. The “pharmaceutical product shall satisfy the requirement of “utilizing new chemicals.” It imposed the obligation of non-disclosure and non-reliance on states.

The second model of protection also provides five year of exclusive right and imposed non-disclosure and non-reliance regulations. However, it added certain favorable pharmaceutical patented products measures. First, it extends the scope of protection of

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<sup>7</sup> The US-FTA signed after 2000 can be roughly classified to three generations. The second generation US-FTA provides five years of data exclusive right and adopts certain favorable pharmaceutical patent measures. See the discussion in 2.2.1.

pharmaceutical product by adopting a narrower definition of "new chemical entity." Second, it counted five years exclusive right from the date of granting the right in the reference countries without triggering any waiting period. By doing so, if the originators do not apply the marketing approval of new drug in the reference countries, the data exclusivity would likely be extended as high as 10 years in the reference countries. Third, it links the marketing approval to patent status. Fourth, it mandatory extends the terms of patent if unreasonable delay in registrations occurs. Five, it requires the notification of patent holders when the same chemical is the target new drug. Those measures block the possibilities of the entry of generic drug during the terms of patent.

The third model stands on the basis of the third model and adds some human right elements. These adjustments include relinquishing of mandatory extension of patent; setting the six-month waiting period; and recognizing the parts of Doha declarations and public health waivers. Overall, those changes balance the interests between the protection of pharmaceutical products and the access to basic medicines.

These differences come from that some states consider the issue of data protection as a subject matter of exclusive right, while other consider it as a subject matter of trade secrets law. Indeed, these two views substantially shaped the issue today. The result is that protection is provided under both approaches, but it depends.

## **2.2 The Multilateral Protection Regime**

The national legal system for intellectual property is established since late 15<sup>th</sup> century.<sup>8</sup> However, not until 19<sup>th</sup> century, the modern International Intellectual Property Rights integrated European national legal systems and established the principals of international Intellectual Property Rights.<sup>9</sup> Two important international intellectual property treaties in history were formed in 1880's: the Paris Convention for the Protection of Industrial Property (Paris Convention)<sup>10</sup>, and Berne Convention for Protection of Literary and Artistic works (Berne Convention).<sup>11</sup> The Paris Convention provides a protection for owners of inventions, trademarks, and industrial design, whereas the Berne Convention provides a protection of authors or owners of creative works. Neither of these agreements does contain any provisions for the protection of trade secret and pharmaceutical test data.

TRIPS adopted the Paris Convention and Berne Convention and extended protection of subject matter and established universally acknowledged international minimum standards for intellectual property protection. These achievements made it the most important Intellectual Property international treaty since 1994. The concept of protection of test data is first time introduced to the international community by the TRIPS, but its

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<sup>8</sup> The first copyright was granted in 1511 in England. The law of trade secrets probably dated back to the Rome's Merges. See Menell Lemley, *Intellectual Property in the New Technological Age*, 27-28, 105-106, 319-320. (3rd ed, 2003).

<sup>9</sup> Edith Tilton Penrose, *The Economics of the International Patent System* (1951), cited in Frederick Abbott, Thomas Cottier & Francis Gurry, *The International Intellectual Property System: Commentary and Material* 633 (1999).

<sup>10</sup> Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention].

<sup>11</sup> Berne Convention for the Protection of Literary and Artistic Works, opened for signature Sept. 8, 1886, as last revised July 24, 1971, 828 U.N.T.S. 221 [hereinafter Berne Convention].

formation and interpretation are related to the Paris Convention. Therefore, an analysis of Paris Convention would be helpful to understand how this concept works.

### 2.2.1 The Paris Convention

The 18<sup>th</sup> century of industrial revolution led European market increasingly and rapidly.<sup>12</sup> The expansion of market increased infringement cases of the patented products in the cross-border transaction. This kind of need motivated inventors, patent owners, and government officials. They met together at Paris to make international norms in 1880. They spent three years in drafting provisions for the protection of industrial property to resolve cross border commercial transaction disputes.<sup>13</sup> Finally, Paris Convention was signed in 1883 and completed by an Interpretative Protocol in Madrid in 1891, which formed a basic model for the protection of intellectual property.<sup>14</sup> With the development of technology, the Paris Convention has been revised several times to encompass the new technology, but it still has some shortages in the protection of new type of industries.<sup>15</sup>

The number of contracting parties has reached to 172 states in 2007.<sup>16</sup> The Convention requires parties to establish a Union for the protection of industrial property.<sup>17</sup> The

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<sup>12</sup> Wikipedia, *Industrial Revolution*, [http://en.wikipedia.org/wiki/Industrial\\_revolution](http://en.wikipedia.org/wiki/Industrial_revolution) (Last visited on October 3, 2008).

<sup>13</sup> Frederick Abbott, Thomas Cottier & Francis Gurry, *The International Intellectual Property System: Commentary and Material* 635-643 (1999).

<sup>14</sup> *Id.*

<sup>15</sup> Paris Convention, concluded in 1883, was revised at Brussels in 1900, at Washington in 1911, at The Hague in 1925, at London in 1934, at Lisbon in 1958 and at Stockholm in 1967, and it was amended in 1979. <http://www.wipo.int/treaties/en/ip/paris/> (Last visit on October 3, 2008).

<sup>16</sup> World Intellectual Property Organization [hereinafter WIPO], *Treaties Statistics: Paris Convention of March 20, 1883*, available at

protections include object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition.<sup>18</sup> Prior to TRIPS, it is the most important international agreement to deal with the protection of inventions.

### 2.2.1.1 The Protection of Unfair Competition under Article 10bis

The original Paris Convention of 1883 did not contain any provisions of the protection from unfair competition for industrial property. To repress unfair competition, the 1900 Brussels additional Act inserted Article 10*bis* to the Paris Convention as a new form of national treatment obligation.<sup>19</sup> Further, the 1911 Washington Act added a norm of protection against unfair competition and confirmed that parties to the Paris Convention are obligated to provide effective protection against unfair competition.<sup>20</sup> Later, 1924 Hague revisions, 1934 London revisions and Lisbon 1958 revisions extended the original

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[http://www.wipo.int/treaties/en/statistics/StatsResults.jsp?treaty\\_id=2&lang=en](http://www.wipo.int/treaties/en/statistics/StatsResults.jsp?treaty_id=2&lang=en) (Last visited on October 3, 2008).

<sup>17</sup> Paris Convention art. 1.1.

<sup>18</sup> Paris Convention art. 1.2.

<sup>19</sup> The national treatment principal is a rule of nondiscrimination, promising foreign intellectual property owners that they will enjoy in a protecting country at least the same treatment as the protecting country gives to its own national. This principal was first time to embody in the Paris Convention and later in TRIPS. See Paul Goldstein, *International Intellectual Property Law* 20 (1999).

<sup>20</sup> G.H.C. Bodenhauser, *Guide to the Application of the Paris Convention for the Protection of Industrial Property*, 1968, Reprinted in Paul Goldstein, *International Intellectual Property Law* 352. The Guide is an unofficial "legislative history", since G.H.C. Bodenhauser was unofficial reporter for the Paris Convention in the last 1960's. See *Id* at 354.

substantive obligations of Article 10*bis* and added a definition and example of unfair competition.<sup>21</sup>

According to paragraph two of Article 10*bis*, the “unfair competition” is “any act of competition contrary to honest practices in industrial or commercial matters . . . .”<sup>22</sup> The concept of “dishonest practice” is established by three examples under paragraph three of Article 10*bis*, it states

“(i)all acts of such a nature as to create confusion by any means whatever with the establishment, the goods, or the industrial or commercial activities, of a competitor;

(ii) false allegations in the course of trade of such a nature as to discredit the establishment, the goods, or the industrial or commercial activities, of a competitor;

(iii) indications or allegations the use of which in the course of trade is liable to mislead the public as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of the goods.”<sup>23</sup>

These three examples deal with three typical case of dishonest practice: first, acts would create consumer confusion; second, false allegation would discredit a competitor and third misleading indications or allegations use in the trade.<sup>24</sup> These specifications made the application of Article 10*bis* (2) clear, but these insertions do not unify state practices

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<sup>21</sup> See Paul Goldstein, *supra* note 19, 548.

<sup>22</sup> Paris Convention, art. 10*bis* (2).

<sup>23</sup> Paris Convention, art. 10*bis* (3).

<sup>24</sup> See Goldstein, *supra* note 19, at 173.

of the law of unfair competition.<sup>25</sup> In particular, this insertion creates a new problem of the protection of trade secrets between civil law countries and common law countries.

Due to no express provisions of protection of trade secrets under Paris Convention, states otherwise provides the protection of trade secrets with their discretions.<sup>26</sup> Prior to the adoption of TRIPS, common law and civil law countries apply different rules for the protection of trade secrets.<sup>27</sup> Civil countries protect interests in undisclosed information under the title of unfair competition and the Paris Convention standard of "honest practices in industrial or commercial matters."<sup>28</sup> Common law countries otherwise protect undisclosed information through theories of contract, tort or property. In those countries that treat undisclosed information as property, a trade secret owner can protect secrets from third parties who obtain information from owner or from a spy and a thief. However, civil countries do not provide the protection under these circumstances because in these cases where third parties do not participate in any dishonest practice. This problem continued in the negotiating process of TRIPS and concluded in TRIPS.

In order to diminish this discordant practice among civil and common countries, Article 39 of TRIPS provides the protection of trade secrets. Besides, TRIPS proposed a definition of "a manner contrary to honest commercial practices," which includes

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<sup>25</sup> Aaron Xavier Fellmeth, Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data under TRIPS Agreement, 45 Harv. Int'l L.J. 443, 453-454 (2004).

<sup>26</sup> Fellmeth, *supra* note 25.

<sup>27</sup> Rudolf Krasser, The Protection of Trade Secrets in TRIPs Agreement, From GATT to TRIPs-The Agreement on Trade-Related Aspects of Intellectual Property Rights 216 (Friedrich-Karl Beier & Gehard Schricker, eds., 1996), cited in Paul Goldstein, *supra* note 21, at 548-549, note 2.

<sup>28</sup> See Goldstein, *supra* note 19, at 549.

“practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.”<sup>29</sup>

#### **2.2.1.2 Protection of Pharmaceutical Test Data and Paris Convention**

The relation between Paris Convention and the concept of protection of trade secrets indirectly guided the development of the concept of protection of test data in TRIPS. This concept is in section seven of protection of undisclosed information and this concept is ensuring the protection of “undisclosed information.” Paragraph 1 of Article 39 directly shows this linkage with Paris Convention. It states “In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.” Accordingly, the objective of protection of data submitted to governments or governmental agencies in accordance with paragraph 3 is to fulfill the obligation of Article 10*bis* of Paris Convention; that is repression of unfair competition.<sup>30</sup>

#### **2.2.2 TRIPS**

WTO’s TRIPS agreement, signed on April 15 1994, was a result of final negotiation of Uruguay Round of GATT in Marrakesh (Morocco). It is the most significant development in international intellectual property law in 20<sup>th</sup> and 21<sup>st</sup> century. It

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<sup>29</sup> TRIP, art. 39.

<sup>30</sup> Jerome H. Reichman, The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods? in *Negotiating Health: Intellectual Property and Access to Medicines*, *supra* note 6, at 137.

established the minimum standards of intellectual property protection found in Berne and Paris Conventions. More profoundly, as an Annex to the Agreement Establishing the World Trade Organization, the TRIPS, brought the intellectual property within the institutional framework of the world's multilateral trading system. TRIPS gives members an option to submit the disputes regarding compliance with TRIPS to the settlement system of the WTO and to resolve the disputes under the WTO system.<sup>31</sup>

TRIPS includes seven important parts: part I provides general provisions and basic principles of the protections of intellectual property; part II establishes the standards of intellectual property, and clarifies the scope and use of intellectual property right; part III sets the measures of enforcement of intellectual property rights; part IV sets the procedures of acquisition and maintenance of intellectual property rights; part V deals with intellectual property disputes prevention and settlement; part VI and VII deal with transitional arrangements and institutional arrangements.

As mentioned, TRIPS covers the previous Berne Convention for traditional work of copyright protection and Paris Convention for the protection of industrial property. In addition, it extended the protection of copyright to software, database, and sound recording in order to meet the need of new technology. It also extended the protection of patent to pharmaceutical products, pesticides and plant varieties.

The significant achievements of TRIPS, stated in the preamble, include certain areas.<sup>32</sup> First, it recognizes intellectual property rights as the private or individual rights in

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<sup>31</sup> Graeme B. Dinwoodie et al., *International Intellectual Property Law and Policy* 45 (2001).

<sup>32</sup> See TRIPS, preamble.

multilateral level; therefore any member should protect the intellectual property rights like the way it protect other property. Secondly, it acknowledges “underlying public policy objectives of national systems for the protection of intellectual property.”<sup>33</sup> This means that members can develop their national intellectual property based on their needs. Third, TRIPS affirms the special needs of the least-developed countries (LDCs), so it gives a maximum flexibility to state members in the domestic implementation of laws and regulations in order to create a sound and viable technological base. Fourth, it is the first to adopt international sanctioning tools for violating obligation to ensure the enforcement of members. Finally, TRIPS establishes a minimum enforcement norm to offer minimum procedural safeguards in order to assure enforceability of the minimum rights under the treaty.

#### **2.2.2.1 The Protection of Pharmaceutical Test Data as an Intellectual Property**

A drug from discovery to marketing has to comply with regulatory requirements. Taking the United States as an example, before marketing approval, the United State Food and Drug Administration (FDA) requires pharmaceutical company to conduct certain preclinical and clinical trials.<sup>34</sup> During the preclinical and clinical trial, a pharmaceutical should follow the strict procedures and provide a considerable data to the FDA. For example, administrating the preclinical trial on animals requires Good Laboratory Practice (GLP) and administrating the clinical trial on human requires Good Clinical Practice (GCP).<sup>35</sup> Those strict procedures and massive data required in the process of

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<sup>33</sup> *Id.*

<sup>34</sup> Ng, Rick, *Drugs: From Discovery to Approval* 175-282 (2002).

<sup>35</sup> Ng, *supra* note 34.

filling process increase the cost of developing new drug and delay the drug marketing for 10 to 12 years. According to the research conducted by Tufts University in 2001, it discovered that the cost of developing a new drug is about \$802 million.<sup>36</sup> This spending includes the cost of developing new patents, and conducting necessary pre-clinical, and clinical trial. These high costs prompted the international pharmaceutical companies to argue that the data exclusivity right is a necessary compensation for such high costs. As Roffe pointed out, this attitude makes the protection of test data a new issue in the international pharmaceutical industry.<sup>37</sup>

While intellectual property by no means is a new subject, the protection of pharmaceutical test data is not discussed until 1980s.<sup>38</sup> In the US, one of problems that contributed to raising this issue of test data protection was the ragging debate with respect to the public's right to access these information *vis-à-vis* the companies' right to guard their information against disclosure. To resolve this issue, the US enacted the Hatch-Waxman Act,<sup>39</sup> which provides the pharmaceutical company five years of exclusive data protection. However, the law also gave the public a right to access this same information within the exclusivity period. These measures give the public an opportunity to supervise trials and guarantee the protection of test data in the US, but it does not secure the

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<sup>36</sup> The Ballooning Price Tag, <http://enews.tufts.edu/stories/120401BallooningCosts.htm> (last visit on August 6, 2008).

<sup>37</sup> Pedro Roffe et al., From Paris to Doha: The WTO Doha Declaration on the TRIPS agreement and Public Health, in *Negotiating Health: Intellectual Property and Access to Medicines* 1, 6 (Roffe, P. et al. eds., 2006).

<sup>38</sup> Correa, M. Correa, Protecting Test Data for Pharmaceutical and Agrochemical Products under Free Trade Agreements, in *Negotiating Health: Intellectual Property and Access to Medicines* 81, 83 (Roffe, P. et al. eds., 2006).

<sup>39</sup> Hatch-Waxman Act.

protection of test data in the global market. Since these measures only apply in the US, a third party out of the US, might acquire the information and go to another country where disclosure of test data is not required. Such third party may easily get licensed and market the drug in that country. This indeed prompted international pharmaceutical companies to do whatever they can in order to secure their profits. Consequently, they pushed hard to form a global protection system for test data through multilateral, regional and bilateral treaties.

### 2.2.2.2 The Conditions of Article 39.3

The pharmaceutical companies' effort is successful. One aspect of this success was the making of TRIPS. Article 39.3 introduced the concept of the protection of pharmaceutical test data in the multilateral level. It establishes a foundation for the protection of test data and directs the development of protection of test data. Therefore, members may use as a basis to adopt suitable ways to protect test data or negotiate an appropriate provision to protect test data in a regional or a bilateral level.

Article 39.3 of TRIPS protects the test data under the title of undisclosed information,<sup>40</sup> it states:

“Member, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use.”<sup>41</sup>

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<sup>40</sup> Pugatch, *supra* note 6, at 98-100.

<sup>41</sup> TRIPS, art. 39.3.

It directly imposes an obligation on State members to take action against unfair commercial use in order to fulfill their obligation under the TRIPS.<sup>42</sup> The scope of obligations includes non-disclosure, but it is not clear whether non-reliance is included.<sup>43</sup>

The obligation under the Article 39.3 is constituted of certain basic terms, such as “submission of data for marketing approval,” “new chemical entities,” “undisclosed data,” “considerable efforts,” and “unfair commercial use.” TRIPS does not provide definitions for those terms, therefore there are lots of controversies over interpretations of those terms. The section below discusses these introduced those interpretations related to the elements of Article 39.3. Those interpretations trigger other revisions of pharmaceutical test data provisions in regional and bilateral agreement.

#### 1. Submission of Data for Marketing Approval

Article 39.3 requires members to protect test data if submission of test data is a condition for obtaining marketing approval. Under the theory of agency, state members are not required to review data by themselves and they may delegate their duties to research groups, non-governmental, or other countries for reviewing the submitted test data. Thus, even delegation would not discharge the obligation of state members under Article 39.3.

A part from the delegation issue, Article 39.3 does not adequately resolve the situation where a member does not request the test data but rely on the prior approval test data submitted in other countries to grant a marketing approval of generic drugs. In such a

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<sup>42</sup> Lee Skillington & Eric M. Solovy, The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement, 24 Nw. J. Int'l L. & Bus. 1, 22-23 (2003).

<sup>43</sup> Pugatch, *supra* note 6, at 100.

case, there are two possible scenarios. The first scenario assumes that the submission of test data for marketing approval process is a necessary element to trigger Article 39.3.<sup>44</sup> Thus, Article 39.3 is not applicable when they rely on prior foreign approval to grant a marketing approval. Not only this, but if an applicant voluntarily submitted test data to the health authorities this would not trigger Article 39.3.<sup>45</sup>

By contrast, in the second scenario the protection test data for marketing approval includes the cases of indirect submission.<sup>46</sup> That is approving the pharmaceutical products on prior approval in other countries or such reliance is, in fact, an indirect act of requiring the submission of protected data. Therefore, even though members do not require the submission of test data for making approval, they still cannot rely on prior foreign approval test data or permit third party to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory.<sup>47</sup>

Looking more squarely to the text of Article 39.3, there is no language to support that members are subject to second interpretation, an obligation of non-reliance. Thus, supporters of non-reliance obligation proposed the unfair competition as a defense. They argued if members rely on the foreign test data to approve new medicines, their practice would constitute an unfair competition. Nevertheless, Canadian court did not accept this

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<sup>44</sup> Carlos Maria Correa, Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for or the Registration of Pharmaceuticals, 3 Chi. J. Int'l L. 69, 73 (2002).

<sup>45</sup> *Id.*

<sup>46</sup> Skillington et al., *supra* note 42, 24-25.

<sup>47</sup> Skillington et al., *supra* note 42, 24-25.

viewpoint even she ratified the NAFTA, in which data exclusivity is granted for five years.<sup>48</sup>

The more explicit languages regarding restriction of reliance in marketing approval process can be found in the subsequent US bilateral and regional agreements signed after 2000. Yet, a general opinion as to whether the obligation of non-reliance can be imposed to the parties is still subject to interpretation by the domestic courts in that jurisdiction.<sup>49</sup>

## 2. The Protected Test Data for Marketing Approval of a New Drug

The protected form of test data under Article 39.3 should be in writing, because health authority can review those test data to make a decision of marketing approval. Indeed, in order to qualify for the protection of Article 39.3, the data must be used in the application submitted for marketing approval of new drug.<sup>50</sup> If the data is used for other industrial purpose, it would not be protected.

Thus, in the United State, before obtaining a marketing approval, the pharmaceutical sponsors are required to conduct a preclinical, a clinical trial and file an IND and NDA applications. In these trials and procedure, human, animal toxicology and other required data would be required for the marketing approval.<sup>51</sup> The data from those trials are

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<sup>48</sup> *Bayer Inc. v. Attorney General of Canada, Apotex Inc. et al., Intervenors*, 87 C.P.R. (3d) 293, (Fed. Ct. of Appeal 1999).

<sup>49</sup> Pugatch, *supra* note 6, at 111.

<sup>50</sup> The protection of test data under Article 39.3 of the TRIPS includes agriculture chemicals and pharmaceuticals, but the protections of data submitted for marketing approval of agriculture chemicals are not included in this thesis.

<sup>51</sup> See Correa, *supra* note 44, at 73.

protected under Article 39.3. Moreover, data regarding manufacturing, conservation and packaging methods are protected data, if all these data are necessary to obtain a marketing approval.<sup>52</sup> The law determines which data is necessary and which is not.

### 3. Undisclosed Data at First Time of Submission

The protected test data under Article 39.3 must be undisclosed and not known for the public. 39.3.<sup>53</sup> Despite that the fact that the test data after submission might be disclosed to the public fully or partially, it would not change the protectable status of the test data under Article 39.3. The rationale here is that permitting a third party to appropriate those submitted data would constitute an unfair practice and undisclosed requirement cannot remain after the first submission.<sup>54</sup>

By contrast, the data that has been disclosed before the first submission for marketing approval, they would not be protected under Article 39.3 because they fall within the public domain.<sup>55</sup> For example, before submitted for marketing approval, the test data published in scientific journals or disclosed to the public would not be protected under Article 39.3, because they are known for the public before they were submitted.<sup>56</sup>

### 4. New Chemical Entities

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<sup>52</sup> See Correa, *supra* note 44, at 73.

<sup>53</sup> Skillington et al., *supra* note 42, at 27-28.

<sup>54</sup> Skillington et al., *supra* note 42, at 27-28.

<sup>55</sup> Ng, *supra* note 34.

<sup>56</sup> See Correa, *supra* note 44, at 74-75.

Article 39.3 requires Member to protect the test data submitted for marketing approval of pharmaceutical that utilizes new chemical entities. This describes the usage and objective of test data. To trigger the application of Article 39.3, the test data must be provided for the marketing approval of pharmaceutical and the pharmaceutical should be new chemical. The meaning of "new chemical entity" is not clear in TRIPS. Thus, members may have different interpretations for the phrase "new chemical entity".<sup>57</sup>

Basically, the interpretation of new chemical involved two issues. First, whether the term of "new" in Article 39.3 refers to the same meaning of "novelty" in the patent system.<sup>58</sup> Second, whether the term of new includes a new use of pharmaceutical, which has approved for other uses.<sup>59</sup>

Regarding the first issue, there are two common interpretations. First, a new chemical is a chemical that has not been used as a registered<sup>60</sup> medicine in human history.<sup>61</sup> Second, a new chemical is a chemical that meets the standard of the novelty in the patent sense.<sup>62</sup>

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<sup>57</sup> Skillington et al., *supra* note 42.

<sup>58</sup> Skillington et al., *supra* note 42.

<sup>59</sup> See Fellmeth, *supra* note 25, at 464-465; Correa, *supra* note 44, at 74-75; Skillington et al., *supra* note 42.

<sup>60</sup> The protection of registered drugs can cover some traditional non-registered medicine. In such cases, those traditional medicines have been used in some society or community, but they have not been approved as a medicine. In the situation, those chemical entities are not new in the word but they are new to be used as medicine. Those application data for those new drugs should be covered under the Article 39.3.

<sup>61</sup> See Correa, *supra* note 44, at 74-75; Fellmeth, *supra* note 25, at 464-465; Skillington et al., *supra* note 44.

<sup>62</sup> According to Professor Scafidi, only in very rare cases and least likely interpretation, a new chemical entity would have to represent a novel patentable invention, and only such products would be entitled to test data protection. See Susan Scafidi, *The "Good Old Days" of TRIPS: The U.S. Trade Agenda and the Extension of Pharmaceutical Test Data Protection*, 4 Yale J. Health Pol'y L. & Ethics 341, 345-346.

Most commentators prefer the first interpretation, because the TRIPS did not purposely restrict the protection in the patentable products.<sup>63</sup> Thus, the new chemical entity is new as a pharmaceutical, but it need not be new chemical in the world. Accordingly, chemicals used in other industrial fields still can be deemed as new if there were no prior application for approval of the same drug, or where the same drug was not previously known in commerce.

Regarding the second issue, there are several US Free Trade Agreements adopted the protection containing the new use.<sup>64</sup> However, scholars overwhelmingly agree that their term only means "new chemical entities," but contain the meaning of new use or new dosage.<sup>65</sup> This opinion is accepted by the European Court.<sup>66</sup> The European Court of Justice indirectly discussed whether the test data submitted for approval of new use is protected in *Regina v. The Licensing Authority Established by the Medicines Act 1968, ex parte Generics (UK) Ltd.*<sup>67</sup> The Court indicated that a subsequent drug would not have a right of marketing exclusivity if it is substantially similar to an earlier approved drug. The Court further explained that substantial similarity between these two drugs means that the two drugs have the same qualitative and quantitative composition in terms of active principles and pharmaceutical forms, and their safety and efficacy are bio-equivalents.

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<sup>63</sup> Novelty is a patentability test. An invention is not patentable if it was already known before the date of filing or before the date of priority if a priority is claimed, of the patent application.

<sup>64</sup> See Fellmeth, *supra* note 25, at note 104. See also the detailed discussion section 2.3.

<sup>65</sup> See Fellmeth, *supra* note 25, at 464-465; Correa, *supra* note 59, at 74-75.

<sup>66</sup> See *Regina v The Licensing Authority Established by the Medicines Act 1968, ex parte Generics (UK) Ltd.* Before the Court of Justice of the European Communities (Fifth Chamber), Case C-368/96, 1998 ECR I-7967, [1999] 2 CMLR 181 (1998), cited in Correa, *supra* note 59, at 74-75.

<sup>67</sup> *Id.*

Similarly, a new drug application for the approval of new indications, dosage forms, combinations, new forms of administration, crystalline forms, isomers, etc., of existing drugs is not applied to Article 39.3, because there is no new chemical in the medical field.<sup>68</sup>

## 5. Considerable Effort

There is no definition of "a considerable effort" in Article 39.3, but most commentators' agree this term should cover technical or economic effort.<sup>69</sup> It is clear that a conduct of collecting test data for approving of a new drug falls within the scope of "considerable efforts", because pharmaceutical company need time, labors, and money to collect data.

However, the concept of rewarding for considerable efforts probably challenges the fundamental theory of intellectual property to reward the creation of mind. According to World Intellectual Property Organization's interpretation as to what intellectual property is, it states that "the intellectual property system protects creations of the mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce."<sup>70</sup> The labor efforts or economical value traditionally are not protected under the intellectual property, but those viewpoints encounter the strict challenges in traditional knowledge.<sup>71</sup> Likewise, the concept of the protection of test data to reward a

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<sup>68</sup> Correa, *supra* note 44, at 74-75.

<sup>69</sup> Correa, *supra* note 44, at 74.

<sup>70</sup> WIPO, *What is intellectual property?* <http://www.wipo.int/about-ip/en/> (last visit on August 12, 2008).

<sup>71</sup> WIPO, *Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore*, [http://www.wipo.int/about-ip/en/studies/publications/genetic\\_resources.htm](http://www.wipo.int/about-ip/en/studies/publications/genetic_resources.htm) (last visit on August 12, 2008).

considerable effort or considerable investments is a new trend that reflects a shift of thinking toward a more stretchy understanding for the very idea of the intellectual property.<sup>72</sup>

#### 6. Protection against Unfair Commercial Use

Article 39.3 limits the protection of test data against "commercial" uses, thus "non-profit use" is not protected. This term is also related to the issue of whether a member may approve generic pharmaceuticals relying on the test data submitted in another country. The US Trade Representatives and their proponents argue that this is a notion of "unfair commercial use." India and her proponents from developing countries relied on those data submitted to other states. Indeed, this disagreement predates the signing of TRIPS.

As the discussion above showed, due to vagueness of "act of competition contrary to honest practices in industrial or commercial matters"<sup>73</sup> in Paris Convention, disputes in the enforcement of the protection of unfair competition are triggered. When Article 39.3 introduced the concept of protection of test data, this concept is established under the section of the protection of undisclosed information. Moreover, Article 39.1<sup>74</sup> declares that Members shall protect undisclosed information data submitted to governments or governmental agencies in accordance with the paragraph is to ensure effective protection

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<sup>72</sup> Recently, the possibilities and scheme of new subject matters of intellectual prosperities became the hot issues in the WIPO. See *id.*

<sup>73</sup> Paris Convention, art. 10bis (2).

<sup>74</sup> TRIPS, art. 39.1 states "In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3."

against unfair competition as provided in Article 10*bis* of the Paris Convention (1967). Thus, the interpretation of “unfair commercial use” in Article 39.3 should follow the interpretative guidelines under Article 10*bis* of the Paris Convention.<sup>75</sup> Accordingly, all controversies over Article 10*bis* of the Convention would occur in Article 39.3; those made this term become the most controversial in Article 39.3.<sup>76</sup>

Reviewing the negotiation history of TRIPS shows this disagreement. During the Ministerial Conference in Brussels in 1990, the facts presented this disagreement. The original provision proposed by the European Community, Switzerland, and the United States, includes five-year data exclusivity,<sup>77</sup> but the text containing five-year protection is debated in the negotiation. The final version of Article 39.3 came from a compromise among members. They retained the concept of protection of test data, but rejected specification of the form of protection.<sup>78</sup> However, this compromise did not put an end as what constitute unfair commercial use under Article 39.3

A researcher has indicated that the current Article 39.3 provides a room for members to construe the meaning of this term, so members may determine how to enforce the

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<sup>75</sup> TRIPS, art. 39.1.

<sup>76</sup> Correa, *supra* note 44, at 77-79.

<sup>77</sup> Draft Final Act embodying the results of the Uruguay Round of Multilateral Negotiations, TNC/W/35 Rev.1, (Dec. 3, 1990), it state “4A PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. [Unless the person submitting the information agrees, the data may not be relied upon for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall protect such data against disclosure, except where necessary to protect the public].” (Emphasis added).

<sup>78</sup> Skillington et al., *supra* note 42, at 31-32.

protection of test data and decide what unfair commercial use is.<sup>79</sup> Consequently, members may provide the protection of test data against disclosure,<sup>80</sup> and rely on the data submitted to other members to approve a new drug in their countries.<sup>81</sup> Instead of granting data exclusivity, the supporters of this opinion include India and other developing countries.

By contrast, the United State representatives argued that reliance on the data submitted to other members to approve a new drug in their countries is an act of unfair commercial use.<sup>82</sup> Obviously, this argument goes against to the national health authority power to grant marketing approval based on reliance of test data submitted by the original applicant.

The US Trade Representatives and their proponents were partially rejected at the end of negotiation of Article 39.3. The final version of Article 39.3 although introduced the concept of protection of test data, it does not recognize the data exclusivity and it does not deal with the members obligations non-reliance. However, the US and their

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<sup>79</sup> Reichman, *supra* note 30, at 144.

<sup>80</sup> Correa, *supra* note 44, at 76-79.

<sup>81</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* ch. 2 (2001); Reichman, *supra* note 30, at 144; Correa, *supra* note 38, at 84.

<sup>82</sup> The US trade representatives stated "TRIPS negotiators understood it [the term "unfair commercial use"] to mean that the data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with the logic and the negotiating history of the provision." U.S. Trade Representative, Office of the General Counsel, *The Protection of Undisclosed Test Data in Accordance with TRIPs Article 39.3*, (1995) (unattributed paper for submission in bilateral discussions with Australia in May 1995), cited in Skillington et al., *supra* note 42, at 33.

proponents still promote the data exclusivity legal scheme and incorporate the non-reliance obligation in regional and bilateral agreements.

### **2.3 Regional Protection Regime**

There are two important regional agreements containing the provisions of data exclusivity. The North American Free Trade Agreement (NAFTA) is the first regional agreement to incorporate the term. It introduced the concept of protection of test data earlier than TRIPS. However, the TRIPS did not follow NAFTA. The second is Central American Free Trade Agreement (CAFTA). It was signed ten years after TRIPS; it provides many protections beyond the scope of TRIPS; that is so called "TRIP-plus" provisions.<sup>83</sup> These two agreements reflect the different needs of the US in two different periods with respect the protection of test data.

#### **2.3.1 North American Free Trade Agreement**

NAFTA<sup>84</sup> was signed on December 17, 1992; it took effect on January 1, 1994. This regional agreement attempted to eliminate all trade restrictions on trade and investment among the United States, Canada and Mexico.<sup>85</sup> These three countries through this

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<sup>83</sup> TRIPS sets a minimum standards agreement, but it does allow for a greater level of protection, which is referred to as "TRIPS-plus" protection. TRIPS-plus protection allows developed countries, through their disparate bargaining power, to force greater IP protections upon developing countries, and to simultaneously decide when to apply Most Favor Nation principles to extend this TRIPS-Plus protection to the countries that would actually benefit from the higher standards. See, Brian Cimboli, *The Impact of Regional Trade Areas on International Intellectual Property Rights*, 48 IDEA 53, 56 (2007).

<sup>84</sup> NAFTA was implemented into U.S. law by North American Free Trade Agreement Implementation Act of 1993. (19 U.S.C. 3301-3473).

<sup>85</sup> NAFTA, art. 102.1 provides: The objectives of this Agreement, as elaborated more specifically through its principles and rules, including national treatment, most-favored-nation treatment and transparency, are to: a) eliminate barriers to trade in, and facilitate the cross-border movement of, goods and services between the territories of the Parties; b) promote conditions of fair competition in the free trade area; c) increase substantially investment opportunities in the territories of the Parties; d) provide adequate and effective protection and enforcement of intellectual property rights in each Party's territory; e) create

agreement created a free trade zone for goods deemed to originate from these three countries.<sup>86</sup> They attempted to obtain the maximum benefits and rights among them in areas of investment, services and intellectual property.<sup>87</sup> NAFTA has twenty-two chapters, including issues ranging from tariffs and non-tariff barriers to services, intellectual property, investment, and dispute settlements.

Although Chapter seventeen of NAFTA on intellectual property rights provides higher standard of protection and enforcement than TRIPS, its structure, form and contents are similar to TRIPS.<sup>88</sup> This chapter is significant in two aspects: first, it requires members apply to the substantive provisions of four important international conventions on intellectual properties,<sup>89</sup> including (1) The Geneva Convention for the Protection of Producers of Phonograms against Unauthorized Duplication of their Phonograms, 1971

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effective procedures for the implementation and application of this Agreement, for its joint administration and for the resolution of disputes; and f) establish a framework for further trilateral, regional and multilateral cooperation to expand and enhance the benefits of this Agreement.

<sup>86</sup> Rules of origin under NAFTA are complex and must be reviewed for each product to determine whether product qualifies for NAFTA treatment. Exporters must complete Certificate of Origin stating whether product is originating good. Special rules exist for energy and petrochemical products and agricultural trade.

<sup>87</sup> NAFTA, preamble.

<sup>88</sup> Cesar Praga, Intellectual Property, in *Toward Free Trade in the America: Free Trade Agreement 207*, 211 (Maryse Robert & Jose Manuel Salazar X. eds, 2001).

<sup>89</sup> NAFTA, art. 1701.2 provides :

To provide adequate and effective protection and enforcement of intellectual property rights, each Party shall, at a minimum, give effect to this Chapter and to the substantive provisions of: (a) the Geneva Convention for the Protection of Producers of Phonograms Against Unauthorized Duplication of their Phonograms, 1971 (Geneva Convention); (b) the Berne Convention for the Protection of Literary and Artistic Works, 1971 (Berne Convention); (c) the Paris Convention for the Protection of Industrial Property, 1967 (Paris Convention); and (d) the International Convention for the Protection of New Varieties of Plants, 1978 (UPOV Convention), or the International Convention for the Protection of New Varieties of Plants, 1991 (UPOV Convention). If a Party has not acceded to the specified text of any such Conventions on or before the date of entry into force of this Agreement, it shall make every effort to accede."

(Geneva Convention); (2) The Berne Convention for the Protection of Literary and Artistic Works, 1971 (Berne Convention); (3) The Paris Convention for the Protection of Industrial Property, 1967 (Paris Convention); (4) The International Convention for the Protection of New Varieties of Plants (UPOV Convention) (1978 and 1991). The adoption of those treaties, to ensure the enforcement of NAFTA, members are required to adopt extra provision to supply the insufficiency of the international treaties.<sup>90</sup>

Second, NAFTA did provide a prototype negotiation of TRIPS and certainly effected the outcome of TRIPS negotiations; because at the time NAFTA was signed, the TRIPS was still in the process of negotiation.<sup>91</sup> Third, NAFTA introduced the new types of intellectual properties other than listed in Paris Convention, such as protection of pharmaceutical test data, Layout Designs of Semiconductor Integrated Circuits,<sup>92</sup> and Geographical Indications<sup>93</sup> etc.

### **2.3.1.1 Trade Secrets and Pharmaceutical Test Data**

NAFTA almost reproduced the US model of protection of test data. Under chapter seventeen of NAFTA, Article 1711 provides the protection of test data of pharmaceutical products under the title of trade secret, but this Article distinguishes the protection of general trade secrets from pharmaceutical test data. The protection of general trade secret under Article 1711.1 is perpetual, as long as the information remains secret and unknown

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<sup>90</sup> Cesar Praga, *supra* note 88.

<sup>91</sup> *Id.*

<sup>92</sup> NAFTA, art. 1710,

<sup>93</sup> NAFTA, art. 1712.

to the general public.<sup>94</sup> The protection under subsection 5, 6 and 7 of Article 1711 otherwise adopt the data exclusivity for the protection of pharmaceutical test data.

### **2.3.1.2 The Distinctive Features of Protection of Pharmaceutical Test Data**

Although NAFTA is signed two years prior to TRIPS, compared with Article 39.3 of TRIPS, the protections of test data under NAFTA are different in many ways:

#### **1. An Exclusive Right for the Protection of Test Data**

Article of 1711.5 provides a general concept of protection of test data and it requires each party should protect the test data from disclosure.<sup>95</sup> Article 1711.6 otherwise incorporates two distinctive features protection of pharmaceutical test data under of NAFTA.

First, Article 1711.6 grants a five-year term of data exclusivity right.<sup>96</sup> It requires the signatories to protect the test data submitted to the health authorities for approving new

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<sup>94</sup> NAFTA, art. 1711.1 provides: Each Party shall provide the legal means for any person to prevent trade secrets from being disclosed to, acquired by, or used by others without the consent of the person lawfully in control of the information in a manner contrary to honest commercial practices, in so far as: (a) the information is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons that normally deal with the kind of information in question; (b) the information has actual or potential commercial value because it is secret; and (c) the person lawfully in control of the information has taken reasonable steps under the circumstances to keep it secret

<sup>95</sup> NAFTA, art. 1711.5, it states as follows: If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.

<sup>96</sup> NAFTA, art. 1711.6, it states as follows: "Each Party shall provide that for data subject to paragraph 5 that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision,

drug for marketing by granting a minimum five-year period of exclusivity. This text almost duplicates the protection scheme in the Hatch-Waxman Act and follows the US model of data exclusivity.<sup>97</sup>

Second, it deals with member's obligation of non-reliance. This issue is not settled in the TRIPS. The obligation of non-reliance requires that a party may not rely on the original registration filed for a drug to approve the subsequent application of the generic drug.<sup>98</sup> Article 1711.6 states ". . . no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission . . . ."<sup>99</sup> It clearly prevents competitors from relying on the initial registrant's test data during the period of exclusivity.

## 2. The Public Health Exception

Basically, Article 39.3 uses the same language of Article 1711.5 of NAFTA, but NAFTA sets up an exception for public health. Article 1711.5 states that the pharmaceutical test data can be disclosed when it is necessary to the public. By contrast, Article 39.3 of TRIPS does not use the same language; thus, it is not clear that the public health

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there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies."

<sup>97</sup> Hatch-Waxman Act.

<sup>98</sup> Pugatch, *supra* note 6, at 100.

<sup>99</sup> See NAFTA, art 1711.6.

exception applies in TRIPS. This issue became more complicated after the Doha Declaration of 2001.<sup>100</sup>

### 3. NAFTA Creates Obligations on Government and Individual

The foregoing discussion reveals that Article 39.3 imposes an obligation on governments. Article 1711.6 of NAFTA, imposes obligations on governments as well as individuals. It requires that the subsequent applicants for marketing approval obtain the permission of the first applicant.

### 4. Protection of Considerable Effort

The qualified pharmaceutical test data under Article 39.3 of TRIPS has to satisfy the requirement of considerable effort. The meaning of "considerable effort" is not clear. Article 1711.5 also used the term "considerable efforts," but Article 1711.6 states that the protection should take account of the nature of the data and the person's efforts and expenditures in producing data. It seemingly suggests that "considerable effort" refers to "person's efforts" and the expenses incurred in producing the data.

### 2.3.2 Central America Free Trade Agreement

The United States-Dominican Republic-Central America Free Trade Agreement (DR-CAFTA),<sup>101</sup> also called CAFTA, is one in a series of Free Trade Agreements (FTAs) that

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<sup>100</sup> The Doha Declaration discussed in chapter 3.

<sup>101</sup> Dominican Republic-Central America-United States Free Trade Agreement, Aug. 5, 2004, 119 Stat. 462, 43 I.L.M. 514 [hereinafter CAFTA], available at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/CAFTA/CAFTA-DR\\_Final\\_Texts/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/Section_Index.html) (last visited Feb. 7, 2008). The parties of CAFTA include Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, and Nicaragua.

the United States has entered into with its neighbors in the Western Hemisphere. In the beginning, five of Central America countries, Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua signed the CAFTA in 2004 and Dominican Republic joined in 2005.<sup>102</sup> The CAFTA like other trade agreements eliminates tariffs and trade barriers and expands regional opportunities for workers, manufacturers, consumers, farmers, ranchers and service providers of all signatories.<sup>103</sup> DR-CAFTA deals with several important trade topics: market access for goods (agriculture, manufactures, textiles and apparel), trade in services and related matters, other disciplines (investment protection, intellectual property rights, labor and environment, government procurement, and other provisions), and the regional application commitments.<sup>104</sup>

Regarding the protection of intellectual property rights, chapter fifteen of DR-CAFTA on intellectual property has two objectives, improving Intellectual Property Rights protection and granting firms nondiscriminatory treatment. It ratifies a number of international treaties dealing with trademark, patent, satellite television; newly develop plant varieties, and other IPR issues. It also establishes the minimum standard for protection of local brands, geographical indications, Internet domains, authors' rights, satellite signals, and patent.<sup>105</sup> Finally, it requires the signatory countries to apply the procedures and resources

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<sup>102</sup> *Id.*

<sup>103</sup> Jaramillo C. Felipe, Challenges of CAFTA: Maximizing the Benefits for Central America 41 (2006).

<sup>104</sup> *Id.*

<sup>105</sup> Article 15.1 of CAFTA ratifies or accedes to the following agreements by the date of entry into force of this Agreement: (a) the WIPO Copyright Treaty (1996); and (b) the WIPO Performances and Phonograms Treaty (1996); by January 1, 2006: (a) the Patent Cooperation Treaty, as revised and amended (1970); and (b) the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1980); by January 1, 2008: (a) the Convention Relating to the Distribution of Programme-Carrying Signals Transmitted by Satellite (1974); and (b) the Trademark Law Treaty (1994).

for the enforcement of intellectual property. Article 15.10 of CAFTA specifically regulates the pharmaceutical product and favors the pharmaceutical companies; however this provision sparked debates on public health issues because it apparently creates inequity in access to medicine.<sup>106</sup>

### 2.3.2.1 Pharmaceutical Data Protection under CAFTA

Whereas the protection of pharmaceutical test data is under the title of undisclosed information in TRIPS or under the title of trade secrets of NAFTA,<sup>107</sup> the CAFTA protected the test data under the title of “Measures Related to Certain Regulated Products.”<sup>108</sup> Article 15.10 of CAFTA replaced certain unclear terms in Article 39.3 of TRIPS and attempted to establish a more complete regime for the protection of pharmaceutical test data than TRIPS. For example, Article 15.10.2 integrates this protection with patent system and in order to provide a strict protection for pharmaceutical products, Article 15.1.10 (b) covers the common situations of data exclusivity and Article 15.10.1 (b) covers situations where a member permits the third

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Also it requires (a) Each Party shall ratify or accede to the International Convention for the Protection of New Varieties of Plants (1991) (UPOV Convention 1991). 1 Nicaragua shall do so by January 1, 2010. Costa Rica shall do so by June 1, 2007. All other Parties shall do so by January 1, 2006.(b) Subparagraph (a) shall not apply to any Party that provides effective patent protection for plants by the date of entry into force of this Agreement. Such Parties shall make all reasonable efforts to ratify or accede to the UPOV Convention 1991. Moreover, it requires each Party shall make all reasonable efforts to ratify or accede to the following agreements: (a) the Patent Law Treaty (2000);(b) the Hague Agreement Concerning the International Registration of Industrial Designs (1999); and(c) the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (1989).

<sup>106</sup> Rahul Rajkumar, The Central American Free Trade Agreement: An End Run around the Doha Declaration on TRIPS and Public Health, 15 Alb. L.J. Sci. & Tech. 433, 438 (2005). See also, Intellectual Property Watch, The Domino Effect of US FTAs: Public Health Groups, Members of Congress claim CAFTA will choke Access to Medicines, Apr. 4, 2004, available at <http://www.ip-watch.org/weblog/index.php?p=8&res=1024&print=0> (Last visited on Oct. 8, 2008).

<sup>107</sup> NAFTA, art. 1711.

<sup>108</sup> CAFTA, art. 15.10.

party to “submit evidence concerning the safety or efficacy of a product that was previously approved in another country.”<sup>109</sup>

### 2.3.2.2 Analysis of Article 15.10

Article 15.10 establishes a comprehensive structure for the protection. It clarifies some unclear terms in TRIPS, adopts data exclusivity, and links the marketing approval with patent status. Scholars point out that certain measures in CAFTA provide better protection for pharmaceutical products than the US domestic law and they predict that this agreement would undermine access to the essential medicines.<sup>110</sup> Comparing Article 15.10 with TRIPS, they are different in several respects:

#### 1. Data Exclusivity Right under Article 15.10.1 (a)

Article 15.10.1(a) involves typical situations<sup>111</sup> of data exclusivity, it states:

“If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.”<sup>112</sup>

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<sup>109</sup> CAFTA, art 15.10.1 (b).

<sup>110</sup> See Robert Weissman, *Dying for Drugs: How CAFTA will Undermine Access to Essential Medicines*, Mar. 5 2004, available at <http://www.essentialaction.org/access/index.php?/archives/21-Dying-for-Drugs-How-CAFTA-Will-Undermine-Access-to-Essential-Medicines.html> (Last visited on Oct. 8, 2008).

<sup>111</sup> The typical data exclusivity right occurs where a country grants data exclusivity to the pharmaceutical holder, then no approval, without permission of holders, could be granted to any generic company during the term of data exclusivity.

<sup>112</sup> CAFTA, art 15.10.1 (a).

It applies in the situation where a party of Central American country requires the submission of undisclosed test data as a condition of approving the marketing of a new pharmaceutical. In such cases, Article 15.10.1 (a) provides the five-year term of data exclusivity from the date of approval of the original medicine in the same countries without the permission of pharmaceutical test data owners.<sup>113</sup>

## 2. Data Exclusivity Right under Article 15.10.1 (b)

Article 15.10.1 (b) deals with the situation where a member permits the third party to “submit evidence concerning the safety or efficacy of a product that was previously approved in another country.”<sup>114</sup> The underlying issue is whether state’s obligation of non-reliance exists. In other words, in order to grant marketing approval of a new drug, whether a party may permit others to submit the evidence concerning the safety or efficacy of a product or it may rely on the original registration test data in a foreign

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<sup>113</sup> Carlos M. Correa, *Bilateralism in Intellectual Property: Defeating the WTO System for Access to Medicines*, 36 *Case W. Res. J. Int’l L.* 79, 85-86 (2005).

<sup>114</sup> CAFTA, art. 15.10.1 (b), states as follows:

If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date approval was granted in the Party’s territory to the person who received approval in the other territory. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory.

country. The views about this issue under the TRIPS are split.<sup>115</sup> One scholar argues that TRIPS only requires Members to protect test data against disclosure.<sup>116</sup> Another opinion favors a test data owner, it argues that the government has non-reliance obligation.<sup>117</sup> Article 15.10.1(b) takes the later position. It favors to the pharmaceutical companies, because it prohibits the use of test data submitted to a foreign authority as well as relying on the prior approval in a foreign country.<sup>118</sup>

Another two issues in Article 15.10.1 (b): the first issue is whether a generic company may register a generic medicine within the five years instead of marketing it,<sup>119</sup> and the second issue is whether a test data owner loses their protection if they do not follow Article 15.1.10 (b) to provide “the information.”

Regarding whether a generic company may register medicine during the exclusivity period, there are two opinions. One scholar argues that Article 15.10.1 (b) strictly prohibits marketing approval grounds on reliance of previously approved test data.<sup>120</sup> The other view is that Article 15.10.1(b) did not restrict the registering of generic product,

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<sup>115</sup> See Pugatch, *supra* note 6, at 114.

<sup>116</sup> See Correa, *supra* note 44, at 76.

<sup>117</sup> Jayashree Watal, *Intellectual Property Rights in the WTO and Developing Countries* ch. 2 (2001); Reichman, *supra* note 30, at 144; Correa, *supra* note 38, at 84.

<sup>118</sup> Rajkumar, *supra* note 106, at 465.

<sup>119</sup> Scholars make a distinction between the process of registering a generic drug and the actual marketing. See Pugatch, *supra* note 6, at 114.

<sup>120</sup> Pugatch, *supra* note 6, at 114.

because it only restricts two acts, obtaining authorization and marketing a product.<sup>121</sup> According to the later opinion, if the generic company did not market the product, it is permissible to register the product during the exclusive period.

CAFTA is not clear with respect to the second issue where health authority does not obtain “the formation” said in Article 15.1.10 (b). According to Article 15.1.10 (b), a party may require the person providing the “information in the other territory to seek approval in the party territory within five years after obtaining marketing approval in other territories.” This measure considers the reality of enforcement, because a party, which not the previous territory of granting making approval, may not have sufficient information to determine whether the submissions of the test data by subsequent generic companies are subject to the protection of test data. However, Article 15.1.10 (b) state would owners lose protection, if they did not provide information.

### 3. Waiting period

According to Article 1711.7 of NAFTA, “When a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connections with obtaining the approval relied on shall begin with the data of the first marketing approval relied on.”<sup>122</sup> In other words, under NAFTA, the data protection period would begin with the date of marketing approval of the original country. Thus, the faster owners register their product in other country after obtaining a marketing approval of the US FDA, the longer exclusivity period owners will receive in other countries.

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<sup>121</sup> *Id.*

<sup>122</sup> Pugatch, *supra* note 6, at 114.

However, due to delay of approving procedure in reference country, pharmaceutical company practically does not receive any data exclusivity protection.<sup>123</sup> To avoid this disadvantage, CAFTA breaks the data exclusivity linkage between reference country and the original granting country.<sup>124</sup> However, this arrangement creates problems.

If the exclusive period did not link the original granting country, the exclusive period in the reference country would begin at the date of making approval in the reference country. The problems come when the test data owners delay the application for marketing approval of its product until the last day of exclusive period; then the data exclusivity would extend to ten years from the first date of marketing approval of the original country.<sup>125</sup> Commentators suggest the cap of data exclusivity or a waiting period should be established in this scenario in order not to improperly undermine the access to essential medicine.<sup>126</sup>

The concept of waiting period is coming form limiting the possibility that the originator pharmaceutical company delay the application for marketing approval of its product but still restrict others from marketing.<sup>127</sup> Normally, the waiting period may vary from six

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<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

<sup>125</sup> Correa, *supra* note 38, at 89.

<sup>126</sup> *Id.*, at 94.

<sup>127</sup> *Id.*, at 89.

months to one year.<sup>128</sup> Because the CAFTA does not set a waiting period, then holders of test data may unfairly extend their exclusive period as high as 10 years.<sup>129</sup>

#### 4. Definition of a New Product

The product qualified for the protection of test data under Article 39.3 of TRIPS must satisfy the criteria of new chemical entity. The term of “new chemical entity” is not defined under TRIPS; thus Members may have their interpretations.<sup>130</sup> Article 15.1.10 (c)<sup>131</sup> otherwise provides a clear definition of “new product,” it states that “a new product is one that does not contain a chemical entity that has been previously approved in the territory of the Party.” This definition is narrower in that, the new chemical is entity not previously approved in the same jurisdiction. Likewise, a product previously approved in a foreign county would still be new for that Party until that party approved it, though it was registered many years after its first marketing approval.<sup>132</sup>

#### 5. Public Health Exception

Similar to Article 1711.5 of NAFTA, Article 15.1.10 (d) provides an exception for states when the undisclosed information is necessary to the public. It states, “. . . each Party

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<sup>128</sup> *Id.*, at 94.

<sup>129</sup> *Id.*, at 89.

<sup>130</sup> The more detailed discussed in 2.1.2.2.

<sup>131</sup> CAFTA, art. 15.1.10 (c) states:

For purposes of this paragraph, a new product is one that does not contain a chemical entity that has been previously approved in the territory of the Party.

<sup>132</sup> Correa, *supra* note 113, at 87.

shall protect such undisclosed information against disclosure except where necessary to protect the public, and no Party may consider information accessible within the public domain as undisclosed data . . . .” The details of the public health exception will be discussed on the later chapter.

## 6. Acting on Behalf of Party

Generally speaking, in order to obtain the marketing approval, a pharmaceutical company is required to submit the test data to the national health agency. However, it is not clear whether Article 39.3 applies if the national health agency delegates the duty of reviewing the test data to institutions, research groups, and other governmental agencies review the submission test data.<sup>133</sup> In this instance, the theory of agency should apply and delegation should not discharge the principal’s obligation, because there is an apparent or implied authority, reviewing agency acting on behalf of government, and reviewing the test data within the scope of employment.

CAFTA otherwise introduced the concept of agency into Article 15.10.1(d), it states

“Notwithstanding the foregoing, if any undisclosed information concerning safety and efficacy submitted to a Party, or an entity acting on behalf of a Party, for purposes of obtaining marketing approval is disclosed by such entity, the Party is still required to protect such information from unfair commercial use in the manner set forth in this Article.”<sup>134</sup>

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<sup>133</sup> Skillington et al., *supra* note 42, at 23.

<sup>134</sup> CAFTA, art. 15.10.2 (d).

It requires a party to protect undisclosed information when she receives this information. In addition, if a party delegates the duty to other entities, such as institution, research, a party is still required to protect undisclosed information. The party cannot discharge her duty to protect undisclosed information, because those entities are acting on behalf of the party.

#### 7. The Patent Protection Measures under Article 15.10.2

In addition to data exclusivity, CAFTA provides more protections for patented pharmaceutical products than TRIPS. Article 15.10.2 directly links the drug registration to patent status.<sup>135</sup> This linkage includes two aspects: first, Article 15.10.2 (a) explicitly restricts the approval of generic product for use on the basis of reliance during the terms of patent of the original product; second, Article 15.10.2 (b) requires the party to inform a patent owner, if claiming the approved product or its approved use is identified as a patented product.

Article 15.10.2 (b) is similar measure to the US law. Under the United States Law, the FDA should inform the patent owner if claiming the approved product or its approved use

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<sup>135</sup> CAFTA, art. 15.10.2, provides: "Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the territory of a Party or in another country, that Party: (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and (b) shall provide that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use."

is identified as a patented product.<sup>136</sup> However, a patent owner is still necessary to bring a suit to claim their right if the patent owners want to claim right or found infringements.<sup>137</sup>

In practice, almost all countries separate the patent application and drug marketing approval procedures.<sup>138</sup> In such cases, the patent office deals with the patent application and health authority deals with the drug approval, because their objectives and procedures are different. These two new measures under Article 15.10.2 linked these two systems together, but this kind linkage is not inconsistent with the current practice of patent and marketing approval process.<sup>139</sup> However, difficulties in enforcement still arise in new systems.

One of these difficulties, as commentators have pointed out is that Article 15.10.2 (a) would make the marketing approval decision by regulatory authorities rely on the will of the patent owner.<sup>140</sup> Therefore, the term of data protection would be effectively extended

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<sup>136</sup> See The Federal Food, Drug, and Cosmetic Act, 21 U.S.C § 355 (c) (3).

<sup>137</sup> *Id.*

<sup>138</sup> According to Rossi, he pointed out states provides the health regulations to guarantee the safety, efficacy, and quality of products to consumers and the intellectual property regulations to secure the personal economic interests. Therefore, in many countries, the health regulations are totally independent of intellectual property regulations. Rossi, F., *Free trade agreements and TRIPS-plus measures*, 1 Int. J. Intellectual Property Management 150, 158, also available at <http://inderscience.metapress.com/media/570cqnvyw17q74nm8eeq/contributions/a/e/2/w/ae2wyqk405r27vme.pdf> (Last visited on October 10, 2008).

<sup>139</sup> Frederick M. Abbott, *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law* 11, International Center for Trade and Sustainable Development Issue Paper No. 12 (2006).

<sup>140</sup> Pedro Proffe & Christoph Spennemann, *The Impact of FTAs on Public Health Policies and TRIPS Flexibilities*, 1 Int. J. Intellectual Property Management 75, 84 (2006), available at <http://ictsd.net/downloads/2008/08/roffe-spennemann.pdf> (Last visited on October 3, 2008).

to the full term of a patent.<sup>141</sup> Another difficulty is that 15.10.2 creates extra burdens for health authorities to determine the validity of patents. They question the capability of the health authorities in developing countries to do patent reviews, a task traditionally done by patent offices.<sup>142</sup> Further, even though health authority did make a decision that the claiming approved product infringed the patent product, the patent office would not bound by health authority opinions.<sup>143</sup> The patent owners still need to take action to protect their right. However, the opinion regarding the patent infringement made by the health authority is enough to undermine the market entry of generic drugs and would prohibit the issuing of compulsory licenses.

The controversy spouses Article 15.10.2 is that it would negate a CAFTA country's ability to grant a compulsory license,<sup>144</sup> because during period of valid patent the health authority cannot grant any marketing approval without the permission of patent owner.<sup>145</sup> This restriction on compulsory license is likely to violate Article 27.1 of TRIPS. Some members of Congress, NGOs and expert saw the impact of US Free Agreements (FTAs) on the access to medicine and made efforts to change US FTAs model language since 2001.<sup>146</sup> In 2007, the USTR adjusted the trade policy and input the public health concern

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<sup>141</sup> *Id.*

<sup>142</sup> Abbott, *supra* note 139, at 11.

<sup>143</sup> *Id.*

<sup>144</sup> Maria Victira Stout, Crossing the TRIPs Nondiscrimination Line: How CAFTA Pharmaceutical Patent Provision Violate TRIPS Article 27.1, 14 B.U.J. Sci. & Tech. L. 177, 195-196.

<sup>145</sup> *Id.*

<sup>146</sup> GAO 2007 Report, *supra* note 21, at 3-4.

into the model template of US FTAs.<sup>147</sup> Following section would examine the transformation of US FTAS.

#### **2.4 Evolution of Data Exclusivity under the Bilateral Agreements**

Given that TRIPS does not follow the US and EU approach to protect test data, the data exclusivity still survives in most FTAs agreements after 2000.<sup>148</sup> After the US failed to insert the data exclusivity into the TRIPS, it becomes one of the priority issues when the USTRs negotiate FTAs with her partners, such as Malaysia, Thailand, and five nations of the African Southern Customs Union (SACU).<sup>149</sup> The USTR uses US FTAs to expand protection standards and provide a higher protection than TRIPS.<sup>150</sup>

As early as 2001, experts, NGOs and human rights advocates pointed that US FTAs provide a higher standard of intellectual property than TRIPS and adopt some measures, which undermine the access to essential medicine in the developing countries.<sup>151</sup> With respect to the protection of test data, commentators argued that most of bilateral FTAS adopt some measures that had not been adopted in Article 39.3 of TRIPS. These measures can be summarized in:

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<sup>147</sup> See section 2.4.3.

<sup>148</sup> Although EU also signed agreements with developing countries, but this studying is only focus the US and other developing countries agreements. See US-Singapore FTA art. 16.8 and US-Australia FTA art. 17.10.1.

<sup>149</sup> Charles T. Collins-Chase, Comment: *The Case against TRIPS-PLUS Protection in Developing Countries Facing AIDAS Epidemics*, 29 U. Pa. J. Int'l L 763, 799-780 (2008). See also, Hamed El-Said & Mphammed El-Said, *TRIPs, Bilateralism, Multilateralism & Implications for Developing Countries: Jordan Drug Sector*, 2 Manchester J. Int'l Econ. L. 59, 59 (2005).

<sup>150</sup> Liew Woon Yin, *Intellectual Property Rights in US-Singapore Free Trade Agreement: Highlights and Insights* 123, 125, (Koh, Tommy eds., 2004).

<sup>151</sup> GAO 2007 Report, *supra* note 21, 38-39.

- (1) FTAs negate the flexibility in TRIPS by granting five years of test data protection.
- (2) FTAs require the health authority to give a notice to the patent holder.
- (3) FTAs link the marketing approval to patent status.
- (4) FTAs mandatory extend terms of patent in case of unreasonable delays in regulatory approval.<sup>152</sup>

It is obvious the USTR through bilateral agreement, the US get more protection for pharmaceutical product than TRIPS and even NAFTA. However, these favorable measures to patent owners are perpetual; they compromise the right of access to medicine. In 2007, the US government revised US FTA model language and affirmed the public health concern in new version of FTAs. Reviewing those bilateral FTAs signed from 2000-2007 would shed some lights on the ongoing development process of data exclusivity.

#### **2.4.1 The First Generation FTA provision - US-Jordan FTA**

The Jordan Free Trade Agreement (US-Jordan FTA),<sup>153</sup> signed in October 24, 2000, is the US first FTA with an Arab state. US expected that Jordan FTA could build a corporate scheme for Jordan's neighbors.<sup>154</sup> The Jordan FTA dealt with significant and

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<sup>152</sup> *Id.*

<sup>153</sup> Agreement on the Establishment of a Free Trade Area, U.S.-Jordan, Oct. 24, 2000, 41 I.L.M. 63, 70 (entered into force Dec. 17, 2001) [hereinafter US-Jordan FTA], also available at [www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Jordan/asset\\_upload\\_file250\\_5112.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Jordan/asset_upload_file250_5112.pdf).

<sup>154</sup> White House Office of Press Secretary, Overview U.S.-Jordan Free Trade Agreement (FTA), on Sep. 29, 2001, available at <http://www.whitehouse.gov/news/releases/2001/09/20010928-12.html>. (Last Visited on October 10, 2008)

extensive trade issues, including all tariff and non-tariff barriers to bilateral trade in virtually all industrial goods and agricultural products within ten years.<sup>155</sup>

Regarding the protection of intellectual property, US-Jordan FTA restated that Jordan is obligated to WTO's obligations, such as providing the protection of intellectual property rights under TRIPS. The Jordan FTA incorporates the international standards for copyright protection,<sup>156</sup> ratifies and implements the World Intellectual Property Organization's (WIPO) Copyright Treaty and WIPO Performances and Phonograms Treaty.

With respect to the test data protection, US-Jordan FTA does not adopt US model; instead it reproduced the text of Article 39.3 of TRIPS for the protection of test data.

Article 4.22 of Jordan FTA states

“Pursuant to Article 39.3 of TRIPS, each Party, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data, or evidence of approval in another country, the origination of which involves a considerable effort, shall protect such information against unfair commercial use. In addition, each Party shall protect such information against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the information is protected against unfair commercial use.”<sup>157</sup>

Generally speaking, Article 4.22 remains the flexibility of TRIPS and leaves a room to Jordan to determine what the terms of protection it should adopt, whether it should notify patent holder when the claiming approved product is identical to the patented product,

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<sup>155</sup> *Id.*

<sup>156</sup> White House Office of Press Secretary, *supra* note 154.

<sup>157</sup> US-Jordan FTA, art. 4.22.

and whether a marketing approval should be linked to patent status. Article 4.22 may also be classified as the first generation provision of FTA for the protection of test data, because the text is similar to Article 39.3 of TRIPS.

#### 2.4.2 Second Generation FTA provision

FTAs, signed between 2003 and 2007, can be classified as the second-generation provision of FTA for the protection of test data. They take a favorable approach to pharmaceutical patent holders and they provide the protection of test data beyond the scope of TRIPS, which critics also called those provisions as “TRIPS-plus” provisions.<sup>158</sup> FTAs at this period were not identical, but they include some common features, such as the requirement of notifying patent holders, making approval linking to patent status and mandatory extensions in case of unreasonable delays in regulatory approval. Some argue that those common features negate the flexibility of TRIPS. These common features include the examples for this period US-Chile FTA,<sup>159</sup> US-Singapore FTA,<sup>160</sup> US-Australian FTA,<sup>161</sup> US-Morocco FTA.<sup>162</sup>

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<sup>158</sup> TRIPS sets a minimum standards agreement, but it does allow for a greater level of protection, which is referred to as “TRIPS-plus” protection. TRIPS-plus protection allows developed countries, through their disparate bargaining power, to force greater IP protections upon developing countries, and to simultaneously decide when to apply Most Favor Nation principles to extend this TRIPS-Plus protection to the countries that would actually benefit from the higher standards. See, Brian Cimboli, *The Impact of Regional Trade Areas on International Intellectual Property Rights*, 48 IDEA 53, 56 (2007).

<sup>159</sup> United States-Chile Free Trade Agreement, June 6, 2003, 42 I.L.M. 1026, available at <http://www.ustr.gov/new/fta/Chile/final.pdf> [hereinafter U.S.-Chile FTA].

<sup>160</sup> United States--Singapore Free Trade Agreement, U.S.-Sing., May 6, 2003 [hereinafter US-Singapore FTA], available at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Singapore\\_FTA/Final\\_Texts/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Singapore_FTA/Final_Texts/Section_Index.html).

<sup>161</sup> U.S.-Austl. Free Trade Agreement, May 18, 2004, 118 Stat. 919 [hereinafter US-Australian FTA].

### 2.4.2.1 The US-Chile FTA

The US-Chile FTA (Chile FTA) was effective on January 1, 2004.<sup>163</sup> It is the first free trade agreement between the United States and a South American country. It provides the protection of intellectual property under chapter seventeen of the US-Chile FTA. Chapter seventeen deals with certain IP regulations, sets certain standards of protection, and builds on the foundations established in TRIPS. In addition, it affirms the rights and obligations set forth in TRIPS Agreement.<sup>164</sup>

Article 17.10 of the US-Chile FTA protected the test data under the title of “certain regulated product.” This article is important in two aspects: namely, granting data exclusivity, and patent linkage measures.

With respect to the protection of test data, Article 17.10.1 grants the five years exclusive right to data owners; it states:

“If a Party requires the submission of undisclosed information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product which utilizes a new chemical entity, which product has not been previously approved, to grant a marketing approval or sanitary permit for such product, the Party shall not permit third parties not having the consent of the person providing the information to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information. A Party shall maintain this prohibition for a period of at least five years from the date of approval for a pharmaceutical product and ten

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<sup>162</sup> US-Morocco United States-Morocco Free Trade Agreement, U.S.-Morocco [hereinafter US-Morocco FTA], June 15, 2004, 44 I.L.M. 544, available at [http://www.ustr.gov/Trade\\_Agreements/Bilateral/Morocco\\_FTA/Final\\_Text/Section\\_Index.html](http://www.ustr.gov/Trade_Agreements/Bilateral/Morocco_FTA/Final_Text/Section_Index.html).

<sup>163</sup> United States-Chile Free Trade Agreement Implementation Act, Pub. L. No. 108-77, 117 Stat. 909, 911 (2003); Office of the United States Trade Representative, *Economic benefit to Chile of FTA*, available at [http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Chile\\_FTA/asset\\_upload\\_file198\\_13333.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Chile_FTA/asset_upload_file198_13333.pdf) (last visited on October 19, 2008)

<sup>164</sup> US-Chile FTA, ch. 17, preamble.

years from the date of approval for an agricultural chemical product. Each Party shall protect such information against disclosure except where necessary to protect the public.”<sup>165</sup>

In TRIPS and NAFTA, the protection of test data is under the title of undisclosed information and trade secrets. By contrast, the protection of test data is under the title of “Measures Related to Certain Regulated Products”.<sup>166</sup> This change did not extend the scope of protection under Article 17.10.1. US-Chile FTA still protected test data that is qualified as “undisclosed information. Chile FTA representatives perceived this is an important accomplishment in negotiations because the US original proposals suggested any information should be protected regardless of disclosure.<sup>167</sup> Another accomplishment is that US-Chile FTA only applies in the case where the pharmaceutical product utilizes a new chemical entity. Chile representatives reject the US proposals dealt with any pharmaceutical product regardless of whether or not it utilized a new chemical product.

Regarding the patent linkage, Article 17.10.2 imposes other three obligations in relation to the protection of test data, it states

“With respect to pharmaceutical products that are subject to a patent, each Party shall:(a) make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process;(b) make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent; and(c) not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the

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<sup>165</sup> US-Chile FTA, art. 17.10.1.

<sup>166</sup> US-Chile FTA, art. 17.10.

<sup>167</sup> Pedro Roffe, *Bilateral Agreement and a TRIPS-plus World: the Chile –US Free Trade Agreement*, Canada Quaker International Affair Programme 24, 2004.

patent owner.”<sup>168</sup>

First, Article 17.10.2 (a) of the US-Chile FTA provides an extension of the patent term to compensate the patent owners for unreasonable curtailment. Second, Article 17.10.2(b) requires government to have a mechanism that patent owner can identify any third party who requests the marketing approval. Third, Article 17.10.2 (c) links marketing approval with patent status. Some commentators argued these linkages create controversy regarding negating the flexibility of TRIPS and license curtailment.<sup>169</sup> Other optimistic commentator say it does not explicitly state that the party cannot grant the marketing approval relied on the test data which the originator apply the marketing approval in another country.<sup>170</sup>

#### 2.4.2.2 US-Singapore FTA

The U.S. has a substantial economic stake in Singapore to enter a free trade agreement (US-Singapore FTA), because Singapore is a member of ASEAN,<sup>171</sup> and it is the second largest Asian investor in the U. S., after Japan.<sup>172</sup> For the US, Singapore FTA can serve as a template in its negotiations with other Asian countries and economies. For the Singapore, this Agreement would secure tariff entry to the U.S. market and also secure

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<sup>168</sup> US-Chile FTA, art. 17.10.2.

<sup>169</sup> Roffe, *supra* note 167, at 26.

<sup>170</sup> See Pugatch, Table 7.4 *Data exclusivity formulas in US-led Free Trade Agreements*, *supra* note 6, at 123. However, US-Chile FTA did not deal with the issue whether the application in other country, so it is unlikely to explain in the same way as the US-Singapore FTA.

<sup>171</sup> KOH, TOMMY, *The USSFTA: A Personal Perspective, in US-Singapore Free Trade Agreement: Highlights and Insights* 3, 8 (2004). With two-way trade of nearly \$168.5 billion in 2006, the 10-member ASEAN group already is the U.S.' fifth largest trading partner collectively.

<sup>172</sup> *Id.*

the most important source of technology and know-how for Singapore. Therefore, to benefit each other and build a close relation between them, they sign free trade agreement in 2003.<sup>173</sup>

Before signing the FTA, Singapore as a member of the WTO is obligated by TRIPS, therefore it has an obligation to provide the minimum protection for the test data based on Article 39.3 of TRIPS.<sup>174</sup> However, US-Singapore FTA incorporated TRIPS-plus measures and provided more protections for pharmaceutical test data than TRIPS. With respect to the protection of test data, Article 16.8 of US-Singapore FTA protected the test data under the title of regulated product not undisclosed information, extended the scope of Article 39.3 and linked the patent status with the marketing approval procedure. Article 16.8 includes four paragraphs dealing with the protection of test data and related protections and also deals with two issues, data exclusivity and patent linkage.

The data exclusivity is incorporated into Article 16.8.1, it states:

“ If a Party requires the submission of information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product prior to permitting the marketing of such product, the Party shall not permit third parties not having the consent of the party providing the information to market the same or a similar product on the basis of the approval granted to the party submitting such information for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product.”<sup>175</sup>

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<sup>173</sup> World of Information, Singapore Business Intelligence Report 5 (2005).

<sup>174</sup> Yin, *supra* note 165, at 125.

<sup>175</sup> US-Singapore FTA, art. 16.8.1.

There are two different points from TRIPS in this Article. First, Article 16.8.1 protected the test data if it is “information” regardless whether it was disclosed or not.<sup>176</sup> This is a higher standard than TRIPS, because Article 39.3 only protected the “undisclosed information.” Second, Article 16.8.1 granted a five-year term of data exclusivity. Those protections are similar schemes to Article 1711 of NAFTA. Article 16.8.1 provides a protection in the first approving country, which is similar to Article 39.3 of the TRIPS.

The Article 16.8.2 otherwise extended the exclusive protection of test data beyond the national territories of the parties involved. It states:

“If a Party provides a means of granting approval to market a product specified in paragraph 1 on the basis of the grant of an approval for marketing of the same or similar product in another country, the Party shall defer the date of any such approval to third parties not having the consent of the party providing the information in the other country for at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product in the territory of the Party or in the other country, whichever is later.”<sup>177</sup>

Under this Article, a domestic health authority cannot grant marketing approval based on foreign approvals at least five years after a pharmaceutical product has been approved for the data originator in the foreign countries or domestically. This would happen even if the applicant cannot obtain the permission of data originator in other countries. That is to say, the data originator once has received marketing approval anywhere or even in a country not a party of FTA, she still gets the protection in a party of the FTA.<sup>178</sup> The views regarding the restrictions of health authority reliance on prior foreign approval are split.

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<sup>176</sup> Roffe et al., *supra* note 140, at 83.

<sup>177</sup> US-Singapore FTA, art 16.8.2.

<sup>178</sup> Roffe et al., *supra* note 140, at 83.

Some argue that the scope is not clear and subject to interpretations,<sup>179</sup> others perceive that the restriction only prevents recognition of foreign marketing approval decision.<sup>180</sup>

Article 16.8.3 clarifies that data exclusivity is a different right from the patent right, which is not clear in TRIPS.<sup>181</sup> It states “Where a product is subject to a system of marketing approval . . . and is also subject to a patent in the territory of that Party. . . .”<sup>182</sup>

It takes a position that the protection of test data can exist even when a pharmaceutical product is not patented. That is to say, the generic company is not able to get marketing approval for its product unless it generates its own test data or waits until the exclusivity period if the patent has expired.

Regarding the linkage with patent, Article 16.8.4 provides three favorable measures for patent holders, which are similar to the CAFTA and US-Chile FTA. It states:

“ With respect to any pharmaceutical product that is subject to a patent: (a) each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process;(b) the Party shall provide that the patent owner shall be notified of the identity of any third party requesting marketing approval effective during the term of the patent; and(c) the Party shall not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or with the acquiescence of the patent owner.”<sup>183</sup>

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<sup>179</sup> Pugatch, *supra* note 6, at 123.

<sup>180</sup> Roffe et al., *supra* note 140, at 83.

<sup>181</sup> Robert Galantucci, Note: Data Protection in a US-Malaysia Free Trade Agreement: New Barriers to Market Access for Generic Manufacturers, 17 *Fordham Intell. Prop. Media & Ent. L.J.* 1083, 1096-1097 (2007).

<sup>182</sup> US-Singapore FTA, art. 16.8.3.

<sup>183</sup> US-Singapore FTA, art. 16.8.4.

First, Article 16.8.4 (a) requires mandatory extension of patent term due to the delay of marketing approval. Second, Article 16.8.4 (b) requires health authority to notify the patent holders. Third, Article 16.8.4(c) links the marketing approval process with patent status. Like CAFTA, there are two criticisms regarding these linkages: one is related to the compulsory licenses,<sup>184</sup> the other is related to the practice of marketing approval procedures.<sup>185</sup> The discussions of these two issues are the same as in CAFTA.

#### 2.4.2.3 The US-Morocco FTA

The US-Morocco signed FTA on June 2004,<sup>186</sup> provides lengthy paragraphs for the protection of test data. Like the Singapore and Chile FTA, the Morocco FTA distinguishes the protection from trade secrets and provides the protection under the title of measures related to certain regulated and grants exclusivity right for pharmaceutical product of five years from the date of original approval. This FTA like the other second generation of FTAs adopts some measures to ensure the benefit of patent holders, such as an extension of patents term,<sup>187</sup> linking the marketing approval with patent status,<sup>188</sup> notice of patent owner.<sup>189</sup> The US-Morocco FTA also includes two important modifications, which are different from other second generations of FTA agreement, providing the definition of new product, and protection of new clinical information.

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<sup>184</sup> Stout, *supra* note 144, 195-196.

<sup>185</sup> *Id.* at 195-197.

<sup>186</sup> US-Morocco FTA.

<sup>187</sup> US-Morocco FTA, art. 15.10.3.

<sup>188</sup> *Id.*

<sup>189</sup> US-Morocco FTA, art. 15.10.4.

### 1. Definition of New Product

Article 39.3 of TRIPS provides the protection of pharmaceutical chemical product, which utilizes new chemical entities, but it does not explain what the “new chemical entities are. Article 15.10 clarifies this sentence, it protects a “new pharmaceutical chemical entities”, and it further explains, “a new product is one that contains a new chemical entity that has not been previously approved in the Party’s territory.”<sup>190</sup>

### 2. The Protection of New Clinical Information

Regarding the scope of protection, Article 15.2 of US-Morocco FTA gives the protection of safety and efficacy as well as new clinical test data.<sup>191</sup> The three years protection for new clinical is a new type of protection, which is not available in the former FTAs, TRIPS and NAFTA.<sup>192</sup>

### 3. Measures Favor Patent Owners

Unlike second generation FTAs, the linkage between marketing approval and patent status in the US-Morocco Agreement is inconspicuous. In most of the second generation FTAs, marketing approval requires the consent of the patent owner if the approved

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<sup>190</sup> US-Morocco FTA, art. 15.10.

<sup>191</sup> If a Party requires the submission of new clinical information that is essential to the approval of a pharmaceutical product (other than information related to bioequivalency), or (b) evidence of prior approval of the product in another territory that requires such new information, the Party shall not permit third persons not having the consent of the person providing the information to market a pharmaceutical product on the basis of such new information or the approval granted to the person submitting such information for at least three years from the date of approval in the Party. A Party may limit such protection to new clinical information the origination of which involves considerable effort.

<sup>192</sup> Scafidi, *supra* note 62, at 349-350.

product is identical to the patented product. However, the text of Article 15.10.4<sup>193</sup> is not clear as to whether the marketing approval is up to the will of patent owners. It requires parties to implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent during the term of that patent, unless the patent owner consented or acquiesced.<sup>194</sup> Thus, if the patent owner does not take any actions to protect her rights, then marketing approval can be granted to a third party.

Meanwhile, it is not clear what “measures in its marketing approval process” to prevent from marketing approval are. One commentator suggests this measure should include the notifying the patent owner under Article 15.10.4 (b) and a court injunction relief.<sup>195</sup>

#### **2.4.2.3 The US-Australian FTA**

The US-Australian FTA was completed and signed on May 18, 2004.<sup>196</sup> At the time the FTA was signed, Australia’s pharmaceutical sector far exceeds most of the developing countries, and it had the fifteenth largest economy. Surprisingly, the US did not propose

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<sup>193</sup> US-Morocco FTA, art. 15.10.4, provides: “With respect to any pharmaceutical product that is subject to a patent, and where a Party permits authorizations to be granted or applications to be made to market a pharmaceutical product based on information previously submitted concerning the safety and efficacy of a product, including evidence of prior marketing approval by persons other than the person that previously submitted such information, that Party: (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent during the term of that patent, unless by consent or with the acquiescence of the patent owner, and (b) if it allows applications to be made to market a product during the term of a patent covering that product, shall provide that the patent owner shall be notified of the identity of any such other person who requests marketing approval to enter the market during the term of a patent notified to or identified by the approving authority as covering that product.”

<sup>194</sup> US-Morocco FTA, art. 15.10.4.

<sup>195</sup> Abbott, *supra* note 139, at 11.

<sup>196</sup> U.S.-Austl. Free Trade Agreement, May 18, 2004, 118 Stat. 919 [hereinafter US-Australian FTA].

favorable terms to Australia.<sup>197</sup> Instead, the US-Australian FTA provision for the protection of test data embodies the same features as most of the second generations FTAs.<sup>198</sup> Moreover, it provides a new protection for the test data which are submitted for certain new uses of the same product; that is, the qualified product for the protection is not limited to the new product and it can be the new uses of the precedent approved product.<sup>199</sup>

The protection of test data is established under the title of “measures related to certain regulated products.” Like other second generation FTAs for protection of test data, it embodies three distinguished features different from TRIPS. These are:

- (1) extension of patent term for the compensation of marketing approval procedure;<sup>200</sup>
- (2) favorable measures for patent holders;<sup>201</sup> and
- (3) the linkages between marketing approval and patent status.<sup>202</sup>

When those provisions incorporated into the Australian Law,<sup>203</sup> they raise concerns regarding the access to medicine as to whether the Australian Health Authority is capable of reviewing the patent claims.<sup>204</sup>

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<sup>197</sup> Charles T. Collins-Chase, Comment: The Case against TRIPS-Plus Protection in Developing Countries Facing AIDS Epidemic, 29 U. Pa. J. Int’L. 763, 793-796 (2008).

<sup>198</sup> US-Australian FTA, art. 17.10.

<sup>199</sup> US-Australian FTA, art. 17.10.1(d).

<sup>200</sup> US-Australian FTA, art. 17.9.

<sup>201</sup> US-Australian FTA, art. 17.10.4.

<sup>202</sup> US-Australian FTA, art. 17.10.4.

### 2.4.3 The Third Generation FTA Provision

The favored measures for patent holders are not ideal to enforce in reality and they raises concerns of violations of TRIPS 27.1.<sup>205</sup> Consequently, the US Congress moved to modify the template of FTA provisions in relation to the protection of test data in 2007.<sup>206</sup> The modifications somehow ameliorate some of Article 27.1 of TRIPS problems and also affirm the Doha Declarations 2003 waivers.<sup>207</sup> Those changes will affect the future US FTAs but they would not affect ratified agreements because they were no retroactive effect clauses. The updated FTA may be named as the third generation of FTA for the protection of test data. Those agreements deal with controversial issues presented in the second generation of FTA provisions.<sup>208</sup> US-Peru FTA,<sup>209</sup> US-Panama FTA<sup>210</sup> are

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<sup>203</sup> Bryan Mercurio, International Law Weekend-West: Panel Presentation: The Impact of the Australia-United States Free Trade Agreement on the Provision of Health Services in Australia, 26 Whittier L. Rev. 1051, 1090-1092 (2005).

<sup>204</sup> *Id* at 1091-1092.

<sup>205</sup> Stout, *supra* note 144, at 198.

<sup>206</sup> *Id*.

<sup>207</sup> World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002), available at [www.wto.org/english/thewto\\_e/mini\\_st\\_e/min01\\_e/mindecl\\_trips\\_e.htm](http://www.wto.org/english/thewto_e/mini_st_e/min01_e/mindecl_trips_e.htm) [hereinafter the Doha Declaration]. Also, Decision by the General Council for TRIPS, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Aug. 30, 2003), available at [www.wto.org/english/tratop\\_e/trips\\_e/implem\\_para6\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm).

<sup>208</sup> Brook K. Baker, Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/ Registration Linkage, 34 Am. J. L. and Med. 303, 337-341 (2008).

<sup>209</sup> United States-Peru Trade Promotion Agreement, U.S.-Peru, art. 16.10.2, Dec. 14, 2007, available at [www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Peru\\_TPA/Final\\_Texts/asset\\_upload\\_file3\\_92\\_9546.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Peru_TPA/Final_Texts/asset_upload_file3_92_9546.pdf) [hereinafter U.S.-Peru FTA]

<sup>210</sup> United States-Panama Trade Promotion Agreement, U.S.-Pan., art. 15.10.2, Dec. 19, 2007, available at [www.ustr.gov/assets/Trade\\_Agreements/Bilateral/Panama\\_FTA/Final\\_Text/asset\\_upload\\_file131\\_10350.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/Panama_FTA/Final_Text/asset_upload_file131_10350.pdf) [hereinafter U.S.-Panama FTA]

examples for this new revision of FTAs. Taking US-Peru FTA as an example, there are certain unique features:

1. Distinctions between Pharmaceutical Products and Non-Pharmaceutical Products in Patent Extensions.

The third generation now provides that a party must adjust the term of a non-pharmaceutical patent to compensate for unreasonable delays that occur in granting the patent.<sup>211</sup> However, a party has discretion to adjust the term of a pharmaceutical product patent to compensate for unreasonable delays in granting patents. In other words, the mandatory extension of patent term is no longer shown in those FTA.

2. Waiting Period is Six Months

The waiting period limits the possibility when the originator pharmaceutical company delays the application for marketing approval of its product but still restricts others from marketing. This concept has been disused for a period of time, but it has not been incorporated into the FTA model until 2007. It comes from the result of the new reform of the US trade policy. Under Article 16.10.2 (c) of the US-Peru Agreement, it was first

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<sup>211</sup> US-Peru FTA, art. 16.10.

in time to limit the waiting period within six months.<sup>212</sup> This limitation encourages data holders for early registration to avoid abridging of data exclusive period.<sup>213</sup>

### 3. Public Health Waiver

Article 16.10.2 (e) recognizes<sup>214</sup> exceptions to data exclusivity that would allow registrations of a follow-on product to meet the public health needs. Article 16.10.2 (e) (i) provides an exception to the data exclusivity obligations for the measures to protect public health in accordance with the Declaration on the TRIPS Agreement and Public Health and other TRIPS amendments. It implies that Doha Declaration can justify overriding a data exclusivity claim.<sup>215</sup> The Doha Declaration explicitly recognizes that: “Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”

### 4. Definition of Chemical Entity

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<sup>212</sup> US-Peru FTA, art. 16.10.2 (c) provides: “Where a Party relies on a marketing approval granted by the other Party, and grants approval within six months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.”

<sup>213</sup> Baker, *supra* note 208, at 338-339.

<sup>214</sup> US-Peru FTA, art. 16.10.2 (e) provides: “Notwithstanding subparagraphs (a), (b), and (c), a Party may take measures to protect public health in accordance with:(i) the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”);(ii) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration and in force between the Parties; and (iii) any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties.”

<sup>215</sup> Center for Policy Analysis on Trade and Health, *New Peru Trade Text: Improvements for Access to Medicines Threats to Public Health Remain*, on July 5, 2007, available at <http://www.cpath.org/sitebuildercontent/sitebuilderfiles/perurevisedcpathcomment7-5-07.pdf>.

The new Agreement limits the application of data exclusivity to “new chemical entities,”(16.10.2(a)), meaning it can only be applied to truly innovative drugs, and not to those that simply entail minor modifications to already known substances.

#### 5. Data Exclusivity and Scope

It protects only “undisclosed data” that is the result of “considerable effort.” Other versions have allowed originator companies to hold up access even to “information” already in the public domain and that required little investment in order to block approval for generics. The data exclusivity period is limited to 5 years, not “at least” 5 years.<sup>216</sup>

#### 6. The Patent Linkage

If Peru grants marketing approval to an originator company within six months of filing, based on prior approval in the U.S., the data exclusivity period begins with the date of approval in the US (16.10.2.(c)).there would be no link between the marketing approval and patent status. Although Article 16.10.4 still provides some measures to link patent, but those mechanism would not negate the ability of health authority to grant marketing approval.

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<sup>216</sup> Letter from Jim Mcdemott, Member of Congress, *Access to Life-Saving Medicine: Real Changes in the Peru FTA*, <http://waysandmeans.house.gov/media/pdf/110/peru%20fta%20materials%20and%20news/PERU%20FTA%20MEDICINES.pdf> (Last visited on October 23, 2008)

Those pharmaceutical related provisions of the US-Peru FTA provide a balance between fostering drug innovation and ensuring access to affordable medicine. Although they are not perfect, but at least this is a right direction toward the access to medicine.<sup>217</sup>

## **2.5 Municipal Law**

The example in this section deals with some countries which have not adopted the US model of data exclusivity or have granted less protection than that of the US's model for the protection of test data. Those countries encounter extreme economic threats from the US and are listed on the US Special 301 of 2008 Report.<sup>218</sup> The USTR warned them to adopt the strong data exclusivity approach, but they argued that the flexibility of TRIPS gave them a room to decide in which way to protect the test data.

### **2.5.1 The Case of India**

As a member of WTO, India was required to implement the obligation of TRIPS. Under the US economical pressure, India reformed the Indian Patent Act of 1970 in 2005.<sup>219</sup> The 2005 of amendment provides for product patent for foods, biotechnology products, chemical and medicines. However, the US and the EU still complained that India has not come into full compliance with all TRIPS obligations, such as the Data Exclusivity. In 2004, the Indian government referred those patent law complaints to an expert group to

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<sup>217</sup>Letter from Henry Waxman, Member of Congress, on November 5, 2007, available at <http://waysandmeans.house.gov/media/pdf/110/peru%20fta%20materials%20and%20news/Peru%20FTA%20-%20Medicines%20DC%20Waxman.pdf> (Last visited on October 23, 2008)

<sup>218</sup> Pharmaceutical Research and Manufacturers of America [hereinafter PhRMA], Special 301 Submission 2008 [hereinafter 2008 Special 2008 Report], February 11, 2008, [http://www.ustr.gov/assets/Trade\\_Sectors/Intellectual\\_Property/Special\\_301\\_Public\\_Submissions\\_2008/as\\_set\\_upload\\_file109\\_14495.pdf](http://www.ustr.gov/assets/Trade_Sectors/Intellectual_Property/Special_301_Public_Submissions_2008/as_set_upload_file109_14495.pdf).

<sup>219</sup> The Patents (Amendment) Act, 2005, effected on March 31, 2005 available at <http://www.indiacode.nic.in> (Last visited on October 26, 2008).

make an overall analysis and propose recommendations in the same year. The committee made the report public in July 2007 and suggested a three-year period of data exclusivity.<sup>220</sup> However, the Indian health authority did not accept this recommendation and refused granting data exclusivity.

The Indian health authority made a public statement and insisted that the protection of test data should still remain in the field of trade secrets.<sup>221</sup> Thus, it is not necessary to grant the data exclusivity in India, because they thought it is enough to protect test data under the trade secret. Obviously, this opinion has a great impact on the generic medicine market since India import more medicine and occupies great global market. It is also affirmed that the data exclusivity is not the only way to protect the test data.

### 2.5.2 The Case of Israel

Israel owned the biggest generic multinational pharmaceutical company in the world, but she did not grant data exclusivity to pharmaceutical companies after it signed the TRIPS. For a long time, the multinational research-based pharmaceutical industries complained that Israel generic pharmaceutical companies caused them to lose considerable profits, because new pharmaceutical products registered in Israel were immediately exposed to generic competitions.<sup>222</sup> The absence of data exclusivity legislation in Israel became one of major disputes between Israel and her trading partners.

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<sup>220</sup> Satwant Reddy & Gurdial Singh Sandhu, Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement on May 21 2007.

<sup>221</sup> Manish Singh Nair, *India: Ministries Say Yes To Data Protection*, Lex Orbis, September 15 2007. available at <http://www.mondaq.com/article.asp?articleid=52316&login=true&newsb=1> .

<sup>222</sup> Pugath, *supra* note 6, at 125.

In 2004, responding to an ongoing pressure from the EU and the US, Israel proposed a bill that introduced legislation for protecting the research data of innovative drug makers.<sup>223</sup> This bill, enacted on March 2005, provides for a five year period of protection for new chemical entities under Article 47 of the Pharmacists Ordinance new subsection D (2), nevertheless this legislation does not meet the expectations of the European Commissions and the US. They had two reservations with respect to the new legislations.

First, they argued that Israel does not provide absolute "five-year" period of data exclusivity. According to Article 47 D (2), it provides a type of protection where the health authority may rely on the test data to register generic products during the exclusivity period. It only secures protection against disclosure of data but allows reliance. Further, 47D (b) (2) of the Pharmacist Ordinance provides five years exclusivity from the day of product registration in Israel, or five and a half years of exclusivity from the day of the earliest registration in any of the 'Recognized Countries'<sup>224</sup>, whichever is shorter. That is to say, the five years period of protection, will commence upon the earlier registration of the pharmaceutical product in either Israel or a "recognized country" by Israel. In addition, the protection period will come to an end as soon as a generic substitute to the original drug is marketed in one of the recognized countries (this latter condition appears to be abolished). That is to say when the process of marketing approval has been delayed, the real data exclusivity in Israel would be less than five years, since

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<sup>223</sup> Market Access Database, *Lack of Data Exclusivity: Israel*, latest update on July 22, 2008, available at [http://mkacddb.eu.int/madb\\_barriers/barriers\\_details.htm?barrier\\_id=050004&version=8](http://mkacddb.eu.int/madb_barriers/barriers_details.htm?barrier_id=050004&version=8) (Last visited on October 23, 2008)

<sup>224</sup> A "recognized country" includes the EU Member States, the United States, Canada, Norway, Switzerland, Iceland, Japan, Australia and New Zealand, as defined in the Israeli Pharmacist Regulations - Pharmaceutical Products - 1986)

the data exclusivity would expire at last day of 5.5 years from the first day of making approval in any recognized countries. As a result, US and other European Countries argued that Israel cuts marketing exclusivity less than five years, if the marketing approval is delayed in Israel.

Second, USTR also complained that the Israel Pharmacist Ordinance offers no protection for new indications (new uses of existing drugs), while the legislations in the U.S. and in the EU provide three years and one year, respectively, and the US provides exclusivity for new presentations and or dosage forms.<sup>225</sup>

Regarding the first observation, the USTR, according to the new trade policy of 2007, may change their opinions regarding the viewpoint of data exclusivity.<sup>226</sup> New bilateral Agreements such as the US-Peru FTA set some limitations on data exclusivity provisions.

### 2.5.3 Other Cases

According to Special 301<sup>227</sup> submission 2008<sup>228</sup>, there are still many countries do not provide data exclusivity legislations for the protection of test data, such as Indonesia,

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<sup>225</sup> 2008 Special 301 Report, *supra* note 208, at .

<sup>226</sup> GAO 2007 Report, *supra* note 21.

<sup>227</sup> Special 301 is originated from President Reagan signed into law the Omnibus Trade and Competitiveness Act of 1988 (the "1988 Trade Act") on August 23, 1988. Special 301, is designed to use the credible threat of unilateral retaliation by the United States to "persuade" trading partners to reform currently deficient intellectual property practices. See Judith H. Bello & Alan F. Holmer, "*Special 301*": *Its Requirements, Implementation, and Significance*, 13 Fordham Int'l L.J. 259 (1989-1990). See also, Office of United States Trade Representatives, Background on Special 301, [http://www.ustr.gov/assets/Document\\_Library/Reports\\_Publications/2007/2007\\_Special\\_301\\_Review/asset\\_upload\\_file694\\_11120.pdf](http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file694_11120.pdf)

Brazil, Algeria, Lebanon, Pakistan, Turkey, Thailand and most of African countries. Other countries provide the protection of test data but PhRMA complained that those protections are not sufficient for the protection of test data.

For example, PhRMA complained that Thailand government provided a weak protection of test data. To implement the obligation of Article 39.3 of TRIPS, the Thai Parliament passed a Trade Secret Act in 2002.<sup>229</sup> However, like India, Thai government protected the test data from disclosure but it did not provide a data exclusivity to exclude the use or reliance on test data for the approval of generic drug.

In the case of China, Regulation of the Drug Administration Law and the Drug Registration Regulation did establish a six-year period of protection for test data. However, PhRMA still complained that weak enforcement of implementation of law of data exclusivity. They also complained that China's regulatory procedures still permit the State Food and Drug Administration (SFDA) to grant marketing approval to products that have previously been outside of China. Besides, through the interpretation of SFDA, PhRMA complained that there is no data exclusivity if originators are not the first application of new drug in China.<sup>230</sup>

Other complaints include that States do not link the marketing approval process with the patent status, or do not provide the protection of certain pharmaceutical test data due to the absence of clear definition of "new chemical."

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<sup>228</sup> 2008 Special 2008 Report, *supra* note 230.

<sup>229</sup> *Id.*, at 37.

<sup>230</sup> 2008 Special Report, *supra* note 240, at 49-54.

## 2.6 Conclusion

Article 39.3 of TRIPS establishes the concept of test data, and recognizes that test data should be protected as undisclosed information. However, it does not specify how to protect it. Through states practice, the protection of pharmaceutical test data can be classified into two forms: trade secrets and data exclusivity. The protection of test data under the law of trade secrets includes states such as India, Thailand and most of WTO members. The data exclusivity has developed in three major models. The first model of data exclusivity simply grants five years of exclusivity. Apparently, the US, NAFTA members, Jordan, Israel, and Taiwan are the states that exemplify this model. The second model of protection not only provides the basic form of data exclusivity but also links the marketing approval with patent status. This model also extends the scope of protected product by giving a definition of pharmaceutical that favors the patent owners. Those who have adopted the third model are Singapore, Australia, and Morocco. The third data exclusivity model is 2007 reforms of US-FTAs, such as US-Peru FTA. These three models, indeed comply with requirement of Article 39.3 of TRIPS even though they follow different approach for the protection of test data.

India is important manufacturer in the global generic drug market. Thus, the US and other EU countries are concerned as to how India provides the protection for pharmaceutical products. Opposed to providing the protection of pharmaceutical products prior to TRIPS, India passed an act to grant the pharmaceutical patent to comply with the requirements of TRIPS in 2005. The Congress of India however declared that they would protect the pharmaceutical test data through the law of trade secrets. They explained that their actions satisfy the requirement of TRIPS. The US and the EU argued that India

violated Article 39.3 of TRIPS, but they have not taken up their case to the WTO. This is the most basic form of protection of test data in India. India also would not spend other expenses to provide the protection and the pharmaceutical holder must meet the requirements of trade secrets in order to obtain the protection.

The first model, which includes the US, Canada, Mexico and early signatory countries of US FTA, grants a five-year exclusionary right. While the time of protection may vary, in general it is in line with the US policy and law. They grant a period of data exclusivity by cloning the US model. This model provides two exclusive rights to ensure the protection of pharmaceutical products: patent and data exclusivity. This form is designed to grant the data exclusivity to keep the generic drugs out of the market for a period of time. This triggers the question of why another exclusive right should be granted to the patented pharmaceutical product. The answer to this question depends on what philosophy of protection a state follows and what are the economic underpinnings that result from following such a philosophy.

The second data exclusivity model includes the members of CAFTA, and recent US-FTA signatory countries (signed 2000-2007). They grant the data exclusivity and moreover they link the marketing approval with patent status. Those bilateral and regional agreements also have the same problems like the second model. In particular, the protection of this group concerning favorable terms for the protection of patented pharmaceutical products creates more questions than the second model. First, this protection blocks the possibilities of granting the compulsory license and has been proved to violate Article 27.1 of TRIPS. Second, this protection raises the concern of violation of

human right laws by blocking the possibilities of entry to generic drug without exceptions. Third, this protection imposes heavy burdens on health authorities to review the patent claims during the approval process. From the pharmaceutical inventors' perspective, this model provides more measures to protect the pharmaceutical product. From the other perspectives, it is not the sound way of the protection of pharmaceutical test data because it raises two important concerns: the capability of health agency and the possibility of violation to human rights law.

The third data exclusivity model, such as that of the US-Peru FTA, basically incorporates parts of Doha Decorations and recognized the waivers of public health. To some degree, it is a response to human right law concerns. This model, although revives parole's hope of balancing the protections of pharmaceuticals and the right to medicine, it is too early to predict its effect.

Among these three models it is notable that countries are attempting to balance their interests. It is a dilemma. Those countries have to promote new inventions but also they have to provide medicines. Granting the data exclusivity means the emergence of a new type of intellectual property, and it can promote the research and development of new drugs. Nevertheless as explained above, it is certain that this new IP scheme would impede the right to medicine.

The protection of pharmaceutical test data cannot be apart from the human rights. This is the stand of the WHO and public health experts. They both agree that TRIPS does not mandate an exclusive protection. Indeed certain kind of protection is needed; however, this protection must be balanced against the right to medicine. This protection must also

reflect the true value of the intellectual efforts that were put to develop the particular drug. In conclusion, the human rights concerns must be taken into account whenever a system for the protection of any data is designed. At the end it is only logical to say because all things must be considered from their beneficial use to human beings, such view must be followed.

### 3 The Waivers of Protection of Pharmaceutical Data

#### 3.1 Introduction

In 2006 the WHO reported that around 2 billion persons, one-third of the global population, do not have regular access to essential medicines. In Africa and lowest-income countries in Asia; an estimated more than half of the population lacks access to essential medicines.<sup>1</sup> There are an estimated 40 million persons infected with HIV/AIDS in developing countries, where only 300,000 of the 5-6 million persons in need of treatment could acquire life-saving antiretroviral medicines (ARVs).<sup>2</sup> The WHO has declared this crisis to be a global health emergency and established strategies to expand access to medicine in these countries.<sup>3</sup>

A report published jointly by the WHO Regional Office for Africa and HAI-Africa, based on a survey conducted in 11 countries found that prices of brand names of medicines found in private sector outlets were to be as much as 7 times higher than the prices of their generic equivalents.<sup>4</sup> Similar finding was also reported in the synthetic report, published in 2007. In Uganda, a country plagued with public health crises, the original

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<sup>1</sup> WORLD HEALTH ORGANIZATION, *WHO MEDICINES STRATEGY: 2004-2007* (hereinafter WHO Medicine Strategy 2004-2007), available at [http://whqlibdoc.who.int/hq/2004/WHO\\_EDM\\_2004.5.pdf](http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.5.pdf).

<sup>2</sup> *Id.*, at 2-3.

<sup>3</sup> WHO, Fact sheets: The 3 by 5 Initiative, December 2003, available at <http://www.who.int/mediacentre/factsheets/2003/fs274/en> (last visited Dec. 2, 2008)

<sup>4</sup> WHO, Regional Committee for the Eastern Mediterranean, Technical discussion on Medicine prices and access to medicines in the Eastern Mediterranean Region, Forty- Fourth Session, Agenda item 5 (a), at page 4, <http://www.emro.who.int/edb/media/pdf/EMRC54TECHDISC01en.pdf> (last visited December 2, 2008).

brand of Atenolol<sup>5</sup> is about 13 times the price of the generic.<sup>6</sup> Even in the US, the average price of a brand name prescription drug was \$96.01, compared to \$28.74 for the generic version.<sup>7</sup> The facts also show, even in developed countries, that expense on public health 100 times more than developing countries, still considerable numbers of persons cannot afford their needs.<sup>8</sup> In the US alone, it was reported in 2005 over 14 million patient with chronic diseases cannot afford their prescription drugs.<sup>9</sup>

High price of brand name drugs drives customers to seek cheaper generic medicines in the US. This shows that opening up the access to generic medicines is not only an issue in developing countries rather it is a global issue.<sup>10</sup> No doubt TRIPS exacerbates this problem, because of its impacts on the import, export, and manufacturing of generic medicines in the territories of the WHO members.<sup>11</sup> Naturally, this crisis flamed the debates concerning the compatibility of the protection of pharmaceuticals and the right to access medicine. To be more specific, it is true that TRIPS as it stands today incorporates certain measures pertinent to public health, exceptions and flexibilities for

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<sup>5</sup> Atenolol is a medicine used to treat cardiovascular diseases and conditions such as hypertension, coronary heart disease, arrhythmias, angina and to reduce the risk of heart complications following myocardial infarction (heart attack). <http://en.wikipedia.org/wiki/Atenolol>. (last visited Dec. 2, 2008).

<sup>6</sup> WHO, Measuring Medicine Prices, Availability, Affordability and Price Components, 2008, page 4. [http://www.who.int/medicines/areas/access/OMS\\_Medicine\\_prices.pdf](http://www.who.int/medicines/areas/access/OMS_Medicine_prices.pdf) (last visited Dec. 2, 2008).

<sup>7</sup> Michelle Meadows, Saving Money on Prescription Drugs, FDA Consumer magazine September-October 2005 Issue, [http://www.fda.gov/fdac/features/2005/505\\_save.html](http://www.fda.gov/fdac/features/2005/505_save.html). (last visited December 2, 2008).

<sup>8</sup> WHO medicines strategy 2004–2007, *supra* note 1.

<sup>9</sup> Marie C. Reed, An Update on Americans' Access to Prescription Drugs Issue Brief No. 95, May 2005, <http://www.hschange.org/CONTENT/738/> (last visited Dec. 2, 2008).

<sup>10</sup> WHO medicines strategy 2004–2007, *supra* note 1, at 2.

<sup>11</sup> Chaudhuri, Sudip, The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries 75-89 (2005).

implementation of intellectual properties, yet, ambiguities of provisions made these measures inoperative in practice.<sup>12</sup> Consequently, developing countries that are most often affected by public health crises, when they issued compulsory licenses to increase access to medicines under the public health exception-which is legal under TRIPS, these states were taken to courts by other members.

After feeling the heat, arising from the debate concerning medicine, and also recognizing the need to make TRIPS flexibilities worthwhile, the WTO members come up with the Doha Declarations. The Doha Declarations addressed, at least in papers, the issue of developing and least developing countries with respect to access to medicines.<sup>13</sup> It assumed these countries that TRIPS would not interfere with access to medicines. Meanwhile, since Doha Declaration was seen as only an inspiration, the need for practical step was urgent. To do this, it came the 2003 Cancun meeting.<sup>14</sup> One of major outcomes of the Cancun meeting was the creation of new compulsory license scheme. With this new compulsory license scheme, people living in the less fortunate countries supposed to be capable to afford medicines. In 2005, WTO members approved the 2003 Decision regarding paragraph 6 to be an amendment to TRIPS and inserted a new provision, Article 31bis.<sup>15</sup> The 2005 Amendment has significant impacts on access to

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<sup>12</sup> Jessica J. Fayerman, *The Spirit of TRIPS and The Importation of Medicines Made Under Compulsory License After the August 2003 TRIPS Council Agreement*, 25 *Nw. J. Int'l L. & Bus.* 257, 261 (2004).

<sup>13</sup> WTO, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter *Doha Declaration*].

<sup>14</sup> General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003), 43 I.L.M. 509 (2004) [hereinafter *2003 Decision*].

<sup>15</sup> General Council, *Amendment of the TRIPS Agreement*, WT/L/641 (Dec. 8, 2005) [hereinafter *2005 Amendment*], available at [http://www.wto.org/english/tratop\\_e/trips\\_e/wtl641\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm). (last visited Dec. 2, 2008).

medicines, in some aspects. First, the Amendment clearly represented the interests of developing countries;<sup>16</sup> in that it temporally suspended the protection of patent for pharmaceuticals under certain conditions. Second, the Amendment represented the first comprehensive attempt to reform the compulsory license scheme for developing countries that lack manufacturing capacity in international level. Yet, for the Doha Declaration, this scheme is not good enough to attain the goal of access to medicines.<sup>17</sup> One of their concerns was that this scheme leaves out another barrier for access to medicines, that is, the protection of pharmaceutical data.<sup>18</sup>

As discussed above, the pharmaceutical companies cannot market a new drug without the permission of the local health authority. To gain the permission, the company should conduct the costly and time-consuming experiments.<sup>19</sup> In order to promote the developing of the new drugs, Article 39.3 of the TRIPS requires that governments provide the protection to the pharmaceutical data that are submitted to the health authorities in that country. In the post-TRIPS era, the US related regional and bilateral FTAS adopted stricter protection measures than TRIPS and this made it impossible to market the generic

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<sup>16</sup> Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 343 (2005).

<sup>17</sup> Amir H. Khoury, *The Public Health of the Conventional International Patent Regime and the Ethics of "Ethicals": Access to Patented Medicines*, 26 *Cardozo Arts & Ent L. J.* 25,37-38, 2008. See also, Brittany Whobrey, *International Patent Law and Public Health: Analyzing TRIPS' Effect on Access to Pharmaceuticals in Developing Countries*, 45 *Brandeis L.J.* 623, 630 (2007).

<sup>18</sup> Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 *IND. INT'L & COMP. L. REV.* 613, 633-72 (2004).

<sup>19</sup> See T Lynn Riggs, *Research and development costs for drugs*, *The Lancet*, January 17, 2004, available at <http://www.cptech.org/ip/health/rnd/riggs01172004.html> (last visited Dec 2, 2008)

medicines even when the compulsory license is issued.<sup>20</sup> It is no question that these restrictions hamper the right to medicines.

Unlike patent under TRIPS, there are no exceptions and compulsory license schemes in the protection of pharmaceutical data. Likewise, there are no such exceptions in the regional and most of the bilateral agreements. Lack of clear exceptions for data exclusivity in TRIPS is likely to negate the ability of states to issue compulsory license and impede the access to medicines. Professor Baker<sup>21</sup> predicted this shortcoming and indicated the international community's need for establishing exceptions for data protections.

In the previous chapter we discussed the necessity of protection of pharmaceutical data. We pointed out that this protection is established through international, regional and domestic law. This chapter discusses when states can legally suspend their obligations under the international law, or what is called "public health" related exception. Under this exception, the state could legally implement the measures to alleviate the emergency if that particular state is encountered with a national emergency of public health crisis. In addition, in what circumstances the protection of pharmaceutical test data could be set aside to ensure access to medicines.

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<sup>20</sup> Baker, *supra* note 18.

<sup>21</sup> *Id.*

### 3.2 The Possible Limitations and Waiver of Protection of Pharmaceutical Data under the TRIPS Regime

Patent and data protection are two major instruments to protect pharmaceutical products under TRIPS. Patent provides the right to exclude third parties from making, using, selling, offering for sale, or importing the patented invention for the term of the patent,<sup>22</sup> while the data protection protects commercial efforts against unfair commercial use.<sup>23</sup> The submission of pharmaceutical data is a requirement to obtain marketing approval from national health authorities, and this requirement ensures the safety of new drugs.<sup>24</sup> The protection of data provides investors incentives to develop new drugs, even when the patent of a chemical has expired or the chemicals are not patentable.<sup>25</sup> However, either conferring patent right or data protection to some degree would delay the entry of generic version of the respective brand drugs. This delay, though inevitable will impede the access to affordable medicines, in particular in developing countries.

The concern that access to medicines would be impeded by the implementation of intellectual property laws in the developing countries has been important issue among

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<sup>22</sup> Article 28.1 of the TRIPS Agreement reads:

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 (6) 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.

<sup>23</sup> The elements of Article of 39.3 are discussed in chapter 2.

<sup>24</sup> Carlos M. Correa, *Unfair Competition Under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 *Chi. J. Int'l L.* 69, 71 (2002)

<sup>25</sup> Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 *Am. J. L. and Med.* 303, 304-305 (2008).

WTO members. As TRIPS by itself reveals,<sup>26</sup> its aim is not only to provide the minimum standard<sup>27</sup> to implement the intellectual property right, but also attempts to make a balance with other social policies.<sup>28</sup> The right to medicine as one fundamental human right should be taken into account when WTO members implement intellectual property.<sup>29</sup>

To balance other social interest, TRIPS establishes exceptions to exclude patent under Article 7, 8 and 30 and 31. Yet, this seemingly well-designed framework cannot guarantee the right to access medicine even though states are under health crises. The framework to exclude data protection is even less complete than patent.<sup>30</sup> This will no

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<sup>26</sup> The WTO Members have adopted the following instruments on TRIPS and public health: first, Paragraph 17 of the main Doha Declaration, adopted on 14 November 2001 by the Fourth WTO Ministerial Conference, Doha, Qatar; second, Declaration on the TRIPS Agreement and Public Health, adopted on 14 November 2001 by the Fourth WTO Ministerial Conference, Doha, Qatar; third, Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the General Council on 30 August 2003; and Decision on the Amendment of the TRIPS Agreement, adopted by the General Council, 6 December 2005; avail at [http://www.wto.org/english/tratop\\_e/trips\\_e/pharmpatent\\_e.htm#declaration](http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm#declaration) (last visited Dec 2, 2008).

<sup>27</sup> Article 1.1 of the TRIPS Agreement reads:

Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

<sup>28</sup> Article 7 of the TRIPS Agreement reads:

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.

<sup>29</sup> Carvalho, Nuno Pires de., *The TRIPS Regime of Patent Rights* 121 (Kluwer Law International ed., 2002).

<sup>30</sup> Baker, *supra* note 25, at 315-316.

doubt delays the entry of generic drugs and keep the essential medicine at unaffordable price.

The default exceptions to suspend the protection of test data are established under Article 39.3, which requires two grounds to exclude the protection of pharmaceutical data, under each of which, the protection of pharmaceutical could be set aside. The first ground, the suspension must be "necessary to protect public"; the second, uses must be fair and non-commercial. Perhaps, a general exception that permits states to take measures to protect public health; this could be considered the third exception.<sup>31</sup> The TRIPS regime of compulsory license could provide the fourth ground to exclude the protection of pharmaceutical test data.

Opinions are split as to how these four exceptions are applied to resolve the issue of access of medicines. Human Right advocates support that those exceptions should be used broadly for cases of emergency or public health,<sup>32</sup> while international pharmaceutical companies and the developed countries argue that those exceptions should be applied strictly and limited to certain situations.<sup>33</sup> These disagreements, indeed, are the result of the broader question of how to harmonize the right to health with TRIPS.

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<sup>31</sup> See infra text 3.2.2 State Right to Public Health in TRIPS.

<sup>32</sup> The case of Brazil presents how difficult a state to use public health ground to suspend the states responsibilities. .

<sup>33</sup> See Special 301 Public Submission 2008 by Pharmaceutical Research and Manufactures of American, [http://www.ustr.gov/assets/Trade\\_Sectors/Intellectual\\_Property/Special\\_301\\_Public\\_Submissions\\_2008/as\\_set\\_upload\\_file109\\_14495.pdf](http://www.ustr.gov/assets/Trade_Sectors/Intellectual_Property/Special_301_Public_Submissions_2008/as_set_upload_file109_14495.pdf)

Since TRIPS was adopted, pertinent provisions, later amendment, as well as decisions concerning the public health have been made. Still, in the global level, WTO members encounter the difficulties in implementing effective measures to access medicines. One reason is resulting from the ambiguities of the TRIPS text. Another reason comes from the rigid application of the exceptions. This rigidity, indeed, makes it difficult to apply the public health exceptions.

### 3.2.1 The Limitations of Article 39

Until today, no jurisprudence or decision of a competent WTO body, or international tribunal concerning the application of article 39.3 is elaborated.<sup>34</sup> Yet this should not be a problem because TRIPS, as an international treaty, its provisions should be interpreted in accordance with the customary rules of interpretation of public international law and their codified versions in Articles 31<sup>35</sup> and 32<sup>36</sup> of the Vienna Convention on the Law of

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<sup>34</sup> WTO, *WTO ANALYTICAL INDEX*: TRIPS, art. 39.3, also available at [http://www.wto.org/english/res\\_e/booksp\\_e/analytic\\_index\\_e/trips\\_03\\_e.htm#article39](http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_03_e.htm#article39) (last visited Dec 2, 2008)

<sup>35</sup> Article 31 of the Vienna Convention on the Law of Treaties concluded at Vienna on May 23, 1969 (UN Doc A/Conf/39/28) (hereinafter designed as "Vienna Convention") reads:

1. 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 context and in the light of its object and purpose.
2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:
  - (a) any agreement relating to the treaty which was made between all the parties in connexion with the conclusion of the treaty;
  - (b) any instrument which was made by one or more parties in connexion with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.
3. There shall be taken into account, together with the context:
  - (a) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
  - (b) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;
  - (c) any relevant rules of international law applicable in the relations between the parties.
4. A special meaning shall be given to a term if it is established that the parties so intended.

<sup>36</sup> Article 32 of the Vienna Convention (Supplementary Means of Interpretation) reads:

Treaties.<sup>37</sup> The sub-paragraph 5(a) of 2001 Doha Declaration on TRIPS and Public Health reiterates the principles of interpreting an international treaty. It states:

“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.”<sup>38</sup>

In accordance with this interpretative guidance, when reading Article 39.3 of the TRIPS, those interpretations should take into account the objectives and principles set forth in Article 7 and 8 of the TRIPS.<sup>39</sup> That is to say, the implementation of data exclusivity should be reconciled with other social interests. This indeed includes the right to medicines. Moreover, a group paper submitted to Doha meeting by the developing countries in 2001 supported such interpretative approach. In this paper, the developing countries pointed out that “the protection of intellectual property rights, in particular patent protection, should encourage the development of new medicines and the

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Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion, in order to confirm the meaning resulting from the application of article 31, or to determine the meaning when the interpretation according to article 31:

- (a) leaves the meaning ambiguous or obscure; or
- (b) leads to a result which is manifestly absurd or unreasonable

<sup>37</sup> See Georges Abi-Saab, *The Appellate Body and Treaty Interpretation* in Giorgio Sacerdoti, Alan Yanovich and Jan Bohanes (eds.), *The WTO at Ten: The Contribution of the Dispute Settlement System* (Cambridge University Press, 2006).

<sup>38</sup> The Doha Declaration, paragraph 5 (a).

<sup>39</sup> Paper submitted by a group of developing countries to the TRIPS Council, for the special discussion on intellectual property and access to medicines (hereinafter Group Paper), 20 June 2001 pointed out “Each provision of the TRIPS Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8. The protection of intellectual property rights, in particular patent protection, should encourage the development of new medicines and the international transfer of technology to promote the development of manufacturing capacities of pharmaceuticals, without restraining policies on access to medications.” IP/C/W/296 (hereinafter group paper IP/C/W/296), advance copy received 19 June 2001, available at [http://www.wto.org/english/tratop\\_e/TRIPS\\_e/paper\\_develop\\_w296\\_e.htm](http://www.wto.org/english/tratop_e/TRIPS_e/paper_develop_w296_e.htm) ( Last visited on Dec 2, 2008)

international transfer of technology to promote the development of manufacturing capacities of pharmaceuticals, without restraining policies on access to medications.”<sup>40</sup>

This viewpoint, eventually was accepted by the paragraph 4 of 2001 Doha Declaration,<sup>41</sup> states:

“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 members' right to protect public health and, in particular, to promote access to medicines for all.”<sup>42</sup>

Applying the logic of paragraph 4 to resolve the ambiguity of TRIPS text, the case of data protection, when looked through Article 39.3 provides two express exceptions in pharmaceutical test data protection.<sup>43</sup> To reach the goal to increase access to medicines; these two exceptions should be read in light of the objectives and principles set forth in Articles 7 and 8.

### 3.2.1.1 Fair Use

The data protection under Article 39.3 confers a right against “unfairly commercial use” on data holder.<sup>44</sup> This means that non-commercial fair use (fair use) is not restricted.<sup>45</sup> A

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<sup>40</sup> Group Paper IP/C/W/296, *supra* note 39, at summary paragraph 4.

<sup>41</sup> Susan K. Sell, TRIPS and the Access to Medicines Campaign, 20 Wis. Int'l L.J. 481, 516-517 (2002).

<sup>42</sup> The 2001 Doha Declaration, paragraph 4.

<sup>43</sup> Carvalho, *supra* note 29, at 315-316.

<sup>44</sup> Carcalho, *supra* note 29, at 272.

<sup>45</sup> With respect to concept of “fairly” “non-commercial use”, it is noted that non-commercial use is fair use. However, some non-commercial use is not necessary to be a fair use. For example, a misappropriate use for non-commercial reason, an act of breaching confidence; cannot be deemed to be a fair use. Moreover, both voluntary and non-voluntary licensees are commercial users, but their uses are fair. Therefore, the use is

use is either a fair use or unfair commercial use subject to the interpretation of Article 10*bis* of the Paris Convention.<sup>46</sup> One scholar pointed out any act without breaching of confidence would not be deemed “unfair.”<sup>47</sup> He exemplified three types of fair uses: (1) an act of state; (2) a voluntary license; and (3) a non-voluntary license.

In the case of an act of state, a government may contract an institution to verify the accuracy and qualities of test data or assign this task to a third party.<sup>48</sup> This act is of a non-commercial nature and as such it is a fair use.

A voluntary license is the second type of fair use. This kind of case can occur when the repetition of test data is inhumane. In such case, the animal and humans would bear suffering during the trials; thus, originators and the subsequent generic manufacturers should enter into the voluntary license to authorize the use.<sup>49</sup> A noted scholar proposed two measures to deal with this situation.<sup>50</sup> He recommended that states should ask the holders of test data to enter into a voluntary agreement with the subsequent applicants or grant a compulsory license to the subsequent applicants with reasonable compensation. Both of these two measures are fair use.

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permitted if acts are deemed to be fair. The eligible fair uses are permitted regardless of commercial or non-commercial.

<sup>46</sup> See *supra* text 2.2.

<sup>47</sup> Carvalho, *supra* note 29, at 272-273.

<sup>48</sup> *Id.*

<sup>49</sup> Carvalho, *supra* note 29, at 272-273. Although Carvalho pointed out this is a case of the voluntary license, but it is, indeed, likely to be another example of non-voluntary license, because state will not give holders of pharmaceutical data a chance to say “no” in this situation.

<sup>50</sup> *Id.*

The third example is the compulsory licensing of the patent to a third party; this is also known as non-voluntary licensing. In such a case, the reliance on the previous data to approve that product by the licensee is deemed to be a fair use. Since the third kind of fair use relied on the granting of compulsory license, it would raise two same issues arising from the issuance of compulsory license.<sup>51</sup> One issue is under what circumstances states may grant compulsory licenses to use such data. Another issue is as to whether bilateral agreements would restrict the use of data even when compulsory license has been issued.

### 3.2.1.2 The Situation Is Necessary to Protect Public

In accordance with an exception set forth in Article 39.3, a state government may suspend their responsibility, if the situations that called for such suspension are necessary to protect the public.<sup>52</sup> This exception involves the interpretations of two terms: “necessary” and “protect public.”

With respect to the term “necessary” under Article 39.3, it would make the application of this exception subject to a “necessity test.”<sup>53</sup> The necessary test is “a tool that reflects the balance between each country's prerogative to regulate in its own jurisdiction and the

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<sup>51</sup> See infra text 3.2.2.

<sup>52</sup> The TRIPS, art. 39.3.

<sup>53</sup> Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement* 21, 2002, South Centre, also available at <http://www.who.int/medicinedocs/en/d/Jh3009ae/#Jh3009ae> (Last visited on Dec 12, 2008).

multilateral interest in progressive liberalization of services trade.”<sup>54</sup> Indeed as the WTO Secretariat pointed out:

“These tests reflect the balance in WTO agreements between two important goals: preserving the freedom of Members to set and achieve regulatory objectives through measures of their own choosing, and discouraging Members from adopting or maintaining measures that unduly restrict trade. Necessity tests typically achieve this balance by requiring that measures, which restrict trade in some way (including by violating obligations of an agreement) are permissible only if they are "necessary" to achieve the Member's policy objective.”<sup>55</sup>

The necessary test only applies when some elements are satisfied. The essential elements of the necessity tests which are used in numerous WTO Agreement include the less/least trade-restrictiveness, balancing, means--ends test, and comparison between alternatives and reasonable availability.<sup>56</sup> The necessary test on the specific context of the measures in issue should be assessed in different manner from in the WTO agreements.<sup>57</sup> Thus, the elements of the necessities are Agreement-specific.<sup>58</sup> This further means, the elements of the necessity test were specified in the agreement, and as such when a state uses this test, it must follow the agreement text.

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<sup>54</sup> Panagiotis Delimatsis, Determining the Necessity of Domestic Regulations in Services :The Best Is Yet to Come, 19 Eur. J. Int'l L. 365, 401.

<sup>55</sup> WTO Secretariat, Necessity Tests in the WTO', Working Party on Domestic Regulation, S/WPDR/W/27, Dec. 2, 2003, p. 1.

<sup>56</sup> A measure is 'necessary' or it is less trade-restrictive refers to no reasonably available alternative measure could attain the same level of protection as the contested measure, or could fulfil a legitimate objective equally satisfactorily with the contested measure. The balancing test will determine whether the necessary could be applied. This test would examine that whether two of the three conditions can be satisfied. First, the suitability requirement would examine whether the measure is suitable to attain the Member's desired objective or the level of protection (causal relationship). Second, it would examine whether the measure is necessary for the achievement of a given objective. See also Delimatsis, *supra* note 54.

<sup>57</sup> Carvalho, *supra* note 29, at 119-120.

<sup>58</sup> *Id.*

In addition, if governments take measures to protect the public or to suspend responsibilities under Article 39.3, those measures are required to comply with four elements under Article 8.1:<sup>59</sup>

- (1) the measures should be law or regulations;
- (2) the measure should be necessary to protect public health;
- (3) the promotional measures should be vitally important in benefiting the sectors;  
and
- (4) all measure adopted should be consistent with the provisions of the TRIPS.

Applying these elements in Article 39.3, measures governments take to exclude the test data protection should consider several points. First, states should have law or regulations to exclude the pharmaceutical protection. Second, the measure cannot violate the TRIPS. Third, the measure to exclude pharmaceutical test is “necessary” to “protect public.” With respect to the term “protect public,” Correa indicated that “public interest” should include the promotion of competition and “no impendence of timely entrance of generic” competitors to off-patent drugs and promoting greater accessibility of medicines.<sup>60</sup> In this regard, the measures to increase access to medicines are deemed to protect public.

However, measures necessary to expand the accesses to medicines should comply with goals and requirements under Article 7 and 8 of the TRIPS. Article 7 demonstrates the objectives of TRIPS would not simply protect the holders of intellectual property, but

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<sup>59</sup> Article 8.1 of the TRIPS reads

Members may, in formulating or amending their laws and regulations, adopt measures necessary to 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. See also Carvalho, *supra* note 29, at 119.

<sup>60</sup> Correa, *supra* note 53, at Exclusive summary.

also seek a balance of users' interests.<sup>61</sup> Thus, the enforcement of intellectual property should balance other social interests. Article 8 allows states to take measures to protect the public, but those measures should be "necessary."<sup>62</sup> These articles seemingly, provide enough room for states to take measures to protect public health and set the enforcement of intellectual property aside temporarily, if there is a national emergency or public health crisis within the territory. Yet, cases in the late 1990 did not show such inspiring outcomes.

In 1997, the South African government amended the South African Medicines and Medical Devices Regulatory Authority Act (Medicine Act). This amendment allowed the government to issue a compulsory license to manufacture cheaper generic HIV/AIDS drugs or import generic medicine from third countries.<sup>63</sup> The South African was immediately subject to lawsuits by multinational pharmaceutical companies because of this amendment.<sup>64</sup>

In 1999, the Brazilian President issued a decree that allowed the government to grant a compulsory license for non-commercial use, national emergency, or public interest.<sup>65</sup>

The Brazilian government used the threats of issuing a compulsory license for the

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<sup>61</sup> Hestermeyer, Holger. Human Rights and the WTO: The Case of Patents and Access to Medicines. *International economic law series* 51 (2008).

<sup>62</sup> The TRIPS, art 8.1.

<sup>63</sup> Sell, *supra* note 41, at 501-502.

<sup>64</sup> Kara M. Bombach, Can South Africa Fight AIDS? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement, 19 *B.U. Int'l L.J.* 273. (2001).

<sup>65</sup> Brazil: Presidential Decree on Compulsory Licenses, available at <http://www.cptech.org/ip/health/c/brazil/PresDecree.html> (last visited on Jan 8, 2009)

manufacture of the antiretroviral drugs to negotiate drug prices.<sup>66</sup> The international pharmaceutical companies and the USTRs were enraged by such actions and brought a WTO case against Brazil.<sup>67</sup>

In these two different circumstances involving South Africa and Brazil, the threats of issuance of compulsory licenses by these two countries or allowance of parallel importing under the compulsory license to combat national HIV/AIDS crisis, jeopardized the trade relations between them and the developed countries.<sup>68</sup> Although the lawsuit against South Africa and the WTO case against Brazil were finally withdrawn,<sup>69</sup> the series of events dramatized the economic pressures from the developed countries<sup>70</sup> and the possible legal challenging when they take some measures on the ground or reason of public health, or access to medicines. These two unsuccessful cases, in fact have weakened the argument that TRIPS provides states with flexible way to provide access to medicines.

In *Canada - Pharmaceutical Patents*,<sup>71</sup> the EC complained that Canada's two pharmaceutical provisions violate its obligations under the TRIPS Agreement. These provisions in questions provide two exceptions to exclude patent: (1) regulatory review

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<sup>66</sup> August 22, 2001. Statement by Jose Serra, Minister of Health, available at <http://www.cptech.org/ip/health/c/brazil/nelf08222001.html> (last visited on Jan. 8, 2009)

<sup>67</sup> Chaudhuri, Sudip, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* 101 (2005).

<sup>68</sup> See *id* and also Sell, *supra* note 41, at 501-502.

<sup>69</sup> The Bureau of National Affairs, Inc., *United States Drops WTO Case against Brazil Over HIV/AIDS Patent Law* (June 26, 2001), also available at <http://www.cptech.org/ip/health/c/brazil/bna06262001.html>, (last visited on Jan. 8, 2009).

<sup>70</sup> Sell, *supra* note 41, at 500-501.

<sup>71</sup> *Canada--Patent Protection of Pharmaceutical Products*, WT/DS114/R, 17 March 2000.

exception;<sup>72</sup> (2) the stockpiling exception.<sup>73</sup> The essential issue in this case is whether these two exceptions satisfy the requirements under Article 30 of TRIPS, which is "limited exceptions to the exclusive rights conferred by a patent."<sup>74</sup>

The EC complained that both two exceptions violated Article 28 of the TRIPS. The Canadian government argued that both two exceptions could be considered to be "limited exceptions" under Article 30. The panel agreed that the regulatory review exception satisfies the elements of Article 30 but the stockpiling exception did not. The Panel further explained that a qualified exception should satisfy three criteria under Article 30:

- (1) the exception must be limited;
- (2) the exception must not 'unreasonably conflict with normal exploitation of the patent;
- (3) the exception must not unreasonably prejudice the legitimate interests of the patent owner.<sup>75</sup>

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<sup>72</sup> The regulatory review exception allows potential competitors of a patent owner to use the patented invention during the term of the patent in order to obtain government marketing approval. It only provides for uses reasonably related to the development and submission of information required under any law that regulates the manufacture, construction, use or sale of a product (subsection 55.2(1) of the Patent Act). The stockpiling allowed competitors to manufacture and stockpile patented goods during a certain period before the patent expires, also available at <http://www.international.gc.ca/trade-agreements-accords-commerciaux/disp-diff/summary.aspx?lang=en#WTO> (last visited on Jan 8, 2009).

<sup>73</sup> The stockpiling allowed competitors to manufacture and stockpile patented goods during a certain period before the patent expires. This exception provides during a limited, prescribed period immediately preceding the expiry of the patent, for the manufacture and storage of articles intended for sale after the patent expires (subsection 55.2(2) of the Patent Act), also available at <http://www.international.gc.ca/trade-agreements-accords-commerciaux/disp-diff/summary.aspx?lang=en#WTO> (last visited on Jan 8, 2009).

<sup>74</sup> Article 30 of the TRIPS (Exceptions to Rights Conferred) reads :

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

<sup>75</sup> Panel Report on Canada - Pharmaceutical Patents, paras. 7.20-7.21.

Prior to this case, a general opinion as to Article 30 is that this provision provides for very broad exceptions to the patent requirements.<sup>76</sup> Thus, developing countries believed that they could use this general exception to grant the compulsory licenses to import the generic medicines without limitation of Article 31 (f).<sup>77</sup> Instead of this broad approach, the Panel took a narrow approach to interpret Article 30.<sup>78</sup> This restrictive approach limited the possibilities that Article 30 could be as an alternate mechanism for compulsory licensing.

The general view point is that if all states recognized the flexibilities in Article 7, 8, 30 and 31 of the TRIPS, those flexibilities provide enough grounds for states to grant a compulsory license in order to manufacture, or import the anti-retro virus medicine for people in need of AIDS treatment. Yet, some scholars and developed countries, such as EU and US do not support this viewpoint.<sup>79</sup> Indeed the difficulties in implementing the TRIPS flexibilities to increase the access to medicines can be attributed to several legal reasons. First, TRIPS lacks express languages concerning the overall public health issue.<sup>80</sup> Second, there is no operative standard to trigger the exception regarding the

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<sup>76</sup> 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, 1081 (1996); Amit Gupta, Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?, 2 Buff. Intell. Prop. L.J. 127, 141 (2004)

<sup>77</sup> Thomas A. Haag, TRIPS Since Doha: How Far Will the WTO Go Toward Modifying the Terms for Compulsory Licensing?, 84 J. Pat. & Trademark Off. Soc'y 945 at 950 (2002).

<sup>78</sup> Frederick M Abbott & Jerome H. Reichman, The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions, 10 J. Int'l Econ. L. 921, 986 (2008)

<sup>79</sup> Canada--Patent Protection of Pharmaceutical Products, WT/DS114/R, 17 March 2000.

<sup>80</sup> Sisule F. Musungu et al, *Utilizing TRIPS Flexibilities for Public Health Protection through South-South Regional Frameworks 2* ( South Center ed., 2004), also available at <http://www.who.int/medicinedocs/en/d/Js4968e/#Js4968e> (last visited on Jan 8, 2009)

public health crisis.<sup>81</sup> Third, many states lack, either entirely or partially, the appropriate legal framework to enforce such kind of exceptions.<sup>82</sup> The fourth reason, also the most important one, is that there are disagreements regarding the legal status of the right to health, or the right to medicines in TRIPS.<sup>83</sup>

Nevertheless, the deepening HIV/AIDS crisis and insufficient access to medicines in most of developing countries turned WTO members' attitude more positive to engage the public health related issue in TRIPS.<sup>84</sup> In 2001, WTO Council addressed the issues concerning intellectual properties and access to medicine in Doha meeting. They made a compulsory license related decision in 2003<sup>85</sup> and finally amended the TRIPS in 2005.<sup>86</sup> These three official texts basically attempted to clarify the relationship between intellectual properties and public health. They also clarify the ambiguities of the states' right to protect public health, and the limitations of this right.

### 3.2.2. State's Right to Protect Public Health in TRIPS

In previous section, the cases discussed proved that the grounds for the exception "protecting public health" under the TRIPS are more complicated than the developing

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<sup>81</sup> Bradly Condon & Tapen Sinha, Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries, 26 Nw. J. INTL L. & BUS. 1, 31-40 (2005).

<sup>82</sup> Musungu et al, *supra* note 80, at 24.

<sup>83</sup> Tina S. Bhatt, NOTE: Amending TRIPS: A New Hope for Increased Access to Essential Medicines, 33 Brooklyn J. Int'l L. 597, 611-615 (2008)

<sup>84</sup> Hestermeyer, *supra* note 63, at 255.

<sup>85</sup> The 2003 Decision, *supra* note 14.

<sup>86</sup> The 2005 Amendment, *supra* note 15.

countries have expected. This section discusses how developing countries addressed these difficulties in WTO Ministerial Conference and attempted to establish public health related exceptions under TRIPS regime in the Doha meeting.

### 3.2.2.1 The Emergence of the Declaration

The developing countries belief that the TRIPS provides sufficient flexibilities for them to take measures, in particular the issuing of compulsory licenses. This belief was attacked after the 1997 South African case<sup>87</sup> and the 1999 Brazilian Case.<sup>88</sup> These two cases illustrated the risks of lawsuits from multinational pharmaceutical companies and the developed countries, when developing countries avail themselves of issuing compulsory licenses. Consequently, developing countries, assertively and actively, sought official confirmation to avoid dispute settlement procedures when states take measures to protect public health.<sup>89</sup>

The anthrax<sup>90</sup> case in US magnifies the significance of issue of compulsory license. In October 2001, the US found itself facing an emergency when some postal and media workers exposed to anthrax spores in tainted mails.<sup>91</sup> Five people died and seventeen people were infected due to this attack. This event raised the fear of bio-terrorism<sup>92</sup> in US

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<sup>87</sup> See *supra* text in page 16-17.

<sup>88</sup> *Id.*

<sup>89</sup> Bhatt, *supra* note 83, at 614.

<sup>90</sup> Wikipedia, *Anthrax*, available at <http://en.wikipedia.org/wiki/Anthrax> (last visited on Jan. 8, 2009).

<sup>91</sup> The 2001 anthrax attacks in the United States occurred beginning on September 18, 2001, [http://en.wikipedia.org/wiki/2001\\_anthrax\\_attacks](http://en.wikipedia.org/wiki/2001_anthrax_attacks) (last visited on Jan. 8, 2009).

<sup>92</sup> US Center of Disease Control defines that "a bioterrorism attack is the deliberate release of viruses, bacteria, or other germs (agents) used to cause illness or death in people, animals, or plants. These agents

and Canada.<sup>93</sup> Immediately, the availability of Ciprofloxacin, the chemical that is used to treat anthrax infections, became at issue.<sup>94</sup> Without this medicine, if an attack occurred such an attack constitutes a threat to national security not just in the US but likely in the whole North American Continent.

As a response to this dire circumstance, the US threatened Bayer, the manufacturer of the Cipro, that it would issue compulsory licenses to domestic manufacturers if Bayer would not lower the price of the Cipro.<sup>95</sup> Eventually, the US did not grant compulsory licenses, but this threat had the price of Cipro been cut through negotiation.<sup>96</sup> This event proves that, even a country with enormous powers and resources, such as the US, could still encounter serious obstacles when issues of public health and national security are at stake. This incident is also significant from the perspective that issues of public health and national security are not just domestic problems, they have their global dimension.

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are typically found in nature, but it is possible that they could be changed to increase their ability to cause disease, make them resistant to current medicines, or to increase their ability to be spread into the environment.” <http://www.bt.cdc.gov/bioterrorism/overview.asp> (last visited on Jan. 8, 2009).

<sup>93</sup> Canada received numerous threats and around October 25th, 2001 at least 11 Jewish organizations in Toronto, Montreal, Ottawa and Windsor received letters purporting to contain anthrax-laced white powder. Police seized the letters and dispatched them for analysis. See Robert Shapiro, *Patent Infringement During a Time of National Emergency: Are Canadian, American and Mexican Governments Permitted to Do So under Their Domestic Law, NAFTA and TRIPS; If So at What Cost?* 18 Windsor Rev. Legal & Soc. Issues 37, 55-56 (2004).

<sup>94</sup> Sell, *supra* note 41, at 515-516.

<sup>95</sup> Ciprofloxacin is a broad-spectrum antibiotic against both Gram-positive and Gram-negative bacteria, available at [http://www.cipro.com/html/pdf/cipro\\_medguide.pdf](http://www.cipro.com/html/pdf/cipro_medguide.pdf) (last visited on Jan. 8, 2009)

<sup>96</sup> Jill Carroll and Ron Winslow, *Bayer to Slash by Nearly Half Price U.S. Pays for Anthrax Drug*, The Wall Street Journal on Oct. 25, 2001.

On November 14, 2001, the Doha WTO Ministerial Conference adopted the Declaration (2001 Declaration) of the TRIPS Agreement and Public Health.<sup>97</sup> The Declaration was initially proposed by a group of 80 countries, led by the African group, India and Brazil.<sup>98</sup> These developing countries attempted to affirm an interpretation of TRIPS that would shield them from any legal proceedings from other members when they take measure to increase access to medicines in their territories.<sup>99</sup> With aggressive diplomacy these countries succeeded in making the conference adopt their viewpoints. Eventually, when the Declaration came out, in 2001, the state right to protect public health was considered huge achievement.

### 3.2.2.2 The Right to Protect Public Health and the Declaration

The Declaration contains seven paragraphs.<sup>100</sup> Paragraph four and five affirm interpretations of flexibility of TRIPS; paragraph six requires an action when resolving

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<sup>97</sup> The Doha Declaration, *supra* note 14.

<sup>98</sup> Sell, *supra* note 41, 516.

<sup>99</sup> *Id.*

<sup>100</sup> The Doha Declaration reads:

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.
  2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.
  3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.
  4. 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 members' right to protect public health and, in particular, to promote access to medicines for all.
- In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

the issue of compulsory license; and paragraph seven provides the extension of transitional period for LDS in relation to the protection of pharmaceutical products. Indeed, the Declaration does not create any exception for the public health. Instead, it reaffirms states right to protect public health and recognizes that this right should not be derogated by the intellectual property. The contributions of the Declaration to access to medicines can be highlighted as follow:<sup>101</sup>

- (1) It declares that “the TRIPS Agreement does not and should not prevent members from taking measures to protect health.”
- (2) It affirms that the Agreement can and should be interpreted and implemented in

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5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:  
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.  
Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.  
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.  
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.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

<sup>101</sup> The Doha Declaration, paragraph 4, 5 and 6.

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

- (3) It reaffirms that WTO members have right to use, to the full, the provisions in the TRIPS Agreement, which provide flexibilities for this purpose.
- (4) It states that members have "the right to determine what constitute a national emergency or other circumstances of extreme urgency," when the states adopt other measures under article 8.
- (5) Finally, the sixth paragraph instructs the Council of TRIPS to find a solution for those members who lack manufacturing capacities so they can make effective use of compulsory licensing under the TRIPS.

Most human right scholars eulogize the achievements of the Declaration on the access to medicines.<sup>102</sup> They recognized that it is a kind of a victory for developing countries. Apparently, the Doha Declaration attempts to establish a general exception to exclude the protection of intellectual property, when states take measures to protect public health. This general exception would likely exclude legal barriers, including the patent and the protection of test data, if it could be worked out.

Despite the optimism of human rights advocates, many scholars argued that the impacts of Doha Declaration are limited, because they did not impose any substantive responsibilities within TRIPS and they are not binding texts.<sup>103</sup> For this reason, after the Doha declaration, the developing countries sought more effective ways to increase the

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<sup>102</sup> Bhatt, *supra* note 83.

<sup>103</sup> Abbott, *supra* note 16, 330.

access to medicines,<sup>104</sup> by reforming the existing compulsory licensing scheme under the TRIPS and pursuing amendment permanent to TRIPS.<sup>105</sup>

### 3.2.3 The Compulsory License Scheme

The compulsory license is a traditional measure that states take to expand access to medicines. Through such measure, a given government could grant a compulsory license that authorizes the use of patent and test data. In practice, there are several pharmaceutical compulsory licenses granted by WTO members. These cases raised the issue of harmonization between the right of health and intellectual property rights. Most of discussions in relation to compulsory licenses are focused on the patent area, but the same logic can be applied in the area of pharmaceutical test data protection. That is to say, if the circumstances allowing for the granting of a compulsory license, these same circumstances can allow the use of patent and test data at the same time; in essence treating both, test data and patents as one issue. Thus, the difficulties in implementing the compulsory license to exclude either protection of patent or data would be the same. One reason for this approach is that, there is no authoritative text dealing with test data compulsory licensing; therefore, the use of test data must be inferred from the use of patented drugs when it comes to the issue of compulsory licensing.

Article 27 of the TRIPS establishes a basic framework for patent right.<sup>106</sup> First, it states that the subject matters of patents can be products or processes. Second, the patent shall

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<sup>104</sup> *Id.*

<sup>105</sup> See *infra* text 3.2.3

<sup>106</sup> Article 27 of the TRIPS reads:

be available for any inventions in all fields of technology. It means that the availability of patent cannot be a discrimination ground on the field technology.<sup>107</sup> In other words, members could not exclude certain areas, which have been traditional subjects to discriminations, in particular the pharmaceutical and chemical field.<sup>108</sup> Third, it requires that the patentable inventions should be new, involving a creative step and capable of industrial application."<sup>109</sup> Fourth, it excludes some areas from patentability, such as therapeutic and surgical methods.<sup>110</sup>

Article 27 embodies the notion that the patent is not an absolute right under the TRIPS. The patent should be balanced with other social interests.<sup>111</sup> Thus, Article 30 and 31 of

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1. 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. (5) 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.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

<sup>107</sup> Carvalho, *supra* note 29, at 161.

<sup>108</sup> *Id*

<sup>109</sup> The terms "inventive step" and "capable of industrial application" may be referred to the terms "non-obvious" and "useful" respectively in some jurisdiction. See *id*.

<sup>110</sup> Article 27.3.

<sup>111</sup> The TRIPS, art. 7.

the TRIPS provides several grounds to exclude patent, such as research exception, Bolar exception, anti-competitive practice measures, and compulsory license scheme.<sup>112</sup> Among them, the most important measure to balance between the right of access to medicines and intellectual property is compulsory license system.<sup>113</sup>

### 3.2.3.1 Granting Compulsory License under Public Health Related Grounds

The compulsory license is the process by which a government authorizes a third party to perform acts that originally requires the authorization of the patentee but because of the public health reason the government need not obtain the patentees' consent. Article 31 does not use the term "compulsory license," because several jurisdictions do not use this term.<sup>114</sup> Instead, it is titled "other use without authorization of the right holder," to represent the same administrative actions.<sup>115</sup>

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<sup>112</sup> The research exception under Article 30 allows researchers to use a patented invention for research during the patent term. The regulatory review exception under Article 30, also known as Bolar exception, allows manufacturers of generic drugs to use the patented product to obtain marketing approval without the patent owner's permission and before the patent protection expires. Under 8 and 40, governments can take measures to prevent patent owners and other holders of intellectual property rights from abusing intellectual property rights, "unreasonably" restraining trade, or hampering the international transfer of technology. See [http://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm#exceptions](http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#exceptions) (last visited on Dec 2, 2008)

<sup>113</sup> Chaudhuri, *supra* note 81, at 83.

<sup>114</sup> Carvalho, *supra* note 29, at 230.

<sup>115</sup> Article 31 of the TRIPS reads:

Where the law of a Member allows for other use (7) 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 other circumstances of extreme urgency, the right

By nature, compulsory licenses are kind of administrative contracts, or a kind of administrative intervention. Such intervention would abrogate the rights of patent holders, because they deprive the right of patent holders to refuse to deal with third parties.<sup>116</sup> Thus, such license should be granted only in limited grounds. Otherwise, it

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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.

<sup>116</sup> Carvalho, *supra* note 29, at 230.

would harm the intellectual property system and impede the promotions of innovation. Further, authorization of such use shall be considered on its individual merits; thus states authorization can be justified on the grounds of social and collective interests.<sup>117</sup> Article 31 of the TRIPS was designed to achieve these ends.

Under Article 31, governments may grant compulsory license to authorize a third party to manufacture the generic medicines, but such authorization must satisfy several requirements:<sup>118</sup>

- (1) the use of the patented product must be predominately to serve the domestic market;
- (2) adequate remuneration based on the economic value of the license must be paid to the patent holders;
- (3) the negotiation process is required in cases of national emergency, extreme urgency, or non-commercial public use; and
- (4) use for the judicial remedy of anti-competitive practices is not required to comply the requirements of negotiation or predominately serving is the domestic the domestic market.

In practice, Article 31 provides a sound basis for compulsory licensing and waives the requirement of negotiation, which is time-consuming process when a public health crisis occurs. Thus, governments can use this measure to provide generic medicines through public health institutions or domestic healthcare scheme without time-consuming negotiation. In such cases, it is easy for governments to pass the requirements of Article 31, because the use of patent product is targeted in the domestic market and provided for

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<sup>117</sup> *Id.*

<sup>118</sup> Condon & Sinha, *supra* note 81, at 7-9.

non-commercial public.<sup>119</sup> Even the originators are willing to negotiate prices with governments, because they understand that governments are not required to do that.<sup>120</sup>

This allows states to determine reasonable prices for medicines.

Yet, in order to apply the exceptions under Article 31, the circumstance must reach the level of national emergency or extreme urgency. Yet, TRIPS lacks operative standards to determine what constitutes “national emergency” or “extreme urgency.”<sup>121</sup> It is not until 2001, when paragraph 5 (c) of the 2001 Declarations bridged this gap. It allows members to determine whether a case constitutes a national emergency or is a case of extreme urgency.<sup>122</sup> Further, it specifies four cases; HIV/ AIDS, tuberculosis, malaria and other epidemics, which are considered national emergencies or other circumstances of extreme urgency.<sup>123</sup> In other words, governments are exempted from proving a case of national emergency or extreme circumstance if they grant compulsory license on these four grounds.

### 3.2.3.2 The 2003 Decision and 2005 Amendment

In the TRIPS Council Meeting of June 2001, Brazil introduced its successful experience of distributing HIV/AIDS medicines at low cost.<sup>124</sup> It proved that taking measures, such

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<sup>119</sup> *Id.*, at 236

<sup>120</sup> Condon & Sinha, *supra* note 81, at 9.

<sup>121</sup> Jennifer Bjornberg, Brazil's Recent Threat on Abbott's Patent: Resolution or Retaliation?, 27 Nw. J. INT'L L. & Bus. 199, 207 (2006).

<sup>122</sup> The Doha Declaration, 5 (c).

<sup>123</sup> *Id.*

<sup>124</sup> See Sell, *supra* note 41, at 513 and also Tina Rosenberg, *Look at Brazil*, N. Y. TIMES, Jan. 28 2001, also available at

as threats of issuing compulsory license is effective way to reduce the price of medicines through negotiations with pharmaceutical companies. The successful AIDS program in Brazil inspired other developing countries to combat HIV/AIDS pandemic and convinced them to support a flexible compulsory license scheme under TRIPS regime.<sup>125</sup> It is noted that the issue presented in 2001 Doha meeting is not whether the compulsory license is permitted under the TRIPS regime but the implementation of the compulsory license.<sup>126</sup> The limitation imposed by Article 31 (f) of the TRIPS requires that a compulsory license predominantly supply the domestic market,<sup>127</sup> because it attempts to confine the geographical scope of each compulsory license within the territory the public interests it is aimed at attaining.<sup>128</sup> The reasoning to impose the limitation of Article 31 (f) on the compulsory license scheme is in compliance with the principle of independence of patents.<sup>129</sup> However, it ignores the unique feature of international pharmaceutical market. According to the 2000's WHO report, manufacturing capabilities of pharmaceuticals are only concentrated in few countries, such as the US, some EU States, Japan, Australia, and India. The rest of the world countries have no manufacturing capabilities.<sup>130</sup> Therefore,

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<http://query.nytimes.com/gst/fullpage.html?sec=health&res=9D05E5DB113CF93BA15752C0A9679C8B63>, (last visited on Jan. 8. 2009).

<sup>125</sup> Sell, *supra* note 41, at 513.

<sup>126</sup> The Doha Declaration, paragraph 6.

<sup>127</sup> Correa, *supra* note 53, at 20.

<sup>128</sup> Carvalho, *supra* note 29, at 240.

<sup>129</sup> The principle of independence of patents was found in Article 4bis of the Paris Convention. It can be understood in simple way; that is all legal effects of patent in one countries would not be necessary the same in another countries. See *id.*

<sup>130</sup> K Balasubramaniam, Equitable Pricing, Affordability and Access to Essential Drugs in Developing, WHO/WTO Secretariat Workshop on Differential Pricing and Financing of Essential Drugs Countries

even if they are willing to issue compulsory licenses; there is no local manufacturer to produce affordable generic medicine for them.

Ironically, one of most powerful measures that attempted to balance between the intellectual properties and the right to access medicines is not producing medicines in developing countries; it was the importation of generic drugs.<sup>131</sup> The limitation requires that the products made under a compulsory license be sold in the licensee's domestic market. Moreover, a compulsory license may not be granted as a response to the interests of a foreign territory. This limitation rendered the compulsory license of little or no use in those countries because they are not capable of manufacturing generic medicines. In 2001 this issue drew attention. Accordingly, it was addressed in paragraph 6 the 2001 Doha Declaration on TRIPS and Public Health.

Paragraph 6 of the 2001 Doha Declarations is an operative provision,<sup>132</sup> which instructs the Council for TRIPS to find a solution regarding the access to medicine in the countries lacking, or with insufficient manufacturing capabilities in the pharmaceutical sector. On August 30, 2003 the TRIPS Council arrived at a decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. Although there is more than one possible solution to deal with this issue, but 2003

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Consumers Perspective, Apr 8-11, 2001, also available at [http://www.wto.org/english/tratop\\_e/trips\\_e/hosbjor\\_presentations\\_e/35balasubramaniam\\_e.pdf](http://www.wto.org/english/tratop_e/trips_e/hosbjor_presentations_e/35balasubramaniam_e.pdf) (last visited Jan. 8, 2009)

<sup>131</sup> See TRIPS and Public Health, WTO document No. IP/C/W/296, Jun. 29, 2001; this a working paper submitted by the AfricaGroup, Barbados, Bolivia, Brazil, Dominican republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela. A total of 30 countries.

<sup>132</sup> The Doha Declaration, *supra* note 14.

decision resolves this issue by waiving certain requirements under Article 31 (f). In 2005, members agreed to make this decision a permanent amendment to the TRIPS Agreement, Article 31*bis*; this amendment will take effect when two third of the members accept it.

The addition of Article 31*bis* to the Agreement adds five new paragraphs.<sup>133</sup> The first paragraph allows pharmaceutical products, made under compulsory licenses to be

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<sup>133</sup> Article 31*bis* of the TRIPS reads

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).

exported to countries lacking production capacity.<sup>134</sup> The second paragraph requires that the compensations is paid by an exporting countries where a compulsory is granted; in this way, double remuneration to the patent-owner cab be avoided.<sup>135</sup> The third paragraph deals with a situation where a developing country or least-developed member is a member of regional trade agreements. In such case, pharmaceutical products imported into one member of regional agreement may also be exported to other developing and the least-developed countries of the region that share the same health problem in question.<sup>136</sup> The forth paragraph requires that WTO members not raise non-violation complaints in connection with Article 31bis.<sup>137</sup> Finally, it retains all existing flexibilities under TRIPS Agreement.<sup>138</sup>

The 2005 Amendment will take effect when two thirds of the WTO's members have accepted the change. Until the end of 2008, less than two thirds of members have ratified the changes. They original deadline set for states to ratify was 1 December 2007 and this date was extended to 31 December 2009 under a decision by the General Council on 18 December 2007.<sup>139</sup>

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<sup>134</sup> Peter K. Yu, *The International Enclosure Movement*, 82 IND. L.J. , 881-886 (2007).

<sup>135</sup> The double remuneration refers to a situation which a patent holder is compensated in both the country ere the pharmaceutical products are manufactured and the country imports the pharmaceutical products. See Thomas, John T., *Pharmaceutical Patent Law Cumulative Supplement* 177 (2006).

<sup>136</sup> Yu, *supra* note 134, at 882-883.

<sup>137</sup> Yu, *supra* note 134,at 883-884.

<sup>138</sup> Thomas, *supra* note 135, at163.

<sup>139</sup> See [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm). (last visited on Jan. 8, 2009)

With respect to this new scheme, Rwanda submitted the first notification of issuing compulsory license on July 17, 2007,<sup>140</sup> and Canada followed on October 4, 2007.<sup>141</sup> With these two notifications, Canada can produce generic medicines for the treatment of HIV/AIDS for Rwanda and Rwanda can import generic medicines from Canada. This kind of model is restricted by Article 31 (f) of the TRIPS. The 2005 Amendment provides the waivers for subparagraph (f) of Article 31 and retains the flexibilities in TRIPS, but its impact, if it could take effects, on the access to medicines is limited for some reasons. First, in order to implement new scheme, the states are required to enact new domestic law to comply with the conditions before issuing compulsory license.<sup>142</sup> Second, the new compulsory license scheme created new problems in implementation.<sup>143</sup> Thus, only few countries used this new compulsory license scheme.<sup>144</sup>

### 3.3 Exception under the Regional and Bilateral Agreement

The previous chapter has shown that there is a trend to provide higher level of protection for pharmaceuticals through a series of regional and bilateral trade agreements between the US and developing and countries, including Chile, Australia, Singapore, Morocco, Central America (including Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua

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<sup>140</sup> Tove Iren S. Gerhardsen, Rwanda Pioneers Use Of WTO Patent Flexibility For HIV/AIDS Medicine, Intellectual Property Watch, available at <http://www.ip-watch.org/weblog/index.php?p=696>, also see Rwanda's submission document IP/N/9/RWA/1.

<sup>141</sup> WTO: 2007 NEWS ITEMS: Canada is first to notify compulsory licence to export generic drug, available at [http://www.wto.org/english/news\\_e/news07\\_e/trips\\_health\\_notif\\_oct07\\_e.htm](http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm); also see Canadian Submission Document IP/N/10/CAN/1/.

<sup>142</sup> Cynthia M. Ho, Comment: VII. Access to Essential Medicines: A New World Order for Addressing Patent Rights and Public Health, 82 Chi.-Kent. L. Rev. 1469, 1490-1493 (2007).

<sup>143</sup> Abott & Reichman, *supra* note 78, at 936-949.

<sup>144</sup> Ho, *supra* note 142, at 1491.

and the Dominican Republic) ('CAFTA-DR') and in signed, but not yet ratified, agreements with Panamá, Peru, Colombia and South Korea.<sup>145</sup> These bilateral and regional agreements vary in context, but they share some features, such as they demonstrate that protection is beyond the scope of TRIPS and negate the flexibilities in TRIPS.<sup>146</sup> Those features in relation to data protection were presented in two aspects: granting a fixed period of marketing exclusivity for clinical trial data;<sup>147</sup> and linking patent with marketing approval process.<sup>148</sup> Unlike Doha Declaration, members in regional and bilateral agreements, lack collective support from the developing countries. They had to face strong economic pressure from the US by themselves.<sup>149</sup> In the negotiation of these treaties, due to the lack of legal expertise, and the weak bargaining power of these countries the right to affordable medicines became less important than other trade issues. As a result, those agreements conceded the issue of pharmaceutical test protection and tighten the scope of exceptions for data protection.<sup>150</sup> These situations, in reality prevented those states from utilizing the easy, flexible standard provided to those

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<sup>145</sup> See *supra* text chapter 2; U.S. Free Trade Agreements can also be found from <http://www.export.gov/fta/> (last visited Jan. 8, 2009)

<sup>146</sup> Testimony of MSF on IP Provisions in DR-CAFTA & Consequences For Access to Essential Medicines, submitted to the Committee on Ways and Means of the House of Representatives April 2005 , April 22, 2005, <http://www.doctorswithoutborders.org/publications/article.cfm?id=1361> (last visited Jan. 8, 2009)

<sup>147</sup> Some commentators pointed out that those agreements also restrict reliance on foreign marketing approval or foreign submission of regulatory data. See chapter 2.

<sup>148</sup> The patent linkage would prohibit health regulatory agent to grant a marketing approval for generic medicine during the patent term without the consent or acquiescence of patent holders. See Abott & Reichman, *supra* note 78, at, 936-949.

<sup>149</sup> Baker, *supra* note 25, at 323-328.

<sup>150</sup> *Id* at 328.

states under TRIPS.<sup>151</sup> Bottom line, those states that are members to those FTAs, and CAFTAs, but also members to TRIPS cannot fully realize their rights under TRIPS.

### **3.3.1 The Regional Agreements**

Two important US related regional agreements represent the trends of data protection; those are NAFTA and CAFTA. The law of data protection in these treaties has been discussed in the previous chapter; here the focus is on the exceptions of data protection and that whether those treaties contain law conducive to the right to public health and right to medicines.

#### **3.3.1.1 Exceptions under the NAFTA**

Article 1711.5 of the NAFTA sets two exceptions for data exclusivity; first, disclosure is permitted when it is necessary to protect the public, and second, it is permitted when it is fair use.<sup>152</sup> Basically, these are the same exceptions guaranteed by Article 39.3 of TRIPS. Likewise, the issues resulting from the interpretations of these two terms under Article 39.3 “the necessary to protect public” and “unfair and commercial” are encountered in Article 1711.5.<sup>153</sup>

The only difference in reality, unlike most WTO members in Africa, members of NAFTA are capable of manufacturing medicines if they had to. Thus, the capability of manufacturing pharmaceutical is not a concern under the NAFTA regime. Nevertheless, when a members deals with a public health crisis, that state may issue a compulsory

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<sup>151</sup> *Id* at 331.

<sup>152</sup> The NAFTA, art. 1711.5.

<sup>153</sup> See detailed the section 3.2.

license because of insufficient availability of medicines. Article 1709(10) (b) of the NAFTA contains an emergency doctrine which allows a Party to expropriate a patent during a national emergency or if the need is urgent.<sup>154</sup> When a party utilizes those exceptions, NAFTA only requires states to give an adequate and prompt notice to the right holders, and then states may grant compulsory license.<sup>155</sup> However, NAFTA, like other instruments did not define the terms "national emergency" or "extreme urgency." Thus it was inevitable states interests had to clash over what constitute national emergency, or extreme exigency. In the Anthrax case of 2001, the Canadian government, attempted to issue a compulsory license for a generic production of the drug Cipro, under the pretext of extreme emergency.<sup>156</sup> Although the Canadian government did not issue the license, the mere idea ignited a debate as to what constitute national emergency and when governments have the power to derogate intellectual property rights for the sake of public health.<sup>157</sup>

Here, in the Canadian case, measuring by the real size of the case there was no public health crisis that should trigger the application of the exception, yet, if Canada insisted on issuing the license it would have done it without fear of any reprisal from the US. There was no credible threat. Ironically, hundred of thousands, in three continents die from deadlier diseases and public emergencies; nevertheless, their situation does not qualify as

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<sup>154</sup> The NAFTA, art. 1.

<sup>155</sup> In case of national emergency or circumstances of extreme urgency, the NAFTA requires a Party to notify the rights holder as soon as reasonably practicable. In the case of fair and non-commercial use, if the government knows or has reasons to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly. See Shapiro, *supra* note 93.

<sup>156</sup> Paul Lungen , Anthrax scare in community, Canadian Jewish News, page 1, Oct. 25, 2001.

<sup>157</sup> Shapiro, *supra* note 93, at 55-56.

public emergency. The argument here is that the term “national emergency” is not static. This term, when interpreted, certain factors must be taken into account. For instance, the number of the patients, the state’s where the emergency is taking place capacity to respond to such situation, and how credible the threat to public health. Indeed these are not all inclusive factors but these must be taken into account when considering the declaration of public emergency on the ground of public health.

### 3.3.1.2 Exceptions under the CAFTA

With respect to the protection of pharmaceutical test data, Article 15.1.10 (d) of CAFTA follows TRIPS regime.<sup>158</sup> The data is protected against disclosure unless it is necessary to protect the public. In addition, the protection is against the unfair commercial use; therefore, the fair non-commercial use is permitted.

The debates in CAFTA are its potential negative consequences on access to essential medicines among members.<sup>159</sup> Commentators argued that the CAFTA provides high level protection by adopting the TRIPS-plus provisions.<sup>160</sup> By country, the USTR asserted that

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<sup>158</sup> Article 15.10.1.(d) of the CAFTA

For purposes of this paragraph, each Party shall protect such undisclosed information against disclosure except where necessary to protect the public, and no Party may consider information accessible within the public domain as undisclosed data. Notwithstanding the foregoing, if any undisclosed information concerning safety and efficacy submitted to a Party, or an entity acting on behalf of a Party, for purposes of obtaining marketing approval is disclosed by such entity, the Party is still required to protect such information from unfair commercial use in the manner set forth in this Article.

<sup>159</sup> Maxwell R. Morgan, *Medicines for the Developing World: Promoting Access and Innovation in the Post-TRIPS Environment*, 64 U. Toronto Fac. L. Rev. 46, 97 (2006).

<sup>160</sup> Christine A. Chung, *NOTE & COMMENT: A Cry for Cheap Drugs: CAFTA'S Inflexible Intellectual Property Protections Create an Ominous Impact on Life-Saving Medicines*, 13 Sw. J.L. & Trade Am. 171, 171-175 (2006)

the US Side Letters about DR-CAFTA and public health had confirmed the conclusion of the Doha Declaration,<sup>161</sup> thus, the CAFTA would not impede the access to medicines. The USTR's arguments are not persuasive, because Central American countries understand that Side Letters are not legally enforceable and would not supersede the texts in the CAFTA.<sup>162</sup> Human right supporters point out that creating a Doha-like declaration that coincides with CAFTA or amending the CAFTA would be a better solution to the access to medicines for the Central American countries, because such amendments would create TRIP-like flexibilities in CAFTA.<sup>163</sup> Those flexibilities would allow member to interpret and implement the CAFTA in a manner furthering the promotion of access to medicines.<sup>164</sup> In addition human rights advocates recommended that CAFTA include a waiver for data exclusive right under the conditions of national emergency or other

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<sup>161</sup> Side Letter of the CAFTA, UNDERSTANDING REGARDING CERTAIN PUBLIC HEALTH MEASURES on August 5, 2004 reads :

The obligations of Chapter Fifteen do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.

In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively the "TRIPS/health solution"), Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution.

With respect to the aforementioned matters, if an amendment of a pertinent provision of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (1994) enters into force with respect to the Parties and that amendment is incompatible with Chapter Fifteen, our Governments shall immediately consult in order to adapt Chapter Fifteen as appropriate in the light of the amendment.

Also available at [http://www.ustr.gov/assets/Trade\\_Agreements/Bilateral/CAFTA/CAFTA-DR\\_Final\\_Texts/asset\\_upload\\_file697\\_3975.pdf](http://www.ustr.gov/assets/Trade_Agreements/Bilateral/CAFTA/CAFTA-DR_Final_Texts/asset_upload_file697_3975.pdf) (last visited on Jan. 8, 2009)

<sup>162</sup> Baker, *supra* note 25, at 332.

<sup>163</sup> Baker, *supra* note 18, at 633-72.

<sup>164</sup> Chung, *supra* note 161, at 186-187.

circumstances of extreme urgency.<sup>165</sup> This would allow generic drug manufacturers to use the data and produce cheaper drugs for national emergency or other circumstances of extreme urgency.

### 3.3.2 Bilateral Trade Agreements

The adoption of data exclusivity and other TRIPS-plus provisions for pharmaceutical products in the US bilateral agreements strengthened the position of originator of pharmaceutical enterprises on national markets by providing strong intellectual property protection.<sup>166</sup> It is noted that strong protection policy would attract more US investments and technology transfers.<sup>167</sup> However, this strong policy towards protection hinders the right to access medicines.

Many commentators found that flexibilities in TRIPS are being weakened by bilateral trade agreements.<sup>168</sup> These trade agreements, in particular, impose restrictions on compulsory licensing. As discussed above, the 2001 Brazil case proved that the compulsory license is a powerful tool for governments to negotiate prices of medicines.<sup>169</sup> Once a state adopts data exclusivity without exceptions, those restrictions would effectively preclude use of compulsory licensing.<sup>170</sup> Moreover, the registration of

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<sup>165</sup> Robert Weissman, Public Health-Friendly Options for Protecting Pharmaceutical Registration Data, *Int'l J. Intell. Prop. Mgm't* 113, 124-27 (2006).

<sup>166</sup> Ho, *supra* note 143, at 1495-1501.

<sup>167</sup> Robert Bird & Daniel R. Cahoy, The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach, 45 *AM. BUS. L.J.* 283, 283&317 (2008)

<sup>168</sup> See Ho, *supra* note 142, at 1496-1501; Abott & Reichman, *supra* note 78, at 962-963.

<sup>169</sup> See *supra* text in page 16-17.

<sup>170</sup> See Baker, *supra* note 25, at 330-331 (2008).

generic medicines produced under compulsory licenses could be excluded, if the bilateral FTAs contain patent linkage provisions.<sup>171</sup> In such case, the marketing approval of generic medicines during the patent term would rely on the consent of the patent holder for marketing approval.

The US Congress found abuse in bilateral trade agreements and began to find a solution for ensuring access to medicines with her trading partners.<sup>172</sup> In 2007, the Congress reformed the existing bilateral template toward the direction of access to medicines. The 2007 reform combines the conclusion of the 2001 Doha Declaration, 2003 Decision and 2005 Amendment.<sup>173</sup> It was reflected, in the terms of the amended FTA between the United States and Peru, by introducing an explicit exception to the data exclusivity obligation for measures to protect public health in accordance with the Doha Declaration and the subsequent protocols for implementation.<sup>174</sup> The result was strengthening the 2001 Decision and 2005 Amendment Article 31bis and makes WHO text become the text

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<sup>171</sup> *Id.*

<sup>172</sup> GAO, Intellectual Property: U.S. Trade Policy Guidance on WTO. Declaration on Access to Medicines May Need Clarification 4, Sep. 2007, available at <http://www.gao.gov/new.items/d071198.pdf> (last visited on Jan. 8, 2009).

<sup>173</sup> See Staff of H. Comm. on Ways and Means, 110th Cong., Peru and Panama FTA Changes, at ¶ III D(3) (Comm. Print 2007).

<sup>174</sup> Article 16.10.2 (e) of the US-Peru FTA reads:

Notwithstanding subparagraphs (a), (b), and (c), a Party may take measures to protect public health in accordance with:

- (i) the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the “Declaration”);
- (ii) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration and in force between the Parties; and
- (iii) any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties.

of trade agreements instead of recognizing those public health exception only in the side letters.<sup>175</sup>

### 3.4 The Domestic Case

#### 3.4.1 The Implementation of 2003 Decision in Canada

On May 14, 2004 Canada amended the Patent Act and the Food and Drugs Act to authorize compulsory licenses for the production of generic drugs. In May 2005, Bill C-9, - an Act to amend the Patent Act and the Food and Drugs Act - came into force.<sup>176</sup> This act made Canada become the first country to amend its domestic law in order to fulfill the 2003 Decision.<sup>177</sup> This amendment made it possible to produce the generic medicine for other developing countries and export to eligible developing countries, which broke the restrictions under 31 (f) of the TRIPS.

The Government of Canada tried to drop the 2003 Decision in a practical way. The Bill sets out detailed procedures.<sup>178</sup> Like TRIPS, the Bill's provisions attempted to reconcile interests between the intellectual property and human rights.<sup>179</sup> As a result, on the one hand, it provides a formula for calculation of remuneration, and therefore it would not

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<sup>175</sup> Abott & Reichman, *supra* note 78, at 964.

<sup>176</sup> Bill C-9, An Act to Amend the Patent Act and the Food and Drugs Act, 3rd Sess., 37th Parl., 2004, online: Library of the Parliament. Available at [http://www.parl.gc.ca/common/Bills\\_ls.asp?Parl=37&Ses=3&ls=C9#1section2101txt](http://www.parl.gc.ca/common/Bills_ls.asp?Parl=37&Ses=3&ls=C9#1section2101txt) (last visited Jan. 8, 2009)

<sup>177</sup> Jim Keon, "Editorial: Canada first to pass legislation on delivering generic medicines to developing countries" (2004) 1:4 *Journal of Generic Medicines* 292 at 292, available at <http://www.who.int/intellectualproperty/events/CGPAPER.pdf>. (last visited Jan. 8, 2009)

<sup>178</sup> Fanni (Faina) Weitsman, *Eliminating Barriers to the Export of Generic Versions of Patented Drugs to Developing Countries - from Doha to Bill C-9*, 6 *Asper Rev. Int'l Bus. & Trade L.* 103, 137 (2005).

<sup>179</sup> *Id.*, at 118-122.

impose economic burden on the developing countries.<sup>180</sup> On the other hand, it limited the list of pharmaceuticals eligible to be subject to compulsory licenses, and therefore the compulsory license would still be an exceptional case of patented drugs.<sup>181</sup> The stated purpose of the legislation is "to facilitat[e] access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."<sup>182</sup> This Act received the support of NGOs, civil society groups, and even the pharmaceutical industry.<sup>183</sup> Nevertheless, there were widespread criticisms within these same groups. They complained that the bill's flaws may prevent it from achieving its goal of improving access to life-saving medicines.<sup>184</sup> Until October 2007, Canada is first to notify compulsory license to export generic drug, and in the same year Rwanda informed the WTO that it intends to import TriAvir made in Canada.<sup>185</sup> It raised a bigger question that whether a restrictive compulsory license scheme is a solution for the access to medicine, since there is only few cases after the new WTO scheme was built.<sup>186</sup>

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<sup>180</sup> *Id.*, at 113.

<sup>181</sup> *Id.* at 132.

<sup>182</sup> Canadian Bill C-9, Section 21.01.

<sup>183</sup> Jennifer A. Lazo, NOTE: The Life-Saving Medicines Export Act: Why the Proposed U.S. Compulsory Licensing Scheme will Fail to Export Any Medicines or Save Any Lives, 33 *Brooklyn J. Int'l L.* 237, 255 (2007).

<sup>184</sup> *Id.* at 264.

<sup>185</sup> Canada is first to notify compulsory license to export generic drug, avail at [http://www.wto.org/english/news\\_e/news07\\_e/trips\\_health\\_notif\\_oct07\\_e.htm](http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm) (last visited on Jan. 8, 2009).

<sup>186</sup> Lazo, *supra* note 183, at 275-276.

### 3.4.2 The Case of the Non-Commercial Use in Thailand

In 2007, the government of Thailand issued compulsory licenses on three patented pharmaceutical products on grounds of governmental use. Two are ARV treatments, and the third one is a medicine used for the treatment of coronary disease, patented in Thailand by Sanofi-Aventis. Immediately, it raised a debate as to whether the government can issue a compulsory license for medicines of chronic deceases.<sup>187</sup> The Thai authorities reasoned that the 'government use' licenses issued for its public health sector would not be used to supply the comparatively small segment of the 'private' commercial pharmaceuticals market, where products are sold at the patentee's prices.<sup>188</sup> Thus, Thai authority asserted this grant is fair non-commercial use. Opponents such as the EU and US argued that the chronic diseases do not meet any requirement of issuing compulsory license.<sup>189</sup>

### 3.5 Conclusion

The concept of data protection is established through multilateral, regional, bilateral and domestic law. However, reviewing the existing legal regimes, we found the exceptions for data protections are incomplete. This incompleteness, no doubt, would delay access to generic medicines and even would paralysis the entire compulsory license by rejecting the marketing approval during patent term.

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<sup>187</sup> Brent Savoie, Thailand's Test: Compulsory Licensing In An Era of Epidemiologic Transition, 48 Va. J. Int'l L. 211 (2007).

<sup>188</sup> Abott & Reichman, *supra* note 79, at 952-955.

<sup>189</sup> Abott & Reichman, *supra* note 79, at 955.

The development of a patented drug is long journey. After a chemical is patented, the process of developing of new drugs has just begun. The entire process will be governed by patent and pharmaceutical law. The goal of patent is to provide incentives for innovation, while the goal of health regulations is to guarantee a safe and effective medicine. Surely, the protection of pharmaceutical test data and patent could encourage the developing of new drugs. Yet, these two laws are not designed to control the market price of medicine.

The 2006 WHO survey showed that still more than half of world population does not have access to essential medicines. The high price is the main factor affecting public access to medicines in the developing countries. As a result, the developing countries need more flexible legal framework for the protection of pharmaceuticals in order to affordably access essential medicines. This question was addressed in the 2001 WTO Doha Declaration. The 2003 Decision and 2005 Amendment were attempts from the WTO members to adopt flexible measures to reach the goal of accessing medicines. This, position, arguably, would be favored, when establishing a flexible framework for the data protection in the future.

Globally, Article 39.3 provides two grounds to exclude data protection; that is the measure is necessary to protect public, and the other is fair use. However, due to the ambiguities of these two terms the actual application of the exceptions became worthless. Although, article 7 and 8, determine the objective of the TRIPS, and this should have provided guidance in the application of the exceptions, the WTO Dispute Panel cases proved to be useless. This attitude discourages the developing countries to use flexible

measures to implement intellectual property. But this restrictive viewpoint may be challenged if the 2005 Amendment passed. Once the 2005 Amendment passed, the exceptions for the data protection would be easily established in certain circumstances, in particular on the ground of public health.

The compulsory license is powerful tool for access to medicines. In the past, most discussions were focused on the authorization of patent holders. However, the compulsory license may be granted in a package, including the authorization of use of pharmaceutical data. Some scholars suggest that the authorization of use of pharmaceutical data under the compulsory license scheme is a fair use but the compensation should calculate the use of data. It is noted that the authorization of the use of pharmaceutical data should be incorporated in the compulsory scheme. Otherwise, the aims of compulsory license would be defeated.

In the regional level, the bilateral and regional trade agreements present a higher level of protection of intellectual property. Those restrictive measures negate the flexibility of TRIPS and make it harder for state members to those agreements to apply the public health related exceptions. Fortunately, states are aware of these drawbacks and, therefore reformed the bilateral agreements. The new trade FTA incorporated the WTO related public health official document. This trend would be effective for establishing exceptions framework for the data protection.

Domestically, the case of Canada amended the Patent Act in order to fulfill the goal of the 2003 Decision. The Canadian law attempts to establish a framework for the compulsory license scheme in order to import the medicines. It is good attempt to

increase the access to medicine in the developing countries. Although some scholars were in a hurry to criticize that law because in their views the law erected other legal barriers, it is still too early to discuss the impact of this scheme. Another case in Thailand showed the different aspects of compulsory license scheme. The Thai government uses this scheme to provide medicines for the heart disease patients. This action raised questions as to whether the country may suspend its obligation based on the public health exception and under what circumstances the states may apply those exceptions.

## 4. The Human Right to Medicines-Jurisprudence and Implementation

### 4.1 Introduction

The adoption of TRIPS establishes a universal protective scheme to pharmaceutical innovations; in particular, it obliges WTO members to provide patent protection to cover all forms of technology, including pharmaceuticals. This uniformed protection scheme, though, diminishes cross borders trade disputes; it brings two significant human rights concerns in relation to the right to health.<sup>1</sup> The first concern is that such scheme cannot provide human rights protection to the traditional knowledge, such as the traditional medicine.<sup>2</sup> The second one is that current intellectual property implementation of the TRIPS might conflict with states' obligation to implement the right to health. This outcome results from the historical separation of the intellectual property law and human rights law.<sup>3</sup>

A consideration of the operating aspects of intellectual property with respect to access to medicines is that access to essential medicines is a human right. However, the impact of implementing TRIPS had not raised the human rights concerns until the several WHO reports evidently pointed out the extreme disparities in access to life-saving medicines.<sup>4</sup> These disparities could not be relieved even though WHO implemented Medicines

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<sup>1</sup> Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?*, 5 Minn. Intell. Prop. Rev. 47, 51-52 (2003).

<sup>2</sup> The issue of protection of the traditional medicine will be discussed in the next chapter.

<sup>3</sup> Helfer, *supra* note 1, at 51.

<sup>4</sup> *WHO Medicine Strategy 2004-2007*, Geneva, World Health Organization (hereinafter WHO Medicine Strategy), 2004 (WHO/EDM/2004.5), available at [http://whqlibdoc.who.int/hq/2004/WHO\\_EDM\\_2004.5.pdf](http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.5.pdf) (last visited Feb, 1, 2009)

Strategies for years. The HIV/ AIDS epidemic opened the eyes of the international community and showed some of the negative impacts of TRIPS on access to medicines.<sup>5</sup> The HIV/AIDS cases, though, have been treated as treatable-like chronic disease since 1996 and patients can live longer at length of 5-10 years than the first time since the beginning of this epidemic.<sup>6</sup> The story is still different in the developing countries even a decade after the first recognized cases of AIDS. In 2006, the WHO reported that an estimated 40 million people were living with HIV/AIDS in the developing countries and 30 % of those were in Africa. The WHO further pointed out only a small portion of them in developing countries had access to antiretroviral medicine (ARVs).<sup>7</sup> The absence of adequate HIV treatment in developing countries is a result of the lack of public health infrastructure, weak domestic regulations, and shortages of medical professionals etc.<sup>8</sup> However, partially to blame, in this crisis is the intellectual property system, which curtailed the production of generic medicines.

The adoption of TRIPS restricted the manufacture, export and import of generic medicines.<sup>9</sup> The WTO members, seemingly, were not aware of this negative impact until the South Africa and the Brazil were sued when they tried to grant compulsory licenses for public health purpose. Members, who support these two countries, argue that even

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<sup>5</sup> Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 *Yale J. Health Pol'y L. & Ethics* 193, 255-257 (2005).

<sup>6</sup> WHO medicine strategy, *supra* note 4.

<sup>7</sup> *Id.*

<sup>8</sup> *Id.*

<sup>9</sup> See Chapter 3.

international trade treaty such as TRIPS should not derogate state's right to protect public health, because the right to health is a fundamental human right.

States that adhere to this view find comfort in the views expressed by the UN human rights organs. In 2000, in its first ever scrutiny of the TRIPS agreement, the UN Sub-Commission on Human Rights has questioned the balance of rights between those promoted by the TRIPS agreement and the broader human rights of individuals.<sup>10</sup> The Sub-Commission was of the view that intellectual property rights or economic policies should not supersede human rights. Indeed, such an opinion is always welcomed by the developing countries.

On the other side, the pharmaceutical companies' argument that higher prices and protection are needed has some legitimacy to promote the medical innovation. Given that the effectiveness and efficiency of the current intellectual property regime, this argument was still working for them.

A recent research showed that drugs makers do not spend their money to further innovation and discovering new drugs; rather they spend the money in advertising, marketing and administrative fees.<sup>11</sup> What they spend in these sectors is much higher than what is devoted to research and development of new drugs.<sup>12</sup> In addition, protection of

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<sup>10</sup> See Someshwar Sing, *Trips Regime At Odds With Human Rights Law, Says Un Body*, at <http://www.twinside.org.sg/title/odds.htm> (last accessed January 26, 2009).

<sup>11</sup> Luke Timmerman, *Demand, marketing bolster sky-high price of new biotech drugs*, The Seattle Times, Apr. 28, 2002. also available at <http://community.seattletimes.nwsourc.com/archive/?date=20020428&slug=drugcosts28> (last visited Jan 20, 2009)

<sup>12</sup> *Id.*

material interests drives pharmaceutical innovation toward “profitable” diseases, but not prevalent diseases in the developing countries.<sup>13</sup> Since the rewards of material interests are not directed towards necessary pharmaceutical research and developments as such, the intellectual property should not focus heavily on promoting private material interests.

Today, as a result of the human rights movements, the incorporation of the right to medicines in all the regional human rights treaties, as well as domestic laws, and the integration of human rights language into trade treaties, it is evident that the right to medicines occupies a high place among human rights. In fact, since the last decade, the United Nation has integrated the right into most international HIV/AIDS strategies, and policies, including the flexible implantations of intellectual properties for pharmaceuticals.<sup>14</sup> Yet, states made less or no efforts in implementing these strategies, because states viewed them as policy statements. Until General Comment 14 was elaborated by Committee on Economic, Social and Cultural Rights, states’ misconception in relation to the implementation of the right to health started to take a different attitude.<sup>15</sup> The one of significant achievements of the Comment is to establish core obligations of the right to health. At the same time, the Comment also connects the concept of essential medicines with the WHO’s Model List of Essential medicines. Such incorporation,

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<sup>13</sup> Arrigo Schieppati, Giuseppe Remuzzi, Silvio Garattini, *Modulating the Profit Motive to Meet Needs of the less-developed world*, *The Lancet*, Vol. 358 Iss. 9293, 1638-1641 (2001).

<sup>14</sup> World Health Organization, *Handbook for Legislators on HIV/AIDS, Law and Human Rights Action to Combat HIV/AIDS in View of Its Devastating Human, Economic and Social Impact* 25 (1999); see also Homester, at 170.

<sup>15</sup> U.N. Econ. & Soc. Council, Comm. on Econ., Soc. & Cultural Rts. [hereinafter, CESCR], General Comment No. 14: The Right to the Highest Attainable Standard of Health, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000) [hereinafter General Comment 14].

besides clarifying state's obligation with regard to the right to medicines, strengthened the functions of the WHO.

In the past, it was not only that states have failed to live up to their obligation to protect the right to medicines, The truth is, even the WHO, the UN default agency mandated with the protection of the right, neglected its obligations. For years, most of this agency's achievements in relation to the right to medicines remained in the stages of either providing information or technical supports. Even among these achievements, perhaps the adoption of Model List of Essential medicine, the 2005 Reform of International Health Law and implementations of Prequalification Program, remain the most noticeable ones.

Another institution, indirectly implicated in the debate concerning the right to medicines and the protection of pharmaceutical innovations is the WTO. Though, the primary function of WTO is to deal with trade issues rather than human rights issues. In any event, by adoption of the TRIPS, WTO's jurisdiction extends the scope of trade related disputes to intellectual property area. In this regard, as the institution overseeing the implementation of TRIPS, the WTO cannot avoid resolving the problems resulting from the implementations of the intellectual property. Thus, when more than 80 WTO members in 2001 Doha Meeting pointed out that they had accepted the obligation to protect public health and such obligation should not be derogated by TRIPS' other provisions, the WTO was aware its duty to settle this issue.<sup>16</sup> This position resulted in the emergence of the 2001 Doha Declaration, 2003 Decision and 2005 Amendment.

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<sup>16</sup> See chapter 3.

The WTO's approach to resolve the issue of access to medicines in TRIPS attempts to develop a framework to reconcile trade and the right to health in the international level. Despite of some shortcomings in these initiatives,<sup>17</sup> it was appreciated attempt to reconcile these divergent interests and broaden access to medicines. Many options have been proposed by scholars to increase the access to medicines based on the decisions of Doha Declarations.<sup>18</sup> This position the WTO took is to strike an adequate balance between intellectual property and states parties' obligations in relation to the right to health.<sup>19</sup>

The previous chapters have discussed the concept of protection of pharmaceutical data and exceptions to exclude the protections. Several exceptions, to maximize access to medicines were presented. All exceptions that we pointed out indeed in one way or another will loosen the protection that pharmaceutical companies traditionally enjoyed, or minimize the scope of data protection. This chapter discusses why the right to medicines can be an additional external limitation on pharmaceutical data protection. In the beginning of this chapter, we define and examine the scope and the content of the right, the right to health as provided for in the various human rights instruments. Part of this discussion is focused on the state obligation to help its citizenry realize their right to medicines. This chapter also discusses the actions of major international organizations

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<sup>17</sup> Frederick M. Abbott & Jerome H. Reichman, The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions, 10 J. Int'l Econ. L. 921, 935-949 (2009).

<sup>18</sup> Sisiule F. Musungu & Cecila Oh, The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines? (South Center, 2006); see also Abbott & Reichman, *supra* note 17.

<sup>19</sup> See *infra* text 4.4.2.

with respect to this issue, such as the WHO and WTO. The final part will discuss how to reconcile trade and the right to medicines.

#### **4.2 The Right to Health and the Right to Medicines**

The term “right to health” is spelled out in international and regional human rights instruments as well as domestic laws, but the language in all these legal instruments does not go far as to say “right to access medicines” the way we using it here. Lack of express language, however does not mean that this right is non-existent or insignificant. To the contrary, this right is recognized as a fundamental human right, since states’ obligation of the right to health is guaranteed by implementing the right to medicines. Indeed, after all, the right to health can easily be interpreted to contain a right to medicines by implication. Thus, the right being implicit in the broader right to health does not relegate it to a lower rank. This view is further reaffirmed by the CESCR’s General Comment 14.<sup>20</sup>

The term “right to health” first appeared in the Constitution of the World Health Organization (WHO) in 1948. The preamble of WHO Constitution proclaims: “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, and political belief, economic or social condition.”<sup>21</sup> This statement is complete enough to spell out the status of right to health in human rights law, but a general opinion about this statement is not legally binding.<sup>22</sup> In any event, in the same year the Universal Declaration of Human Rights was

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<sup>20</sup> The General Comment 14, *supra* note 15 and see also *infra* text 4.2.1.2.

<sup>21</sup> WHO Constitution, preamble.

<sup>22</sup> Holger P. Hestermeyer, *Access to Medications as a Human Right*, Max Planck UNYB8, page 145 (2004).

adopted and the legal status of the “right to health” was further concretized.<sup>23</sup> Since then, this right is replicated in a series of international, regional and domestic laws.<sup>24</sup>

#### **4.2.1 Scope and Content of the Right to Medicines**

##### **4.2.1.1 Overview of International Human Right Instruments**

Human rights recognition can be dated back to Hammurabi Codes of ancient Babylon,<sup>25</sup> but the UN Charter remains the first, legal instrument to declare human rights in the international level.<sup>26</sup> This recognition is the beginning of the development of modern human rights. In 1948, the United Nations General Assembly adopted the Universal Declaration of Human Rights.<sup>27</sup> The Declaration incorporated not only the traditional civil and political rights but also further recognized a series of economic and social rights.<sup>28</sup> These recognized human rights later were incorporated in two important international human rights instruments; the International Covenant on Civil and Political Rights (ICCPR)<sup>29</sup> and International Covenants on Economic, Social and Cultural Rights

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<sup>23</sup> Universal Declaration of Human Rights, G.A. Res. 217, U.N. GAOR, 3d Sess., U.N. Doc. A/810 (1948).

<sup>24</sup> See infra text 4.2.1 and 4.2.2.

<sup>25</sup> The Basis of Human Right, <http://www.udhr.org/history/overview.htm#Above%20Picture> (last visited Feb. 1, 2009).

<sup>26</sup> The UN Charter, Preamble, art 55, art. 56 and art. 68. see also the history of human right, <http://www.udhr.org/history/default.htm> (Last visited Feb. 1, 2009)

<sup>27</sup> Universal Declaration of Human Rights [hereinafter UDHR], G.A. Res. 217A, at 71, U.N. GAOR, 3d Sess. 1st plen. mtg., U.N. Doc. A/810 (Dec. 12, 1948)

<sup>28</sup> Peter Bailey, *The Creation of the Universal Declaration of Human Rights*, available at <http://www.universalrights.net/main/creation.htm> (last visited Feb. 1, 2009).

<sup>29</sup> International Covenant on Civil and Political Rights [hereinafter ICCPR], G.A. Res. 2200A (XXI), Dec. 16, 1966, 21 U.N. GAOR Supp. (No. 16) at 52, U.N. Doc. A/6316 (1966).

(ICESCR).<sup>30</sup> These two documents together with the UDHR architected the basis of modern human rights law.

With respect to the right to health, Article 25.1 of UDHR,<sup>31</sup> in broad language proclaims that: "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary."<sup>32</sup> Article 12.1 of the ICESCR elaborates more on this right and defines what the essence of the phrase "adequate health living." In accordance with Article 12.1,<sup>33</sup> the right to health contains three elements. First of all, it is a matter of a right to enjoy the highest attainable health standard; second, this right is to be exercised without discrimination or whatsoever preferences as regards sex, color, nationality, political, social status, etc.; and third, the right to health includes two areas, physical and mental health. Article 12.2 of the ICESCR further establishes correlative governmental

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<sup>30</sup> International Covenant on Economic, Social and Cultural Rights [hereinafter ICESCR], opened for signature Dec. 16, 1966, art. 12.1, 993 U.N.T.S. 3, 8 (entered into force Jan. 3, 1976)

<sup>31</sup> Although UNDR is solely a resolution of the General Assembly of the United Nations, a general opinion recognizes that UDHR is binding or at least has obtained some legal effect. See Hestermeyer, *supra* note , at 156; also Hurst Hannum, *The Status of the Universal Declaration of Human Rights in National and International Law*, 25 Ga. J. Int'l & Comp. L. 287 (1995/96).

<sup>32</sup> Article 25 of the UDHR reads:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

Motherhood and childhood are entitled to special care and assistance. All children, whether born in or out of wedlock, shall enjoy the same social protection.

<sup>33</sup> Article 12.1 of ICESCR reads:

The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

obligations to protect this right.<sup>34</sup> In order to assist states to achieve this end, Article 12.2 provides guidance for governments to follow when implementing the right to health. This guidance contains several necessary steps that must be followed in order to protect this right. First, it requires states to take measures to reduce the stillbirth-rate and of infant mortality as well as guarantee for the development of the child. Second, it obligates states to improve all aspects of environmental and industrial hygiene. Third, it mandates states to prevent, control epidemic, endemic, occupational and other diseases and provide treatment for such diseases. Fourth, it instructs states to create conditions, which would assure to all, medical service and medical attention in the event of sickness.

Article 12 of the ICESCR completes a structure for the protection of the right to health. Subsequent international human rights instruments focus on vulnerable groups strengthened the importance of this right and addressed this right in various ways.<sup>35</sup> For example, the International Covenant on Civil and Political Rights (ICCPR) recognizes an inherent right to life.<sup>36</sup> As the Committee has explained, in its authoritative Comment No 6 on article 6 of the ICCPR, the use of the word “*inherent*” in the ICCPR signifies that

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<sup>34</sup> Article 12.2 of ICESCR reads:

- The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
- (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
  - (b) The improvement of all aspects of environmental and industrial hygiene;
  - (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
  - (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

<sup>35</sup> Office of the United Nations High Commissioner for Human Rights, The Right to Health, Fact Sheet No. 31, page 9-10 (2008), available at [www.ohchr.org/Documents/Publications/Factsheet31.pdf](http://www.ohchr.org/Documents/Publications/Factsheet31.pdf) (last visited Feb. 1, 2009)

<sup>36</sup> ICCPR, art 6.

states must take measures to ensure effective protection of the right to life. Indeed, one kind of protection is through providing medicines.<sup>37</sup> The Human Rights Committee, which monitors compliance with the ICCPR, further strengthens this right and explains this right imposes on states an obligation to undertake measures to eliminate epidemics.<sup>38</sup> The 1965 International Convention on the Elimination of All Forms of Racial Discrimination (ICERD) against racial discrimination obliges states to take further steps to prohibit and eliminate racial discrimination in all its forms and to guarantee the right of everyone, without distinction as to race, colour, national or ethnic origin, the enjoyment of the right to public health and medical care.<sup>39</sup> The 1979 Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW)<sup>40</sup> requires states to take all appropriate measures to eliminate discrimination against women in the field of health care.<sup>41</sup> The CEDAW provides a comprehensive scheme for states to ensure women's equality of access to health care services.<sup>42</sup> Such scheme mandates states to adopt

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<sup>37</sup> Human Rights Committee, General Comment 6, Article 6, (Sixteenth session, 1982), Compilation of General Comments and General Recommendations Adopted by Human Rights Treaty Bodies, U.N. Doc. HRI/GEN/1/Rev.1 at 6 (1994) [hereinafter General Comment No. 6].

<sup>38</sup> See Audrey R. Chapman, *The Human Rights Implications of Intellectual Property Protection*, 5 J. Int'l Econ. L. 861, 873-875.

<sup>39</sup> Article 5 (e) (iv) of the International Convention for the Elimination of All Forms of Racial Discrimination, opened for signature Mar. 7, 1966, art. 5, S. Exec. Doc. C, 95-2, at 4 (1978), 660 U.N.T.S. 195, 220-21 (entered into force Jan. 4, 1969).

<sup>40</sup> Articles 11(1) f, 12 and 14 (2) b of the Convention on the Elimination of All Forms of Discrimination Against Women [hereinafter CEDAW], GA Res 34/180, UN GAOR, 34th Sess, Supp No 46, UN Doc A/34/46 (1980), reprinted in 19 ILM 33 (1980), entered into force 3 September 1981.

<sup>41</sup> Article 12.1 of CEDAW reads: States Parties shall take all appropriate measures to eliminate discrimination against women in the field of health care in order to ensure, on a basis of equality of men and women, access to health care services, including those related to family planning.

<sup>42</sup> Article 12.2 of CEDAW reads: Notwithstanding the provisions of paragraph 1 of this article, States Parties shall ensure to women appropriate services in connection with pregnancy, confinement and the

measures related to family planning, pregnancy, confinement, and the post-natal period, granting free services where necessary. In the area of child protection, the 1996 Convention on the Rights of the Child (CRC) extends scope of the right to health established in ICESCR;<sup>43</sup> it instructs states to take appropriate measures to diminish infant and child mortality, ensures the provision of necessary medical assistance and health care to all children with emphasis on the development of primary care, combat disease and malnutrition, provide clean drinking water, and combat the dangers and risks of environmental pollution.<sup>44</sup>

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post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation.

<sup>43</sup> Art 24, Convention on the Rights of the Child [hereinafter CRC], GA Res 25 (XLIV), UN GAOR, 44th Sess, Supp No 49, UN Doc A/RES/44/25 (1989), reprinted in 28 ILM 1448 (1989).

<sup>44</sup> Article 24 of CRC reads:

1. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.
2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures:
  - (a) To diminish infant and child mortality;
  - (b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;
  - (c) To combat disease and malnutrition, including within the framework of primary health care, through, inter alia, the application of readily available technology and through the provision of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution;
  - (d) To ensure appropriate pre-natal and post-natal health care for mothers;
  - (e) To ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents;
  - (f) To develop preventive health care, guidance for parents and family planning education and services.
3. States Parties shall take all effective and appropriate measures with a view to abolishing traditional practices prejudicial to the health of children.
4. States Parties undertake to promote and encourage international co-operation with a view to achieving progressively the full realization of the right recognized in the present article. In this regard, particular account shall be taken of the needs of developing countries.

The international human rights instruments mentioned above refer to what the right to health should be and take account of the different needs of specific groups. However, ambiguous languages in these instruments rendered the right to health as merely inspirational statements rather than an enforceable individual right.<sup>45</sup> These deficient has the enforceability of this individual right being challenged since the adoption of these treaties. These general critics include the lack of guidance as to the scope of states' obligations, the definition of "highest attainable standard" and specifying entitlements of the individual right to health.<sup>46</sup>

#### **4.2.1.2 States' Obligation to Ensure the Right to Health; General Comment 14**

In 2000, the Committee on Economic, Social and Cultural Rights (Committee) attempted to resolve the issue of the deficient of workable standard in the implementation of the right to health by the adoption of the noted General Comment 14.<sup>47</sup> This Comment no doubt overcomes some barriers in the area of implementing the right to health. The first remarkable achievement is to establish criteria for states to evaluate the enforcement of right to health. These four important criteria are 1) availability, 2) accessibility, 3) acceptability, and 4) quality.<sup>48</sup> It further provides how states approach these four criteria.<sup>49</sup> The "availability" is used to evaluate whether the quantity of functioning public

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<sup>45</sup> Tony Evans, *A Human Right to Health*, 23 *Third World Q.* 197, 199-203 (2002);

<sup>46</sup> Benjamin Mason Meier, *Employing Health Rights for Global Justice: The Promise of Public Health in Response to the Insalubrious Ramifications of Globalization*, 39 *Cornell Int'l L.J.* 711, 733-35 (2006).

<sup>47</sup> General Comment 14, *supra* note 15.

<sup>48</sup> General Comment 14, *supra* note 15, at paragraph 12.

<sup>49</sup> *Id* and see also *The Right to Health, Fact Sheet No. 31*, *supra* note 36.

health and health-care facilities, goods and services is sufficient. The accessibility is a standard to evaluate whether members can access to health facilities, goods and services without discrimination, within the jurisdiction of their states. The criteria of acceptability concerns whether all health facilities, goods, and services are complied with medical ethics and cultural norms. The last requirement is quality, which addresses the parallel need for health facilities, goods and services to be scientifically and medically appropriate and of good quality.

Another significant achievement of General Comment 14 is the specification of the core obligations of the right to health.<sup>50</sup> The core obligation with respect to general obligations imposed different degree of obligations on signatory states parties of ICESCR. The general obligations require states to give effect the human rights announced by the ICESCR within their jurisdictions. In accordance with Article 2 (1) of ICESCR, states have obligations to “progressively achieve the full realization of the right under ICESCR through all appropriate means, including particularly the adoption of legislative measures.”<sup>51</sup> Under the general obligation, it is recognized that states have resources constraints and therefore this obligation solely requires states to makes efforts within available resource to protect and promote the rights under the Covenant.<sup>52</sup> This means within these available resources states should strive to enable their citizens to realize the right to health in accordance with the guidance provided in the Comment. For example, even poor states that can barely afford to offer medical services cannot discriminate, on

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<sup>50</sup> General Comment 14, paragraphs 43-45.

<sup>51</sup> ICESCR, art. 2 (1).

<sup>52</sup> The Right to Health, Fact Sheet No. 31, *supra* note 36, at 23-24.

whatsoever basis when providing such services.

By contrast, the core obligation requires a higher degree of compliance than those imposed by under article 2 of ICESCR. In accordance with General Comment 3, the Committee states that core obligation is applicable for all states regardless of their level of development, the availability of resource, or any other social, economic factors and difficulties.<sup>53</sup> In other words, core obligations are the minimum level to each of rights under ICESCR; therefore states cannot justify a failure to realize the right because of a lack of resources. In this context, the right to access essential drugs is specified by General Comment 14 as one of core obligation of states.<sup>54</sup> This notion requires states to ensure the right to access essential medicines to the maximum of their available resources, even if they lack availability of resource.<sup>55</sup>

In this respect, states' obligations in relation to the right to health and medicines can broadly be categorized in three main obligations; namely, the obligation to respect, protect and fulfill.<sup>56</sup> The obligation to respect requires states to avoid interfering so as to violate the right to health directly or indirectly. In accordance with General Comment 14, the violation of obligations to respect occurs when States' actions, policies or laws contravene the standards set out in article 12 of the ICESCR; and such violation likely results in bodily harm, unnecessary morbidity and preventable mortality. Two scenarios

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<sup>53</sup> U.N. Econ. & Soc. Council, Comm. on Econ., Soc. & Cultural Rts., General Comment No. 3: The Nature of States Parties Obligations, U.N. Doc. E/C.12/1990/8 (Dec. 14, 1990) [hereinafter General Comment 3]

<sup>54</sup> *Id.*, at 37.

<sup>55</sup> *Id.*, at 5.

<sup>56</sup> General Comment 14, paragraph 50-52.

provided by General Comment 14 are directly in relation to the right to access to medicines. The first scenario occurs when states suspend legislations or adopt laws or policies that interfere with the enjoyment of any of the components of the right to health. The second one occurs when states fail to take into account their legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other states, international organizations and other entities, such as multinational corporations.

The obligation to protect under General Comment 14 requires states to prevent third parties from violating the right to health. This further requires states to take all necessary measures to safeguard persons within their jurisdiction from infringements of the right to health by third parties.

Finally, a state's obligation to fulfill requires a state to adopt every appropriate measure to fully realize the right to health, such as legislative, administrative, budgetary and judicial measures.<sup>57</sup> A violation of the obligation of fulfill occurs when a state party fails to take all necessary steps to ensure the realization of the right to health.

In sum, with respect to right to access to medicines, states will meet their obligations, if they met the following obligations:

- (1) States cannot enter a regional or bilateral agreement which would impede the access to medicines.
- (2) States should police the infringement of right to access to medicines by private sectors within its jurisdiction.
- (3) States should establish a legal frame word to promote the access to medicines.

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<sup>57</sup> The Right to Health, Fact Sheet, *supra* note 36, at 27.

#### 4.2.2 Regional Human Right Instruments

There are several regional instruments recognize the right to health, such as American Declaration of the Rights and Duties of Man (ADRD),<sup>58</sup> and European Social Charter (ESC)<sup>59</sup> and American Convention on Human Rights: Additional Protocol (ACHR AP)<sup>60</sup> as well as African Chapter on Human and Peoples' Rights (AfCHPR).<sup>61</sup> Those provide a similar definition of the right to health in article 12.1 of ICESCR.

Article 11 of the ADRD states that, "Every person has the right to the preservation of his health through sanitary and social measures relating to food, clothing, housing and medical care, to the extent permitted by public and community resources."<sup>62</sup> The access to "essential" medicines is not exemplified in this article, but it is a measure permitted by public and community resources under Article 11 of ADRD. Article 10 of the ACHR AP provides a definition and also provides applicable measures that states may take to ensure the right to health.<sup>63</sup> Article 16 of AfCHPR also provides for the right in similar terms to

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<sup>58</sup> American Declaration on the Rights and Duties of Man, O.A.S. Res. XXX (1948), reprinted in Basic Documents Pertaining to Human Rights in the Inter-American System, OEA/Ser.L.V/II.82, doc. 6, rev. 1, at 17 (1992)

<sup>59</sup> European Social Charter (Revised), May 3, 1996, 36 I.L.M. 31, European Social Charter, Oct. 18, 1961, 519 U.N.T.S. 89.

<sup>60</sup> Additional Protocol to the American Convention on Human Rights, Nov. 17, 1988, 28 I.L.M. 156.

<sup>61</sup> African Charter of Human and People's Rights, June 27, 1981, 21 I.L.M. 58 (1982).

<sup>62</sup> ADRD, art. 11.

<sup>63</sup> Article 10 of the ACHR AP reads:

1. Everyone shall have the right to health, understood to mean the enjoyment of the highest level of physical, mental and social well-being.

2. In order to ensure the exercise of the right to health, the States Parties agree to recognize health as a public good and, particularly, to adopt the following measures to ensure that right:

that of the UDHR and the ICESCR. It states the right to health is a right “to enjoy the best attainable state of physical and mental health”.<sup>64</sup>

ESC Part 1(11) recognizes that the right to benefit from any measures to enjoy the highest possible standard of health attainable.<sup>65</sup> Further, ESC Part 2, article 11 mandates states undertake, either directly or in co-operation with public or private organizations to take appropriate measures to ensure the effective exercise of the right to protection of health.<sup>66</sup> Regarding the enforcement of the right to health, ESC Committee of Independent Experts pointed out states may be considered as the fulfilling its obligation to ensure the right to health if national and health systems passed the following

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- a. Primary health care, that is, essential health care made available to all individuals and families in the community;
  - b. Extension of the benefits of health services to all individuals subject to the State's jurisdiction;
  - c. Universal immunization against the principal infectious diseases;
  - d. Prevention and treatment of endemic, occupational and other diseases;
  - e. Education of the population on the prevention and treatment of health problems, and
  - f. Satisfaction of the health needs of the highest risk groups and of those whose poverty makes them the most vulnerable.

<sup>64</sup> Article 16 of AfCHPR reads:

1. Every individual shall have the right to enjoy the best attainable state of physical and mental health.
2. States parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.

<sup>65</sup> ESC, Part I (11).

<sup>66</sup> ESC, Part II, article 11.

standards:<sup>67</sup>

- (1) whether medical, paramedical professional and adequate medical equipments are available;
- (4) whether medical care ensures for the whole population, the prevention and diagnosis of disease;
- (5) whether states provide special measures to protect the vulnerable groups, such as mother, children and senior adults;
- (6) whether states provide healthy environment;
- (7) whether there is a system of health education in place;
- (8) whether states take adequate measures or provide means to combat epidemic and endemic diseases; and
- (9) whether the cost of health service is equally divided.

Unlike General Comment 14, ESC Committee attempts to set up a more stringent standard to evaluate whether an European state has fulfilled her obligations to ensure the right to health. This EU standard is higher than the internationally recognized standard established by the Comment 14. In addition, this EU system is much more comprehensive and sophisticated. Therefore, even if a European state does not meet the obligations under the ESC or the EU human right treaty, but still this state may likely not be delinquent under the ICCPR or the ICESCR.

#### **4.2.3 Domestic Law**

As of December 2008, more than 160 countries have adopted the ICESR and more than this number of states adopted regional human rights instruments; thus, either way, most

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<sup>67</sup> ESC Committee of Independent Experts, Conclusions 1, 59 quoted from Nihal Jayawickrama, *The Judicial Application of Human Right Law, National, Regional and International Jurisprudence*, page 884 (2003).

countries have recognized the right to health.<sup>68</sup> At least, 115 countries have recognized the right to health care in their constitutions.<sup>69</sup> In addition, more than six other constitutions impose on governments a duty in relation to health.<sup>70</sup> The domestication of the right to health left the states with obligation to take actions to realize or fulfill the right to health. This indeed will require states to strive to realize the right regardless of the issue of resources. The adoption of General Comment 14 galvanized this issue and now it is well settled that states bear an obligation to enable their citizens to fully realize this right.

In addition, a recent research showed that states practices in this area are encouraging. The research shows that states are willing to enforce this right regardless of how many

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<sup>68</sup> Hans V Hogerzeil et. al., Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts? *The Lancet*, Vol. 368, Iss. 9532, p305-311 (2006).

<sup>69</sup> The Right to Health, Fact Sheet, *supra* note 36, at 10.

<sup>70</sup> *Id* at 10-11.

Chapter II, Section 27: Health care, food, water and social security of Constitution of South Africa (1996):

(1) Everyone has the right to have access to a. health-care services, including reproductive health care; b. sufficient food and water; [...]

(2) The State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights.

(3) No one may be refused emergency medical treatment.”

Constitution of India (1950): Part IV, art. 47, articulates a duty of the State to raise the level of nutrition and the standard of living and to improve public health: “The State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties...”

Chapter IV: Economic, Social and Cultural Rights, art. 42 of Constitution of Ecuador (1998):

“The State guarantees the right to health, its promotion and protection, through the development of food security, the provision of drinking water and basic sanitation, the promotion of a healthy family, work and community environment, and the possibility of permanent and uninterrupted access to health services, in conformity with the principles of equity, universality, solidarity, quality and efficiency.”

resources they hold.<sup>71</sup> In addition, it identifies and analyzes 71 court cases from 12 low and middle-income countries. In these cases, individuals or groups claimed they have a right to access essential medicines on the basis of human right treaties signed by their state. The results showed that 59 cases won and 12 cases lost. Half of those cases have dealt with HIV/AIDS cases; other cases with leukemia, diabetes, and renal dialysis. The research also found that 93% of successful cases from Latin America and the rest of them are from India, South Africa, and Nigeria.

In this research, several important findings can be discovered. First, 66% of 59 successful cases rulings concern life-saving medicines. Second, the successful cases are often supported by Constitutional provisions, which were drawn from human rights treaties. The cases link the right to health to the right to life. The way which these cases was advocated was that since the right to life requires the state to take positive measures to protect this right, the right to medicines, is the first step to save the right to life. Third, the limits in social security cannot be a defense for the right to health. Fourth, government policies can successfully be challenged in court if state's national medicine policy<sup>72</sup> is lacking. The significance of these cases is that the right to health is not an abstract; it is rather enforceable right. This is rather extremely significant, since all these cases were decided in developing countries' courts.

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<sup>71</sup> Hogerzeil et.al., *supra* note 74.

<sup>72</sup> According to the WHO, a national medicine policy (NMP) is a commitment to national pharmaceutical goals. In addition, regardless of country specific circumstances, a comprehensive national medicine policy should take into account all components of the pharmaceutical sector and all relevant stakeholders. See WHO, Essential Medicines and Pharmaceutical Policies, available at [http://www.emro.who.int/emp/medicines\\_policy.htm](http://www.emro.who.int/emp/medicines_policy.htm) (last visited Feb. 10, 2009).

### 4.3 WHO's Implementation of the Right to Access to Medicines

#### 4.3.1 Introduction

The WHO is the first established U.N. agency in 1948. Under the WHO's constitution, it has responsibilities to reach the goal of attainment of "the highest possible level of health."<sup>73</sup> Unfortunately, this agency did not meet this high expectation since it was established.<sup>74</sup> One scholar even criticized that most of WHO's policies are based on political concerns rather than reflection of the needs of their member states, in particular, neglecting the interests of developing countries.<sup>75</sup>

By law, the WHO can be developed as a powerful normative agency, but the current situation goes to opposite way.<sup>76</sup> In accordance with WHO's constitution, the WHO has extensive normative powers to adopt conventions,<sup>77</sup> promulgate binding regulations,<sup>78</sup>

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<sup>73</sup> WHO Constitution, Preamble.

<sup>74</sup> Lawrence O. Gostin, A Proposal for a Framework Convention on Global Health, 10 J. Int'l Econ. L. 989, 993-994 (2007).

<sup>75</sup> *Id.*

<sup>76</sup> *Id.*; Allyn L. Taylor, Making the World Health Organization Work: Universal Access to the Conditions for Health, 18 Am. J.L. & Med. 301 (1992)

<sup>77</sup> Article 19 of WHO Constitution reads:

The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization.

A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes. The Health Assembly shall have authority to make recommendations to Members with respect to any matter within the competence of the Organization.

Article 20 of WHO Constitution reads:

Each Member undertakes that it will, within eighteen months after the adoption by the Health Assembly of a convention or agreement, take action relative to the acceptance of such convention or agreement. Each Member shall notify the Director-General of the action taken, and if it does not accept such convention or agreement within the time limit, it

make recommendations,<sup>79</sup> and monitor national health legislation.<sup>80</sup> Through these legislative power, the WHO can adopt binding conventions or agreements which, affirmatively require States to 'take action' through submitting the convention for ratification and notifying the Director General of the action taken.<sup>81</sup> In addition, WHO's broad authorities can adopt any regulations related to health topics.<sup>82</sup> That is to say once World Health Assembly (WHA) adopted a regulation within its scope of tasks, such as standards of safety, potency and advertising of biological and pharmaceuticals, the

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will furnish a statement of the reasons for non-acceptance. In case of acceptance, each Member agrees to make an annual report to the Director-General in accordance with Chapter XIV.

In accordance with Article 19 and 20 of WHO Constitution, The World Health Assembly, by a two-thirds vote, may adopt conventions or agreements, while such conventions or agreements are not binding until accepted. In addition, member states must 'take action' within 18 months, even if its delegation voted against the convention. See Gostin, *supra* note 74, at 994.

<sup>78</sup> Article 21 of WHO Constitution reads:

The Health Assembly shall have authority to adopt regulations concerning:

- (a) sanitary and quarantine requirements and other procedures designed to prevent the international spread of disease;
- (b) nomenclatures with respect to diseases, causes of death and public health practices;
- (c) standards with respect to diagnostic procedures for international use;
- (d) standards with respect to the safety, purity and potency of biological, pharmaceutical and similar products moving in international commerce;
- (e) advertising and labelling of biological, pharmaceutical and similar products moving in international commerce.

<sup>79</sup> Article 23 of WHO Constitution reads:

The Health Assembly shall have authority to make recommendations to Members with respect to any matter within the competence of the Organization.

<sup>80</sup> Article 63 of WHO Constitution reads:

Each Member shall communicate promptly to the Organization important laws, regulations, official reports and statistics pertaining to health which have been published in the State concerned.

<sup>81</sup> Gostein, *supra* note 74, at 994.

<sup>82</sup> *Id.*

regulations would be applicable to all WHO member countries in most of circumstances.<sup>83</sup>

It is incontestable that the WHO's impressive normative powers are sufficient to establish an efficient international legal scheme to enforce the right to health. However, the WHO has exercised its normative power only twice in its existence; that is the adoption of two significant laws, Nomenclature with Respect to Disease and Causes of Death<sup>84</sup> and International Health Regulation (IHR).<sup>85</sup> These initiatives indeed have more impacts on technical support rather than normative value.<sup>86</sup> The Nomenclature Rule is the first international health law adopted by the WHO. It sets a completed technical classification of disease. Yet, this Rule has no normative value. It recommends states to do such classification rather than impose obligation on states. Another noted WHO regulation, International Health Regulations (IHR), focuses on the issue of cross-broader effects of infectious diseases. Before the revision of 2005, the IHR applied only to cholera, plague, and yellow fever.<sup>87</sup> Many critics were disappointed because the old IHR's scope was

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<sup>83</sup> Only in a circumstance where the government specifically notifies WHO that it rejects the regulation or accepts it with reservations, member states are not bound to regulation. Otherwise even those that voted against it, they are bounded by such law adopted by WHA.

<sup>84</sup> World Health Organization, History of the International Classification of Diseases (ICD), available at <http://www.who.int/classifications/icd/en/> (last visited Jan. 20 2009).

<sup>85</sup> World Health Assembly, Third Report of Committee A, A58/55 (May 23, 2005), (hereinafter IHRs 2005), available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA58/A58\\_55-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA58/A58_55-en.pdf) (last visited Feb. 12, 2009). In this report, the World Health Assembly officially adopted the IHRs 2005 and included its provisions in the document.

<sup>86</sup> Gostin, *supra* note 74, at 994.

<sup>87</sup> Eric Mack, Comment, The World Health Organization's New International Health Regulations: Incursion on State Sovereignty and Ill-fated Response to Global Health Issues, 7 *Chi. J. Int'l L.* 365, 367-368 (2006).

same as in the 1889 international sanitary conference.<sup>88</sup> The WHO's passive attitude was not adjusted until the SARS outbreak in 2001.<sup>89</sup> It is the first time that the WHO, actively, took action.<sup>90</sup> It issued the controversial travel advisory over the economic interests of member states, because the prevention of the spread of the SARS was the priority for the WHO at that time.

Overall, with respect to the WHO's work in relation to the right to access medicines, the Agency only has had a limited contribution in legal framework. Nevertheless, within this limited normative framework, there are some significant contributions that cannot be overlooked when making an analysis of the global health governance. These initiatives have had an impact, at least in the rhetorical level, on the issue of medicines accessibility.

These features can be summarized in:

- (1) the adoption of Model List of Essential Medicine;
- (2) defining the global health by the revising the 2005 IHP;
- (3) the adoption of Prequalification Program.

These three initiatives, if taken seriously, have the potential of increasing access to medicines and alleviate the impacts of the implementation of TRIPS and other trade agreements.<sup>91</sup> The Model List of Essential Medicines linked with the national drug policy and allows states to determine which medicines they should cover in their health care.

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<sup>88</sup> See *id* and Gostin, *supra* note 74.

<sup>89</sup> Mack, *supra* note 93, at 365-366.

<sup>90</sup> David P. Fidler, Developments involving SARS, International Law, and Infectious Disease Control at the Fifty-Sixth Meeting of the World Health Assembly, June 2003, ASIL Insights, also avail at <http://www.asil.org/insigh108.cfm> (Last visited Feb 10, 2009).

<sup>91</sup> The impacts of TRIPS and bilateral agreements on access to medicines have been discussed in Chapter 2.2 and 2.3.

This means that a given country can customize a plan that fits the health realities in that country. The International Health Regulation provides a measure to determine what health emergency is in global level. The Prequalification Project, to some degree, suspends the issue of protection of pharmaceutical data.

#### **4.3.2 Equitable Access to Essential Medicines**

##### **4.3.2.1 The Concept of Essential Medicines and Core Obligation**

In 1975, WHO introduced the concept of Essential Medicine by the adoption of the WHA 28.66.<sup>92</sup> The concept was built up for the need of developing countries to determine what kind of medicines should be covered by their health care and insurance programs. The first WHO Model List of Essential Drugs was prepared by a WHO Expert Committee in 1977. The List is updated every 2 years following the first Model List. By the end of 2003, 156 Member States used this Model List to develop national official essential medicines lists.<sup>93</sup>

So basically the concept of essential medicines as the WHO points out is established to satisfy the priority health care needs of the population.<sup>94</sup> They are intended to be available within the context of functioning health systems at all times, in adequate

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<sup>92</sup> By the resolution WHA 28.66, Assembly requested the Director-General to assist member States by “advising on the selection and procurement, at reasonable cost, of essential drugs of established quality corresponding to their national health needs” (Resolution WHA28.66), Handbook of resolutions and decisions of the World Health Assembly and Executive Board, Volume II, 1973-1984. Geneva, World Health Organization, 1985:129.

<sup>93</sup> WHO, Essential Medicines List and WHO Model Formulary, available at , [http://www.who.int/selection\\_medicines/list/en/](http://www.who.int/selection_medicines/list/en/) (last visited Feb. 10, 2009)

<sup>94</sup> The World Health Organization (“WHO”) defines “essential medicines” as “those that address the priority health care requirements of a given population.” <http://www.who.int/mediacentre/factsheets/fs325/en/index.html> (last visited Feb 10, 2009).

amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.<sup>95</sup> When WHO Model List of Essential Drugs was prepared in 1977, this concept did not connect to the right to health.<sup>96</sup> The WHO for years overlooked the connection between the essential medicines and the right to health and left this concept in a contentious and uncertain status.<sup>97</sup> Until the adoption of General Comment 14, this gap was sealed.

General Comment 14 highlighted the right of access to essential medicines as a core obligation of the right to health. This linkage imposes on states an obligation to ensure the access to essential medicines with its maximum efforts by any appropriate means. Since the core obligation is the minimum level states should attain, states apparently can no longer raise any financial defense to relieve this obligation. Such unalienable obligation also provides states justified grounds to apply exceptions to exclude the protection of intellectual property if states lack access to essential medicines.

#### **4.2.3.2 The Application of the Model List of Essential Medicines**

The General Comment 14 highlighted states have obligations to ensure the access to essential medicines regardless of how many resources they have. Still in reality, the realization of this obligation will rely on how many available resources states have. The concept of the essential medicines helps states to set priorities for all aspects of the

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<sup>95</sup> WHO, *Equitable Access to Essential Medicines: A Framework for Collective Action*, Mar, 2004 [http://whqlibdoc.who.int/hq/2004/WHO\\_EDM\\_2004.4.pdf](http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.4.pdf) (last visited Feb. 10, 2009).

<sup>96</sup> WHO, *The WHO Essential Medicines List (EML): 30th anniversary*, <http://www.who.int/medicines/events/fs/en/index.html> (last visited Feb 10, 2009).

<sup>97</sup> Jonathan D Quick & Hans V Hogerzeil. *Ten best readings in . . . essential medicines*, *Health Policy and Planning*. Mar 2003. Vol. 18, Iss. 1, p. 119.

pharmaceutical system and use essential medicines appropriately. Through careful selection of an appropriate range of essential medicines, states may allocate their available resource to provide a "higher quality of care, better management of medicines (including improved quality of prescribed medicines), and more cost-effective use of health resources."<sup>98</sup>

According to the WHO, the concept of essential medicine can be applied in the following areas:<sup>99</sup>

- (1) Basic and in-service training of health care providers
- (2) Public-sector procurement and distribution
- (3) Medicine benefits as part of health insurance
- (4) Drug donations and international aid
- (5) Monitoring systems on availability and pricing
- (6) Public education.

Apparently, the Model List is designed to assist states to formulate their national health policies. Yet, the research showed that it could help in breaking down the price of medicines.<sup>100</sup> The Model List provides developing countries as a reference to establish its national essential list and require their health institutions and health care scheme to cover the drugs under the lists. Thus, the Model List though is not binding, but it is a powerful

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<sup>98</sup> WHO, WHO Medicines Strategy Revised Procedure for Updating WHO's Model List of Essential Drugs Report by the Secretariat, EXECUTIVE BOARD 109th Session, EB109/8, page 1 (Dec. 7 2001), [http://www.who.int/selection\\_medicines/committees/subcommittee/2/eeb1098%5b1%5d.pdf](http://www.who.int/selection_medicines/committees/subcommittee/2/eeb1098%5b1%5d.pdf) (last visited Feb 12, 2009)

<sup>99</sup> WHO, *The Selection of Essential Medicines*, WHO Policy Perspectives on Medicines, Issue No.4, June 2002, page 2, [http://whqlibdoc.who.int/hq/2002/WHO\\_EDM\\_2002.2.pdf](http://whqlibdoc.who.int/hq/2002/WHO_EDM_2002.2.pdf) (last visited on Feb 12, 2009)

<sup>100</sup> John D. Pinzone, Note, The Affordable Prescription Drug Act: A Solution for Today's High Prescription Drug Prices, 16 J.L. & Health 145, 167 (2001).

tool to reduce the price of medicines than other price control tool.<sup>101</sup> Currently, the concept of essential medicine has become a basis that developed countries develop an optimal compulsory licensing system to implement the 2003 WTO Decision. In accordance with this Decision, the developed countries can grant compulsory license to manufacture life-saving medicines for export to developing countries, such as 2006 US Life-Saving Medicines Export Act<sup>102</sup> and the 2004 Canadian Pledge to Africa Act.<sup>103</sup> Therefore, once a medicine selected to be placed in the Model List, then the price will be predictably reduced to the price of the comparative generic medicine. In this manner the longer the list of essential medicines the more capable individuals will have access to medicines.

Expanding the Model List could provide more access to medicines provided that the selection of essential medicines can include all new medicine without limitations. Yet, this is not realistic. The adequate selection of essential medicines should be based on factors such as disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. In such way, the protection of the right to health can strike a balance with the promotion of the pharmaceutical research as well as effective protection of material interests of innovators. Nevertheless, how to select essential medicines to meet the goals set by the WHO is a real challenging.

In practice, many human right advocates criticized the WHO's selection criteria of Model

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<sup>101</sup> Jennifer A. Lazo, NOTE: The Life-Saving Medicines Export Act: Why The Proposed U.S. Compulsory Licensing Scheme will Fail To Export any Medicines or Save any Livesname: 33 Brooklyn J. Int'l L. 237, 2007.

<sup>102</sup> See 152 CONG. REC. S233-01, S5245 (daily ed. May 25, 2006) (statement of Sen. Leahy).

<sup>103</sup> See The Jean Chrétien Pledge to Africa Act, 2004 S.C., ch. 23 (Can.).

List based mainly on the cost of medicines rather the effectiveness of drugs.<sup>104</sup> They argued that the Model List of Essential Medicines supposed to be a list of medicines to save human lives, but the selection criteria excludes some expensive newer treatments that remain covered by patents. Many critics even derided the Model List is not essential and pointed out that it is not a list of all life-saving medicines.<sup>105</sup> The WHO's expert countered this argument by saying that the selection criteria expanded after 2002, the current selection criteria was not limited on the patent status and prices of medicines alone. However, WHO's explanations are not persuasive, because ninety-eight percent of drugs in the Model List are off-patent products in the US.<sup>106</sup> Moreover, 11 are patented antiretroviral drugs used for the treatment of AIDS and only three patented drugs on the ED.<sup>107</sup> In this regard the scope of essential medicines should be revised at concerns of cost-effectiveness, as it claimed. The essential medicines should be considered to list the patent medicines if they are deemed to be "essential"; that is no other comparative generic drugs provide same "significant" effective treatment.

### **4.3.3 The Definition of Health Emergency and Compulsory License Scheme**

The International Health Regulations, adopted in 1969 were primarily intended to monitor and control six serious infectious diseases: cholera, plague, yellow fever,

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<sup>104</sup> David W. Opperbeck, Patents, Essential Medicines, and the Innovation Game, 58 Vand. L. Rev. 501 (2005)

<sup>105</sup> Amy Kapczynski et al., Addressing Global Health Inequities: An Open Licensing Approach for University Innovations, 20 Berkeley Tech. L.J. 1031, 1047-49 (2005).

<sup>106</sup> James Packard Love, Letter asking WHO review of the Essential Drugs List (EDL) as it relates to patented products, Dec. 2006, also available at <http://www.cptech.org/blogs/ipdisputesinmedicine/2006/12/letter-asking-who-review-of-essential.html> (last visited Feb. 12, 2009)

<sup>107</sup> *Id.*

smallpox, relapsing fever and typhus.<sup>108</sup> It was revised in 2005 and its scope was broadened.<sup>109</sup> The main function of current IHR establishes a cooperative scheme that countries can work together to save lives and livelihoods caused by the international spread of diseases and other health risks without interference of trade and travel. This set of rules includes instructions for states to determine a health emergency in international level. According to the IHR, a “public health emergency of international concern” is defined as “an extraordinary event which is determined (i) to constitute a public health risk to other member states through the international spread of disease and (ii) to potentially require a coordinated international response.”<sup>110</sup> The WHO Director further added; “the health emergency shall be determined, on the basis of the information received . . . whether an event constitutes a public health emergency of international concern in accordance with the criteria and the procedure set out in these Regulations.”<sup>111</sup>

The 2005 IHRs provides an instruction for WHO members to identify what may or may not constitute a public health emergency of international concern. The instruction has members go through the questions under Annex 2 of the 2005 IHRs.<sup>112</sup> If there are more than two “yes” answers to any of the following four questions in a given event or risk,

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<sup>108</sup> The former set of international health regulations, adopted in 1969, applied only to cholera, plague, and yellow fever. See, WHO, Frequently Asked Questions about the International Health Regulations, No 1, available at <http://www.who.int/csr/ihr/howtheywork/faq/en/index.html> (visited Feb 10, 2009).

<sup>109</sup> World Health Assembly, Third Report of Committee A, A58/55 at art 2 (May 23, 2005), available at [http://www.who.int/gb/ebwha/pdf\\_files/WHA58/A58\\_55-en.pdf](http://www.who.int/gb/ebwha/pdf_files/WHA58/A58_55-en.pdf) (last visited Feb. 10, 2009) (hereinafter IHRs 2005). In this report, the World Health Assembly officially adopted the IHRs 2005 and included its provisions in the document.

<sup>110</sup> IHR, art. 1.

<sup>111</sup> IHR, art. 12.1.

<sup>112</sup> IHR, art. 12.4.

health risk or event in question potentially may be indentified as a public health emergency of international concern. Then, members must report that emergency to the WHO for final determination. The four identification questions are listed as follows:<sup>113</sup>

- (1) "Is the public health impact of the event serious?";
- (2) "Is the event unusual or unexpected?";
- (3) "Is there a significant risk of international spread?"; and
- (4) "Is there a significant risk of international travel or trade restrictions?"

The IHRs 2005 provides guidance as to how to indentify a "public health emergency of international concern" through the criteria mentioned above. The new revision is no longer using a rigid standard to indentify an internal emergency. Instead, this revision provides a more responsive way to indentify the international emergency. This means that a public health emergency is not only an outbreak under a list of communicable diseases. It may cover more situations, such as an outbreak of new infectious disease not in the list. It is true that the regulations is not the best way for states to determine what "public heath emergency" is, because some may argue the measures are too broad and procedure will take long time to run.<sup>114</sup> Yet, still this procedure is helpful to resolve the issues raised by TRIPS, when it comes to declaring health emergency.<sup>115</sup>

As noted in the previous chapter, in case of a health emergency, the definition of health emergency results in a significant legal effect in TRIPS. Article 31 of TRIPS provides members a ground to grant authorization of use of patent without permission of patent

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<sup>113</sup> Mack, *supra* note 93, at 374-375.

<sup>114</sup> *Id.*

<sup>115</sup> See our discussion of this aspect in chapter three

holders, if states raised the health emergency defense. In such an authorization, the government can waive the negotiating process with patent holders. Moreover, states may use TRIPS flexibilities to increase the access to medicines, when they are under the circumstance of health emergency. Thus, the definition of public health emergency of international concern provides a basis as to how to evaluate the situation as an emergency.

The standards set out by the IHR do not only provide states with a framework to determine whether an international health crisis exists; it also guides states as to how to respond to such a crisis. Moreover, once an event reaches a level of a health emergency, states, can, no doubt grant the compulsory license if the availability of necessary medicines is in question. The typical situation was the bird-flu case in Asia,<sup>116</sup> and the 2001 anthrax cases in North American.<sup>117</sup>

#### **4.3.4 WHO's Prequalification Project and Data Protection**

The Prequalification Program is a procedure that provided by the WHO to evaluate the quality, safety and efficacy of generic medicines to facilitate access to HIV/AIDS, malaria and tuberculosis medicines.<sup>118</sup> The idea of this program is to establish a international pharmaceutical marketing approval scheme to increase to access to medicines in the disease-plagued, African nations.<sup>119</sup> The function of WHO in this

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<sup>116</sup> Kathrin Hille, Taiwan licenses Tamiflu for local companies, Financial Times, (London UK), Nov 26, 2005. p. 4.

<sup>117</sup> See chapter 3.

<sup>118</sup> WHO, The WHO prequalification project, 2004, <http://www.who.int/mediacentre/factsheets/fs278/en/> (last visited Feb. 10, 2009).

<sup>119</sup> David W. Childs, The World Health Organization's Prequalification Program and Its Potential Effect on Data Exclusivity Laws, 60 Food & Drug L.J. 79, at 79-80 (2005).

program is similar to the US Food and Drug Administration (FDA) to grant a marketing approval for drugs, in particular generic drugs.

The procedure includes two types;<sup>120</sup> one is for approving generics and another is for new chemicals. In case of approving products containing new active pharmaceutical ingredients, pharmaceutical innovators generally must submit a complete data set. Those data can be approved by any one of the regulatory authorities in the International Conference on Harmonization (ICH)<sup>121</sup> region and associated countries including among others the EU, Japan and the USA.<sup>122</sup> Thus, the standard for the approval of new chemical in Prequalification Program is based on the same standard of the ICH. When the product submitted for prequalification is a generic product, the applicant should provide only a summary of pharmaceutical data. A copy of summary usually includes toxicological, pharmacological and clinical information on each of the Active Pharmaceutical ingredients.<sup>123</sup> Currently, 150 medicines have been approved through this program and only several medicines are patented.<sup>124</sup>

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<sup>120</sup> Guide on Submission of Documentation for Prequalification of innovator Finished Pharmaceutical Products (FPPs) used in the treatment of HIV/AIDS, malaria and tuberculosis and approved by Drug Regulatory Authorities (DRAs) in the International Conference on Harmonization (ICH) region and associated countries, including among others the EU, Japan and USA, <http://healthtech.who.int/pq/> (last visited Feb. 10, 2009).

<sup>121</sup> The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.

<sup>122</sup> Childs, *supra* note 119, at 79-80 (2005).

<sup>123</sup> Guideline on Submission of Documentation for Prequalification of Multi-source (Generic) Finished Pharmaceutical Products (FPPs), Used in the Treatment of HIV/AIDS, Malaria and Tuberculosis, <http://healthtech.who.int/pq/> ( last visited Feb. 10, 2009)

<sup>124</sup> *Id.*

The Prequalification Project can increase access to medicines because it avoids having generic drug manufacturers submit existing pharmaceutical data. The examiner of the project requires the applicant only to show that the generic product has the same effect and as safe as the brand-name product it purports to copy.<sup>125</sup> To prove such effect, the applicant for approving generic products must offer data on the active pharmaceutical ingredients, the specifications, the product formula, the manufacturing method, stability, and interchangeability, but no clinical trials are required for the approval.<sup>126</sup> The active pharmaceutical ingredient, specifications and interchangeability information guarantees the effect of products is the same as the brand-name product. In addition, the manufacturer is required to meet the WHO Good Manufacturing Practices (GMPs). Under the GMP system, pharmaceutical products can be ensured that they are “consistently produced and controlled according to quality standards appropriate to their intended use and as required by the product specification.”<sup>127</sup>

The Prequalification Program is a service, to provide the examination of the safety and efficacy of drugs used to fight diseases plaguing Africa.<sup>128</sup> The aim of the program is to select a list of products, which comply with the international quality standard. As WHO proclaims:

“The Prequalification project is part of these activities and mandate. It does

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<sup>125</sup> Childs, *supra* note 119.

<sup>126</sup> *Id.*

<sup>127</sup> WHO, Good Manufacturing Practice, available at [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/production/en/index.html](http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/index.html), (last visited Feb 10, 2009)

<sup>128</sup> Childs, *supra* note 119.

not intend to replace national regulatory authorities or national authorization systems for importation of medicines. Prequalification draws from the expertise of some of the best national regulatory authorities to provide a list of prequalified products that comply with unified international standards.”<sup>129</sup>

From a legal perspective, the Project has the potential effect of alleviating impacts of data exclusivity because no clinical trials are required for obtaining WHO’s approval. Assuming that, WHO could establish itself as the principal internationally-recognized authority on the safety and efficacy of generic pharmaceutical products in developing countries, the generic medicines can rely on such reference without waiting the expiry of data protection.<sup>130</sup> In this way, the WHO can become the gateway for distributing generic pharmaceutical products to the developing countries, or other necessary countries. This may be an alternative way to resolve some difficulties relating to the implementation of compulsory licenses and other mechanisms to increase access to medicines.

#### **4.4 Recent WTO Developments Relating to the Implementation of the Right to Medicines**

##### **4.4.1 The Relationship between Human Rights and Intellectual Property**

There is no doubt that the implementing of TRIPS raises the cost of protection of intellectual properties for all states, but in particular, developing countries are hardly hit. Because of this, the developing countries argued that strict intellectual property laws is the reason that they can no longer afford basic human needs, such as healthcare, food, and educational materials. The tension between the protection of human rights and the implementation of TRIPS draw the attention of the U.N. Sub-Commission on the

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<sup>129</sup> WHO, The WHO prequalification project, 2004 <http://www.who.int/mediacentre/factsheets/fs278/en/> (last visited Mar 2, 2009).

<sup>130</sup> Childs, *supra* note 119, at 97

Promotion and Protection of Human Rights (the Sub-Commission) in 2000. On August 17, 2000, the Sub-Commission adopted Resolution 2000/7, entitled "Intellectual Property Rights and Human Rights."<sup>131</sup> The Resolution attempts to reduce intellectual property rights by asserting the priority of human rights over economic policy. The Sub-Commission's stated that international intellectual property laws were not adequately accounting for human rights norms.<sup>132</sup> Further, Resolution 2000/7 also called on U.N. Member States, intergovernmental bodies, and various U.N. entities to reaffirm their commitments towards of human rights, adopt a human rights approach to the development of international intellectual property regimes, and further study the interaction between intellectual property protection and human rights. The resolution; though not binding, its language firmly supports the position that human rights must not be compromised.

#### **4.4.2 The Implementation of TRIPS flexibilities to Access to Medicines**

In previous chapter, we have discussed Doha Declaration, subsequent Decision and Amendment. This series of events showed WTO's efforts to increase access to medicines by providing a framework for the implementation of intellectual property in a contemporary sense; that is balancing other social interests. The framework is established based on the expanding the flexibilities in TRIPS to increase the access to medicines.<sup>133</sup>

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<sup>131</sup> UN ESCOR: Sub-Commission on the Promotion and Protection of Human Rights, 52nd Sess, UN Doc E/CN.4/Sub.2/RES/2000/7 (2000) ("Resolution 2000/7").

<sup>132</sup> David Weissbrodt & Kell Schoff, Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7, 5 Minn. Intell. Prop. Rev. 1 (2003).

<sup>133</sup> Musungu & Oh, *supra* note 18..

These flexibilities at least include several measures as follows:<sup>134</sup>

- (1) Least Developed Countries should suspend the operation of their patent, test data protection and market exclusivity with respect to medicines until 2016.<sup>135</sup>
- (2) To ensure the widest possible use of compulsory license, the countries should incorporate within their patent law and other related regulations to grant compulsory licenses.
- (3) In order to raise the exception of governmental use (Public and non-commercial Use), states should incorporate within domestic regulation to allow governmental uses.
- (4) Countries should avail themselves of the widest scope in terms of parallel imports and incorporate explicit provisions to put into effect an international exhaustion regime in their nation patent law.
- (5) Expand the exceptions of patent right under Article 30.
- (6) Exclude the new use of know product or process from patentability.
- (7) Limits on the Protection of Pharmaceutical Data.

The WTO members expected that implementing TRIPs flexibilities through the adoption of the Doha Declarations would efficiently increase access to medicines. However, a research in 2006 revealed that these expectations were misplaced. The research found only few developing countries availed themselves from the TRIPs flexibilities.<sup>136</sup> In these countries, “governmental use” and compulsory licenses are the only ways state use to increase access to medicines. It is obvious that this outcome was likely a result of restrictions as to how to use the flexibilities and the lack of knowledge of using other flexibilities. In either case, the majority of states who are in bad need to expand access to

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<sup>134</sup> *Id.*, at 12-72.

<sup>135</sup> See, The TRIPs Council’s Decision of June 27, 2002, WTO Document IP/C/W/25.

<sup>136</sup> Musungu & Oh, *supra* note 18, at exclusive summary.

medicines were not able to. Moreover, it is likely that developing countries are afraid to use the flexibilities because such a move would likely move foreign investments to other countries. The best example is Thailand. The grant of compulsory license to the manufactures of heart disease or AIDS resulted in withdrawal of foreign pharmaceutical investment in Thailand in 2007.

#### **4.5 Reconciling Trade-Intellectual Property with the Right to Medicines**

Why intellectual property regime should be reconciled with the Right to Medicine? The first question to be asked is that why countries protect intangible rights? In the answer to this question lies the first clue, which the key to understanding the function of protection in different parts of the world is. While the developed countries protect intellectual property in order to promote research and develop technology, developing countries protect them, mainly, to secure good trade relations and keep or attract foreign investments.<sup>137</sup> It is true that many factors affect the direct foreign investment, but strong, protective intellectual property system is the determinant factor for multinational corporations to consider technology transfer and investment.<sup>138</sup> This situation provides developing countries the first strong ground to adopt the strong intellectual property policy. The need to enter bilateral or regional trade agreements is another ground, perhaps the most important one, to force the developing countries to adopt the strict intellectual property laws.

To enter the bilateral agreement or regional agreement, the developing countries are

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<sup>137</sup> Robert Bird and Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 *Am. Bus. L. J.* 283, at 285-286.

<sup>138</sup> *Id.*

required to adopt the same level of protection of intellectual property in their trade partners, such as the US or the EU. The developing countries need to sell their agriculture products or other goods in the developed countries as well as obtain foreign investments and technology transfer, while the developed countries hope to sell their technology products in developing countries. The profit the developed countries expect is relied on the protection of technology. Such profit cannot be secured if the developing countries cannot provide the same level of protection as the US or the EU. Once the developing countries enter into regional or bilateral agreements, they may attract the foreign investments but they lose their freedom to decide what kind of intellectual property system they should adopt. Hence, they find themselves adopting a system that goes against their own interest and against their understanding of intellectual property rights.

According to Article 15 paragraph 1 (c) of the ICESCR, the right of to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author, is a human right. In General Comment 17, the Committee pointed out that the human right recognized in Article 15 paragraph 1 (c) of the ICESCR safeguards the personal link between authors and their creations as well as their basic material interests, which are necessary to enable authors to enjoy an adequate standard of living. That is states are obligated to protect intellectual property to ensure authors or inventors to enjoy an adequate standard of living under ICESCR.<sup>139</sup>

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<sup>139</sup> In fact, in General Comment 17, the Committee distinguished the human right recognized in article 15, paragraph 1 (c) from the intellectual property rights in two aspects. First, it pointed out the intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else, while human rights are timeless expressions of fundamental entitlements of the human person.

The second difference between them is human right recognized in article 15, paragraph 1 (c) safeguards the personal link between authors and their creations and between peoples, communities, or other groups and their collective cultural heritage, as well as their basic material interests which are necessary to enable

Apparently, it is not legally wrong to protect the intellectual property, but the protection is not absolute. The General Comment 17 clarified that the protection of material interests resulting from one's scientific productions should constitute no impediment to states' ability to comply with their core obligations in relation to the rights to health. Further, it tells us that intellectual property is a social product and has a social function; thus when States parties protect the material interests of authors or creators, they have a duty to prevent unreasonably high costs for access to essential medicines. This reasoning echoes the underlying philosophy of General Comment 14. General Comment 14 requires states to make the maximum efforts to ensure access to essential medicines; this obligation cannot be absolved regardless of whether states have sufficient resources. Consequently, the right to access medicines and the right to protect the material interests of authors or creators to provide basic living standard are equally important. On one hand, through the realization of the right to access medicines, the goal of right to protect the material interests can be attained; on the other hand, the realization of the right to protect material interests can ensure the right to access to medicines. In this way both rights are reconciled.

#### **4.5.2 Approaches to Reconcile Trade-Intellectual Property and Access to Medicines**

##### **4.5.2.1 New Development, Introduction to the Medical Research and Development Treaty**

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authors to enjoy an adequate standard of living, while intellectual property regimes primarily protect business and corporate interests and investments. In this sense, the protection of intellectual property can be a human right if its protections are only to enable authors to enjoy an adequate standard of living; then it is the human right. Therefore, the difference between intellectual property regime and the human right of 15 (c) is the level of protection but not the essence of the rights.

The Medical Research and Development Treaty (MRDT)<sup>140</sup> was submitted to WHO by more than 150 NGOs, public health experts, economists, and legal scholars in February 2005.<sup>141</sup> The treaty aims to establish a new legal framework to promote research and development for pharmaceuticals and other medical treatments. In particular, this treaty, for the first time incorporates the right to essential medicines into an intellectual property treaty. It recognizes human rights and the goal of all sharing in the benefits of scientific advancement.

Taking the human right approach, this treaty attempts to reshape the protection of pharmaceutical patent and data protection under the TRIPS and other regional or bilateral agreements. The drafter argued that expansive intellectual property protection rules in the TRIPS and other bilateral, regional agreements made it hard to use TRIPS flexibilities, which harm the right to access essential medicines. Further, they argued that the expansion of protection of intellectual property only formed the commercially oriented pharmaceutical researches. Thus, the pharmaceutical companies manufacture costly and wasteful marketing of drugs and medical products because they are profitable. In addition, the economic incentive intellectual property scheme drives the pharmaceutical companies toward developing the profitable medicines rather than the necessary medicines that can treat individuals throughout the developing countries.<sup>142</sup> By contrast, this treaty is highly

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<sup>140</sup> Treaty on Medical Research and Development [hereinafter MDRT, 2005 Draft], available at <http://www.cptech.org/workingdrafts/rndtreaty4.pdf> (last visited Feb. 12, 2009).

<sup>141</sup> Proposal for Treaty on Medical Research and Development (Feb. 2005), available at <http://www.cptech.org/workingdrafts/rndtreaty.html> (last visited Feb. 12, 2009).

<sup>142</sup> Helfer, *supra* note 1, at 1007-1009.

focused on balancing the right to access medicines in the following aspects:<sup>143</sup>

- (1) promoting medical investments to meet greatest global need;
- (2) fairly allocating the costs of such innovation among governments, and sharing the benefits of medical innovation;
- (3) promoting equitable access to new medical technologies; and
- (4) enhancing the transfer of technological knowledge.

There are two distinctive features of MRDT from the current intellectual property scheme.<sup>144</sup> First, the treaty adopts the concept of public good; which takes some fields of medicines out of the protection of patents. It means that all governments develop the medicines in these fields together and share the benefits of research. In this way, the research can be focused on medicines for neglected diseases rather than only profitable

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<sup>143</sup> 2.1 Objective of Treaty (MRDT, 2005 Draft) reads: Members seek to promote a sustainable system of medical innovation that will:

- i. ensure adequate and predictable sources of finance for medical research and development,
- ii. allocate fairly the costs of supporting medical research and development,
- iii. identify priority areas of research and development,
- iv. encourage the broad dissemination of information and sharing of knowledge, and access to useful medical inventions,
- v. enable medical researchers to build upon the work of others,
- vi. support diversity and competition,
- vii. utilize cost effective incentives to invest in promising and successful research projects that address health care needs,
- viii. enhance the transfer of technological knowledge and capacity in a manner conducive to social and economic welfare and development, and
- ix. promote equitable access to new medical technologies, so that all share in the benefits of scientific advancement.

<sup>144</sup> 2.2 Mechanisms to Support Research and Development reads (MDRT, 2005 Draft): The treaty will provide:

- i. Obligations for minimum levels of investment in medical research and development,
- ii. Processes for priority setting,
- iii. Obligations and Incentives to support
  - a. Medical research and development, including priority research and development,
  - b. broader dissemination of scientific information and knowledge,
  - c. enhanced transfer of technology and capacity for research and development in developing countries, and
- iv. Obligations and standards for transparency, including mechanisms to report, measure and understand the nature of the scientific, economic and

diseases. In order to enforce this treaty without restrictions of other agreements, this treaty requires all the signatories to agree “to forgo dispute resolution cases” that concern (1) the TRIPS provisions protecting patents and undisclosed test data, or (2) the “pricing of medicines.”

The treaty is the fruit of reconciling related interests, including the intellectual property, human rights and the promotion of technology. As the letter to WHO proclaimed, it was

“One that seeks to provide the flexibility to reconcile different policy objectives, including the promotion of both innovation and access, consistent with human rights and the promotion of science in the public interest. The draft treaty provides new obligations and economic incentives to invest in priority research projects, and addresses several other important topics.”

Its emergence demonstrates that the need of new element to the current intellectual property. Although treaty's provisions and underlying philosophy are arguable, it is incontestable that the readjustment of current intellectual property scheme is necessary.

#### **4.5.2.2 A New Limit of Intellectual Property Regime**

Because the treaty might take a long time to be adopted, people should explore other possibilities to reconcile Intellectual property and human rights. In this regard, General Comments 14 and 17 might give an insight on how to achieve this end. Through the overall analysis of General Comment 14 and General Comment 17, it is recognized that states' obligations to ensure the right to access essential medicines and states' obligations to protect the material interests of creator are compatible. Indeed, the access to medicines should be a new limit of implementing intellectual property law. This limit is incorporated in Article 7 of TRIPS, which identifies the need to balance rights with obligations. However, neither Article 7 nor TRIPS provide guidance on how to strike this balance. The lack of guidance, in turn, has confused members as to how they use the

flexibilities in accordance with its own objectives. This shortage results in some disputes in the late 1990s when states implemented the TRIPS flexibilities. The Doha Declaration tried to clarify the ambiguous flexibilities in the TRIPS, but a research in 2006 showed the measures that states adopt limited on the compulsory license and governmental use. The result has been predicted by 2001 Report of the High Commissioner on the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights (2001 Expert Report). In the Expert Report, it was pointed out that “although the TRIPS provides sufficient flexibilities to ensure the right to access to medicines, the prevention of anti-competitive practices and the abuse of rights, the promotion of technology transfer, special and differential treatment for least developed countries are merely referred to, the TRIPS does not establish the content of these responsibilities, or how they should be implemented.”<sup>145</sup> It suggested that states should use these flexibilities to establish an intellectual property scheme to reconcile the right to medicines, by observing the followings:<sup>146</sup>

- (1) The scope of IP systems should not be too broad to block future medical research. For example, the patent of “me-too” drugs<sup>147</sup> should be prohibited, because they are similar to the existing patent but no significant difference.
- (2) The promotion of the right to health.
- (3) The prevention of the abuse of IPRs. For example, Articles 8 and 40 of the TRIPS prohibit anti-competitive practices. Thus, the use of patent or pharmaceutical data block further medical research and development efforts

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<sup>145</sup> Report of the High Commissioner on the impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights, E/CN.4/Sub.2/2001/13, 27 June 2001.

<sup>146</sup> *Id.*

<sup>147</sup> A drug that is structurally very similar to already known drugs, with only minor differences.

can be restricted.

- (4) The promotion of access to affordable essential drugs. Using TRIPS flexibility increase the access to affordable essential drugs, such as the grant of compulsory licenses for patents grounds on Article 31 of TRIPS, parallel importation of patented pharmaceuticals.

Basically, the 2001 Expert's Report develops a new theory for states to build up an ideal intellectual property system. That is adding the new element into the current intellectual property regime. By adding this new element, the access to medicines, becomes a limit to the unlimited expansion of intellectual property from up to down. That is to say, the scope of exclusive rights, exceptions of exclusive rights, anti-competitive practice, patent misuse, eligibilities of parallel importation, compulsory license scheme and all measures consistence with the TRIPS should be considered from the perspective of the right to access to essential medicines.

#### **4.6 Conclusion**

Since the international community, as far as the late 1990s is aware of the potential conflict between the implementation of TRIPS Agreement and the realization of the rights to health, series of actions were taken. These actions attempted to resolve any possible conflict that might affect the right to health and medicines. The approach was that this issue must be resolved in a way that does not overstate the importance of the right to health or the protection of pharmaceutical innovation, but rather that to reconcile these two interests step by step. The process of reconciliation can be summarized in three historical stages; namely the Pre-Doha, the Doha Round, and after Doha era. These three stages is the key to understand the recent developments relating to both, the right to medicines and the protection of pharmaceutical products. In each of these stages, it was

obvious that states attempted to develop normative framework, guidelines and instructions that preserve the integrity of the current intellectual property regime but also respond to the recurrent shortcomings of the global health system.

The Pre-Doha stage is the initial process of the reconciliation. This stage began from the late 1990s until the adoption of the Doha Declaration in 2001. In this stage, it was apparent that the international community is aware of the impact of implementing the TRIPS on the right to health or the right to medicines. Their awareness became the underlying incentive for a movement that, in depth, explored the right to health and clarified states' obligation to protect this right. Indeed, the term right to health has been incorporated into the various global and regional human rights instruments since World War II. These human rights instruments, though in theory guarantee the individual's right to health, in reality this right remains just a lofty ideal for many. One of the factors that contributed to the right being unrealizable for many was that, the right's content and scope were not clear. In fact the jurisprudence relating to the right to health and the requirements to fulfill this right were not established, not until the adoption of General Comment 14. In this respect, perhaps the adoption of the Comment remains the most significant achievement of this stage. The Comment clarifies several things about the right to medicines and gives clear instructions for states as to how to enforce this right. It adopted the concept of essential medicines and Model List of Essential Medicine, which were introduced by the WHO in 1977. By adoption of these two concepts, the Committee successfully connected the WHO's functions with human right and this made the WHO regulation binding on states. More importantly, it clearly states that the right to health, including the right to essential medicines is a fundamental "human right." The states have

obligation to protect this right with maximum efforts to ensure the access to essential medicines. Therefore, states realized that national policies, in every aspect, should take account of the right to access essential medicines, and this consideration, in turn, impacted the intellectual property law.

In the second stage, 2001-2005, namely the Doha Round stage, states recognized their obligation to protect the right to health and to ensure access to essential medicines. The jurisprudence, established by General Comment 14 and subsequent intellectual property and human rights debates made by the UN Sub-Commission on Human Rights, namely resolution 2001/21 have greatly influenced this era. These initiatives coupled with the mounting international concern from NGOs and developing countries called on WTO members to implement the right to access medicines. After prolonged negotiations, the WTO completed the 2001 Doha Declaration, 2003 Decision and 2005 Amendment. These documents attempted to strike a balance between the intellectual property and the access to medicines. Indeed, these three documents regardless of how much positive impact they had on the implementation of the right to medicines, they began a new relationship between intellectual property and human rights. The WHO as the default UN agency to promote the right to health also has a few contributions on access to medicines. By adoption of the International Health Regulation, it defined the term "health emergency", which provides WTO member states a standard to trigger the health emergency exception to exclude patent or data exclusivity in TRIPS. Meanwhile, the adoption of Prequalification of Program also alleviates the impact of implementing data exclusivity on access to medicines. In sum, this stage successfully introduced the human right element-the right to health into the intellectual property regime.

The third stage, namely After-Doha Round is after the emergence of the 2005 Amendment until today. This stage is evolving. By the introduction of the new element into the intellectual property, i.e., human rights, the international community began to design various strategies to meet the goals set out in the Doha Declaration on the TRIPS Agreement and Public Health. Not long after the emergency of the 2001 Doha Declaration and 2005 Amendment of TRIPS, their influence began to appear. In the global level, in 2008, the WHO adopted the Global Strategy and Plan of Action on public health, innovation and intellectual property, which is focused on access to essential medicines for diseases specifically found in developing countries.<sup>148</sup> Unlike human rights instruments, the Strategy does not use the human rights' inspirational and lofty language, it is rather quite practical. It specifies every task, itemizes every action and distinguishes the obligations of states, WHO, and international organizations. In the regional level, the US trade policy incorporated the Doha Declaration, recognized the flexible interpretation of TRIPS and confirmed to use the flexibilities in TRIPS to increase the access to medicines. In the domestic level, at least the US, and Canada have adopted new compulsory license scheme in order to provide medicines which are needed in the developing countries.

The main underlying idea of the Doha Declaration is based on the reform of the current compulsory license scheme and mitigating the impact of some hardships that was existed because of the rigid requirements of the exceptions that was originally allowed by

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<sup>148</sup> The Intergovernmental Working Group (IGWG) on Intellectual Property (IP), Innovation and Health was established under the World Health Assembly (WHA) Resolution 59.24 and completed Global strategy and plan of action on public health, innovation and intellectual property on WHA61.21, May 2008, available at [http://www.who.int/gb/ebwha/pdf\\_files/A61/A61\\_R21-en.pdf](http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf) (last visited Feb. 10, 2009).

intellectual property law. This approach seems to be the best the international community can do right now. The rest, i.e., the implementation, the international community through international cooperation, can achieve it. In fact the fruit of this new Amendment of the TRIPS, though not binding,<sup>149</sup> began to appear immediately; in 2007 according to this new compulsory license scheme Canada exported generic medicines to Rwanda.<sup>150</sup> Not only this, but there seems to be an expansion of the flexible compulsory license scheme, because this very scheme was used to provide essential medicines and medicines for the treatment of chronic diseases.

While it is true that this new scheme is still evolving, it is predicted that it will likely to become a powerful measure to resolve, if not ease the tension between the right to medicines in the developing countries and the protection of pharmaceutical innovations. However, in the long run, the intellectual property in relation to the pharmaceutical products, in particular in the area of essential medicines, should be adjusted. In 2005 public health experts, economists, legal scholars and more than 150 NGO, with the support of developing countries, submitted to the WHO the Medical Research and Development Treaty (MRDT). The MRDT attempts to establish a new legal framework to promote research and development for pharmaceuticals and other medical treatments. The treaty adopts the concept of public good, which takes some fields of medicines out of the protection of patent law. Although the fate of the treaty is not yet clear, but the proposal of such a treaty *per se* is indicative of how things might, or should go in the

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<sup>149</sup> Currently, WTO members are not bound to the 2005 Amendment to the TRIPS, because it has not been ratified by two thirds of members.

<sup>150</sup> See discussion in Chapter 3.

future.

Apparently, access to medicines will be the new element or factor that shapes and defines intellectual property law. How knows, perhaps the right to medicines will be the new frontier of the intellectual property law. If this should be the case, in the near future, from bottom to top, the whole intellectual property system is likely to be adjusted and accommodated to conform to this new development. This means any measure favors the expansion of access to medicines such as limitation of scope of pharmaceutical patents or pharmaceutical data, the prohibition of anti-competitive practice, the exceptions of exclusive right, including patent and pharmaceutical data, would likely be widely used to broaden access to medicines.

## 5 A Case Study of Taiwan's Pharmaceutical Patent & Data Protection and Access to Medicines

### 5.1 Introduction

It is uncontested that the right to access medicines is successfully realized in Taiwan through the implementation of National Health Insurance, which covers 99 % of the island population.<sup>1</sup> The total health spending for this high coverage rate is about 6% of the GDP in 2008, less than 13.0 % in the US, 9.2 % in Canada, and 7.1 % in the United Kingdom, respectively.<sup>2</sup> The modest expenditure even provides the highest average number of outpatient visit per capita in the world<sup>3</sup> and low fee around \$1.5-5 for an outpatient visit.<sup>4</sup> Amazingly, this high success does not trade off the protection of pharmaceutical innovation. To the contrary, the protection of pharmaceutical patent and data adopts the same standards as the US. This made it more significant to study the Taiwanese case to understand how a developing country implements the protection of intellectual property without prejudicing the right to medicines.

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<sup>1</sup> Ma Kang-Yao, *The Achievement of National Health Insurance The Achievement of National Health, Insurance*, Jan. 8, 2006, also available at [http://www.nhi.gov.tw/english/webdata.asp?menu=11&menu\\_id=298&webdata\\_id=1929](http://www.nhi.gov.tw/english/webdata.asp?menu=11&menu_id=298&webdata_id=1929) (last visited Feb. 20, 2009)

<sup>2</sup> Tammy Chang et. al., *How Taiwan Does It: Seeing More Patient for Less*, Physician Executive, July/August 2005, page 38.

<sup>3</sup> DOH, Co-Payment Rate, available at [http://www.nhi.gov.tw/webdata/webdata.asp?menu=1&menu\\_id=6&webdata\\_id=384&WD\\_ID=](http://www.nhi.gov.tw/webdata/webdata.asp?menu=1&menu_id=6&webdata_id=384&WD_ID=) (last visited Feb. 25, 2009).

<sup>4</sup> Nicole Huang, Winne Yip, Yiing Chou and Pen-Jem Wang, *The Distribution of Net Benefits under the National Health Insurance Programme in Taiwan*, Health Policy and Planning Issue 22, 49-59 at 51 (2007).

In the previous chapters, we have explored the potential conflicts between the protection of TRIPS and access to medicines. It is also noted that these two interests should be reconciled because both of them are equally important for states. This chapter is a case study of Taiwan. Picking Taiwan was not a coincidence; it is a rather deliberate attempt to show how a developing country adopts TRIPS to protect pharmaceutical innovation in one hand and realize the right to medicines on the other hand; i.e., the reconciliation objective we want to attain. In order to analyze Taiwan case, this chapter overviews the pharmaceutical industry in Taiwan, demonstrate pharmaceutical patent and data protection, discuss the implementation of national health insurance.

Learning from Taiwan case will give some lessons as to how a country, on one hand cannot but adopt the US style protection for pharmaceutical and on the other hand, meets its obligation to ensure the right to health. Additionally, the case of Taiwan also shows that the protection of pharmaceutical innovations can be reconciled with the right to medicines even in a country, like Taiwan that has limited pharmaceutical manufacturing capabilities.

### **5.1 An Overview of Pharmaceutical Industry in Taiwan**

According to the 2008 Taiwan Pharmaceuticals and Healthcare Report, the total Taiwan's pharmaceutical market is \$4.29 billion.<sup>5</sup> This amount is less than 1 percent of global pharmaceutical market (\$735-745 billion in 2007).<sup>6</sup> The small market though is not favor

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<sup>5</sup> Taiwan Pharmaceuticals and Healthcare Report Q4 2008, at summary (Business Monitor, 2008)

<sup>6</sup> IMS Health Predicts 5 to 6 Percent Growth for Global Pharmaceutical Market in 2008, According to Annual Forecast, available at <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=2ddb1d3be7a29110VgnVCM10000071812ca2RCRD&vgnnextfmt=default> (last visited Feb. 25, 2009)

to develop a research oriented pharmaceutical market. However this small market supplied half of the country's medicines in Taiwan. Another half is imported from developed countries, such as Germany, the US, England, etc.<sup>7</sup>

The certain features with regard to Taiwan's pharmaceutical industry distinguish it from the pharmaceutical industries in Research and Developed (R&D) oriented countries. The first of these features is foreign R&D technology. The pharmaceutical industry in Taiwan normally produces products licensed by foreign manufacturers. The marketing pharmaceuticals manufactured in Taiwan only comprised about 77%. Nevertheless, 80% sale of medicines in Taiwan is produced by foreign pharmaceutical companies.<sup>8</sup> The Taiwanese Pharmaceutical companies though did some genetic related research and developed certain biotechnological products; they do not have capability to develop patent drugs. Realizing this fact, Taiwanese government had to provide higher standard of protections of pharmaceutical innovations than that offered by other developing countries in order to attract foreign investments and exchange technology transfer.

The second important feature is that local based pharmaceutical companies that are capable of manufacturing are small in terms of size and capital. Due to high cost of developing a new drug, these local companies do not have sufficient fund to do that kind of R&D. The Taiwanese government was aware about this weakness. Thus, the

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<sup>7</sup> Industry Technology & Intelligence Service (IT IS), 醫藥產業年鑑2005 [Pharmaceutical Industry 2005 Report] page 219-210, <http://www.itis.org.tw/FreePDF/25604155/台灣製藥產業概況.pdf> (last visited on Feb. 25, 2009)

<sup>8</sup> ITIS, 我國利用舊藥開發新適應症的產業機會與策略模式 [The Taiwanese Strategy and Strengthens in Developing New Drug for New Use ] available at <http://www.itis.org.tw/FreePDF/61100450/我國利用舊藥開發新適應症的產業機會與%0B策略模式.pdf>, (last visited on Feb. 25, 2009)

development strategy of pharmaceutical is focused on two aspects. With respect to R&D, governmental research centers and public universities will transfer the local pharmaceutical manufactures at low price.<sup>9</sup> With respect to manufacturing, the focus is on strengthening the ability of clinical trials and raising quality of manufacturing instead of the capability of developing new drugs. In 2003, there are 243 qualified Good Manufacturing Practice (GMP) pharmaceutical companies in Taiwan. This approach has at least two benefits for Taiwan. First, the government can decide the research focus on the medicines, which are necessary to citizens. Second, the government can build up the capability of local pharmaceutical companies to supply generic medicines.

Apparently, lack of capability of pharmaceutical R&D is the weakness of Taiwanese pharmaceutical industry. Therefore, boosting international technology transfer from multinational corporations to domestic corporations becomes the most important strategy to build up local capability of pharmaceutical manufacturing in Taiwan. In 2002, the Taiwanese Government adopted the national plan for the Development of Biotech and New Pharmaceuticals Industry<sup>10</sup> and further passed the Biotech and New Pharmaceutical Development Act in 2007.<sup>11</sup> This Act containing thirteen articles to develop biotech,

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<sup>9</sup> Mei-Yu Wang, *The Impact of Information Cultures on Managing Knowledge, a Double Case Study of Pharmaceutical Manufactures in Taiwan*, Library Review; 2006; 55, ¾; Research Library Core, pg. 29. See also, R&D <http://www.bpipo.org.tw/en/rd.html> (last visited on Feb. 25, 2009).

<sup>10</sup> The Biotechnology & Pharmaceutical Industries Office (hereinafter BPIO), Biotech Policy and Promotion Status in Taiwan, <http://bpipo.moeaidb.gov.tw/en/policy.html> (last visited Feb. 9, 2009)

<sup>11</sup> Annie Huang, Legislature Passes Biotech Act, June 09, 2007. See also Taiwan Development Center for Biotechnology (DCB), *The Overview of Biotechnology: Taiwan*, Sep 8, 2008, available at <http://www.bionetasiapacific.com/bnap/overview/taiwan.pdf> (last visited on Feb. 25, 2009).

attempts to strengthen technology transfer.<sup>12</sup> In order to establish a friendly investment environment of biotech industry, the Taiwanese government provides many incentives, such as preferential taxes, low interests loan, preferential location with low rent, and special governmental subsidies program for forging direct investments.<sup>13</sup>

With respect to the legal framework, Taiwanese government has built a legal environment to protect the foreign investments through strengthening the protection of intellectual property rights of biotechnology. The entire structure for pharmaceutical innovations is based on the intellectual property law and pharmaceutical law. The related laws with respect to the intellectual property include Patent Act, Trademark, Copyright Act, and Trade Secret Act etc.<sup>14</sup> The related pharmaceutical law and regulations includes 1993 Regulation of local clinical trial requirements, the Pharmaceutical Affairs Law, Orphan Drug Law, Good Manufacturing Practice for Medical Devices, Clinical Good Manufacturing Practice (cGMP) for Pharmaceutical Drugs, and Good Manufacturing Practice for Pharmaceuticals.<sup>15</sup>

## 5.2 Pharmaceutical Patent

Taiwan joined World Trade Organization (WTO) in 2002. Before accession, the Taiwanese government set being a WTO member state as the top priority of policy not

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<sup>12</sup> The Biotech and New Pharmaceutical Development Act (Taiwan), passed Jun 15, 2007, available at <http://lis.ly.gov.tw/npl/fast/02814/960614.htm> (last visited Feb. 20, 2009).

<sup>13</sup> BPIO, The Biotechnology Industry Investment Incentives in Taiwan 2007 – 2008, available at <http://www.biopharm.org.tw/en/download.html> (last visited Feb. 25, 2009).

<sup>14</sup> BPIO, Laws and Regulation regarding Taiwan's Biotech Industry, available at <http://www.bpipo.org.tw/en/laws.html> (last visited Feb. 25, 2009)

<sup>15</sup> *Id.*

only for economic reasons but also political considerations. Prior to accession, the Taiwanese government took several steps to remove a wide variety of tariff and non-tariff barriers, including the reform and the protections of Intellectual Property Rights (IPR). In the WTO accession agreement, the Taiwanese government promised to amend its IPR protection regime to conform the TRIPS.<sup>16</sup> Thus, the current protection of pharmaceutical patent meets the standards of the TRIPS. In the protection of pharmaceutical innovation, Taiwan government is obligated to enforce Article 27 and pertinent provisions, which require states to grant the patent to pharmaceutical products. In addition, the US laws have significant influence on Taiwanese Intellectual Property system, in particular patent law. Like US, a Taiwanese patentee has twenty years from the grant of the patent and has right to restore the patent term if it is pharmaceutical product.

### 5.2.1 The Recent Reform of Patent Act

The Patent Act was enacted in 1944.<sup>17</sup> Since then, it has been amended several times. The recent important reform of the Act resulted from the accession to the WTO. This reform appeared in the Amendments of 1997, which adjusted the existing patent act to comply with TRIPS standards.<sup>18</sup> The 1997 reform includes the right of priority,<sup>19</sup> deregulation of

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<sup>16</sup> Report of the Working Report of the Working Party on the Accession on the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu submitted to Ministerial Conference, Fourth Session, Doha, 9-13 November 2001, by Chinese Taipei, 11 November 2001, WTO document WT/MIN(01)/4, also available at [http://www.wto.org/english/thewto\\_e/acc\\_e/completeacc\\_e.htm#tpkm](http://www.wto.org/english/thewto_e/acc_e/completeacc_e.htm#tpkm) (last visited Feb. 25, 2009).

<sup>17</sup> The History of Patent Act, available at [http://www.tipo.gov.tw/ch/AllInOne\\_Show.aspx?guid=098527fc-4dac-473c-9b83-11dd6b9bc662&lang=zh-tw&path=379](http://www.tipo.gov.tw/ch/AllInOne_Show.aspx?guid=098527fc-4dac-473c-9b83-11dd6b9bc662&lang=zh-tw&path=379) (last visited Feb. 25, 2009).

<sup>18</sup> Part of Patent Act Articles Amended in May 1997 (for WTO), available at [http://www.tipo.gov.tw/en/AllInOne\\_Show.aspx?guid=47862cc7-7a88-4b8e-968b-0195850015bd&lang=en-us&path=1450](http://www.tipo.gov.tw/en/AllInOne_Show.aspx?guid=47862cc7-7a88-4b8e-968b-0195850015bd&lang=en-us&path=1450) (last visited Feb. 25, 2009).

<sup>19</sup> Before the accession of WTO, the Taiwanese government has recognized the patent right of other countries through bilateral agreements, such agreements with Spain, Phillips, Austria, France, Costa Rica,

the pre-requisites of microorganism patent for foreigners,<sup>20</sup> restoration of patent term for pharmaceutical-related or agrochemical-related patents, and extending new design patent term to 12-year, amending provisions concerning patent marking requirements, grounds of unauthorized use, etc.<sup>21</sup>

The current patent system affects pharmaceutical industry in three aspects: First it determines the subject matters of the patent; second, it deals with restoration of patent terms; and third, with respect to the right to medicines, it governs the application of the exceptions to exclude the patent protection under emergency situations. These three aspects are pretty much the legal framework by which the government protects pharmaceutical products and strikes a balance between this protection and other social interests, including the right to medicines.

## 5.2.2 Patentable Subject Matter

In Taiwan, patent are granted to three types of innovations:<sup>22</sup>

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Chile, England, Germany and the US etc., available at [http://www.tipo.gov.tw/ch/AllInOne\\_Show.aspx?path=354&guid=21f49b4b-4542-44ce-b6b1-bcf4b55c0199&lang=zh-tw](http://www.tipo.gov.tw/ch/AllInOne_Show.aspx?path=354&guid=21f49b4b-4542-44ce-b6b1-bcf4b55c0199&lang=zh-tw) (last visited Feb. 25, 2009).

<sup>20</sup> See Taiwan Intellectual Property Office (hereinafter TIPO) comment regarding the patent of microorganism (Document TIPO No. 0910002350) available at [http://www.tipo.gov.tw/ch/AllInOne\\_Show.aspx?path=1676&guid=dac84723-0fbc-46fa-a5f5-4103d591d320&lang=zh-tw](http://www.tipo.gov.tw/ch/AllInOne_Show.aspx?path=1676&guid=dac84723-0fbc-46fa-a5f5-4103d591d320&lang=zh-tw) (last visited Feb. 25, 2009).

<sup>21</sup> TIPO, Q&A about Patent, available at <http://oldweb.tipo.gov.tw/eng/howto/procedures-pl.asp#2> (last visited Feb. 25, 2009).

<sup>22</sup> Article 2 of the Patent reads:

The term "patent" referred to in this Act is classified into the following three categories:

1. Invention patents;
2. Utility model patents; and

- (1) Invention patents;
- (2) Utility model patents; and
- (3) Design patents.

The invention patent is granted for any creation of technical concepts by utilizing the rules of nature.<sup>23</sup> The utility model patent is available for the creation of any form, formation or apparatus of a structure created by technical concepts by utilizing the acts of nature, while the design patent is not required to be made by technical concepts by utilizing the acts of nature.<sup>24</sup> The design patent is distinguished from the utility patent because it is only available for any creation of the shape, pattern, color, or combination thereof of an article through eye appeal.<sup>25</sup>

In 2002, the Taiwanese Intellectual Property Office published an official comment (document no. 91 TIPO 09100041340) to distinguish these three types of patents.<sup>26</sup>

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### 3. Design patents.

<sup>23</sup> Article 21 of the Patent Act reads:

The term "invention" as used herein refers to any creation of technical concepts by utilizing the rules of nature.

<sup>24</sup> Article 93 of the Patent Act reads:

The term "utility model" shall refer to any creation of technical concepts by utilizing the acts of nature, in respect of the form, construction or installation of an article.

<sup>25</sup> Article 109 of the Patent Act reads:

The term "design" shall refer to any creation made in respect of the shape, pattern, color, or combination thereof of an article through eye appeal.

The term "associated design" as used herein refers to a creation made by the same person, which is originated from and similar to his/her original design.

<sup>26</sup> TIPO, Document No 09100041340, available at [http://www.tipo.gov.tw/ch/AllInOne\\_Show.aspx?path=1675&guid=a50940af-2db9-41e0-a022-8efd611a9868&lang=zh-tw](http://www.tipo.gov.tw/ch/AllInOne_Show.aspx?path=1675&guid=a50940af-2db9-41e0-a022-8efd611a9868&lang=zh-tw) (last visited Feb. 25, 2009).

According to this comment, the subject matters of invention patent can be a physical object or a method. A physical object includes material and physical formation. The material contains chemical, pharmaceuticals, eatable object, and bacterial. Thus, the pharmaceutical inventions are protected under the invention patent.

The protection of patent is not absolute under the Taiwanese Patent Act. Patent Act excludes certain areas to grant invention patent, utility patent and design patent. With respect to the invention patent, three areas are excluded as follows:<sup>27</sup>

- (1)Animals, plants, and essentially biological processes;
- (2)Diagnostic, therapeutic or surgical operation methods; and
- (3)An invention is contrary to public order, morality or public health.

This limitation is introduced at the time of accession to the WTO, therefore the scope of this provision, essentially is same as that of Article 27.3 of TRIPS.

In the utility patent, the Patent Act excludes the inventions contrary to public order, morality or public health to be protected. In design patents, the invented item can be rejected under any of the five enumerated grounds:<sup>28</sup>

- (1)The design is solely dictated by the function of the said article;
- (2)the design only contains art meaning;
- (3)the design is a layout of integrated circuits and electronic circuits;
- (4)the design is contrary to public order or public health; and
- (5)the shape is identical or similar to the symbols or service marks used by nations,

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<sup>27</sup> Patent Act, art. 24 (Taiwan).

<sup>28</sup> Patent Act, art. 97 (Taiwan).

political party.

In accordance with the definition of invention patent, the pharmaceutical product is patentable subject matter in Taiwan. It can be granted a patent, if the new product can meet three requirements: being novel,<sup>29</sup> being non-obvious<sup>30</sup> and being useful.<sup>31</sup>

### **5.2.3 The Patent Term and Restoration Patent Term**

The Restoration Patent Term strikes a balance between the regulations of pharmaceutical products and protection of patent. The US began to extend the patent term in 1984. The purpose to extend the patent term for another five years is considered that the effective pharmaceutical patent life is frequently less than 20 years because pharmaceutical patents only make profits after pharmaceutical products were actually marketed. According to Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act, applicants for the approval of new human drug should undergo extensive testing in animals and humans to show that the drugs are both safe and effective.<sup>32</sup> These requirements shortened the patent life of pharmaceuticals. Thus, in order to stimulate the development and innovation of pharmaceutical product, the US Congress in 1984 passed the Title II of the Drug Price Competition and Patent Term Restoration Act to extend pharmaceutical patent life to compensate patent holders for the lost of marketing time

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<sup>29</sup> The requirement of utility can be read in Article 22.1, 94.1 and 110.1 of Patent Act.

<sup>30</sup> The requirement of novelty can be read in Article 22.1, 23, 94, 95, 110 and 111 of Patent Act.

<sup>31</sup> The requirement of being non-obvious can be read in Article 22.4, 94.4 and 110.4.

<sup>32</sup> FDA, Frequently Asked Questions on the Patent Term Restoration Program, Question 1, available at, [http://www.fda.gov/CDER/about/smallbiz/patent\\_term.htm](http://www.fda.gov/CDER/about/smallbiz/patent_term.htm) (last visited Feb. 25, 2009).

while developing the pharmaceutical product and awaiting health agency approval.<sup>33</sup> The Act in the beginning applied to patent only holders whose patents claim a human drug product, medical device, food additive or color additive could recoup some of the lost patent time. In 1988, Congress extended the scope of patent restoration to animal drug products.<sup>34</sup>

The basis for patent extension is to compensate the lost of time due to pharmaceutical regulatory review.<sup>35</sup> Basically, a regulatory review period contains two parts: a testing phase, and an approval phase.<sup>36</sup> The testing phase is a period from the date of an Investigational New Drug Application) to submission of Drug Application. The approval phase is a period from the submission to obtain the marketing approval. Under the Drug Price Competition and Patent Term Restoration Act, the restoration of patent can be granted for five years because of the delay of regulatory review. In addition, the Congress limited on total patent life for the product with a cap that the patent extension cannot exceed 14 years from the product's approval date.<sup>37</sup> In this sense, if the pharmaceutical products after approval still can market 14 or more years, then patent extension is not applicable for them.

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<sup>33</sup> John R. Thomas, *Pharmaceutical Patent Law*, page 293-299 (2005).

<sup>34</sup> See *Generic Animal Drug and Patent Term Restoration Act* (Public Law 100-670) .

<sup>35</sup> FDA, *supra* note 32, at Question 8.

<sup>36</sup> *Id.*

<sup>37</sup> *Id* at Question 3.

Normally, in Taiwan, the patent term is 20 years from the date of filing for invention patent, 10 years for utility model patent and 12 years for design patents respectively.<sup>38</sup> The Taiwan Patent Act also provides the patent term extension for the pharmaceuticals.<sup>39</sup> Article 55 of the Patent Act grants a period of 2-5 years to restore the pharmaceutical patent.<sup>40</sup> This extension is restricted to exceed the actual period of regulatory review. This

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<sup>38</sup> The Patent Act, art 51 III (Taiwan), states "The term of an invention patent right shall end with twenty (20) years from the filing date of the patent application."

The Patent Act, art. 101 III (Taiwan), states "The duration of a utility model patent right shall be ten (10) years from the filing date of the patent application."

The Patent Act, art. 113 III (Taiwan), states "The duration of a design patent right shall be twelve (12) years from the filing date of the patent application; and the duration of an associated design patent right shall expire simultaneously with the duration of the original design patent right."

<sup>39</sup> Article 52 of Patent Act (Taiwan) reads:

In the case of invention patents covering pharmaceuticals, agrichemicals, or processes for preparing the same, a patentee may apply for an extension of his/her patent term for two (2) to five (5) years, if, pursuant to other acts or regulations, a prior government approval must be secured to practice such patents, for which the processing exceeds two (2) years after the publication of the patents. Only one such extension shall be permitted provided, however, that the patent term extended shall not exceed the length of time required for obtaining an approval from the central government authority in charge of end enterprises. In case the length of time required for obtaining an approval exceeds five (5) years, the term of extension shall still be limited to five (5) years.

Any application for an extension of the term of a patent right must be filed with the Patent Authority by submitting a written application together with supporting evidence within three (3) months from the date of the first government approval involved provided, however, that no extension application shall be filed within six (6) months prior to the expiration of the original patent term.

To determine the term of extension of a patent under the preceding Paragraph, the Competent Authority shall take into consideration the impact of the extension on the health of nationals in general and shall prescribe the approving rules in conjunction with the central government authority in charge of the end enterprises concerned.

Article 53 of Patent Act (Taiwan) reads:

The Patent Authority shall designate examiner(s) to examine an invention patent extension application and shall make written decision which shall be served on the patentee or his/her patent attorney.

<sup>40</sup> Article 55 of Patent Act (Taiwan) reads:

In the case of invention patents covering pharmaceuticals, agrichemicals, or processes for preparing the same, a patentee may apply for an extension of his/her patent term for two (2) to five (5) years, if, pursuant

means that the extension might be less than 2 years if the period of actual regulatory review is less than 2 years. Unlike the US law, the patent extension is only applicable to pharmaceuticals and agrichemicals.<sup>41</sup>

To be eligible for the restoration, the applicant should submit the application before six months prior to the expiration of the original patent term.<sup>42</sup> The extension is revocable if any person files a complaint against the extension on the following grounds:<sup>43</sup>

- (1) if it is not necessary to obtain a government approval for practicing the patented invention at issue;
- (2) if the patentee or his/her licensee has not obtained a government approval as required;
- (3) if the approved term of extension exceeds the length of time in which the patented invention can not be practiced;
- (4) if the patent extension application is filed by a person other than the patentee;

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to other acts or regulations, a prior government approval must be secured to practice such patents, for which the processing exceeds two (2) years after the publication of the patents. Only one such extension shall be permitted provided, however, that the patent term extended shall not exceed the length of time required for obtaining an approval from the central government authority in charge of end enterprises. In case the length of time required for obtaining an approval exceeds five (5) years, the term of extension shall still be limited to five (5) years.

Any application for an extension of the term of a patent right must be filed with the Patent Authority by submitting a written application together with supporting evidence within three (3) months from the date of the first government approval involved provided, however, that no extension application shall be filed within six (6) months prior to the expiration of the original patent term.

To determine the term of extension of a patent under the preceding Paragraph, the Competent Authority shall take into consideration the impact of the extension on the health of nationals in general and shall prescribe the approving rules in conjunction with the central government authority in charge of the end enterprises concerned.

<sup>41</sup> Patent Act, art. 55 (Taiwan).

<sup>42</sup> Patent Act, art. 52 (Taiwan).

<sup>43</sup> The Patent Act, art. 54 (Taiwan).

(5) if the patent right is jointly owned by two or more persons, and the extension application is not filed in the name of all co-owners;

(6) in case the application for extension was based on the time spent in conducting experiments or testing in a foreign country, the extended term allowed by the Patent Authority exceeds the duration recognized by the patent authority of such foreign country; or

(7) the time required for obtaining an approval is less than two years.

#### 5.2.4 The Grounds to Exclude Patent

In accordance with Article 1 of Patent Act, the aim of patent is to encourage, protect and utilize inventions and creations so as to promote the development of industries. However, Article 76 of the Patent Act provides several grounds to exclude protection of patent to strike a balance of public interests.<sup>44</sup> The Chinese term “特許實施” used in Article 76

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<sup>44</sup> Article 76 of Patent Act reads:

I. In order to cope with the national emergencies, or to make non-profit-seeking use of a patent for enhancement of public welfare, or in the case of an applicant's failure to reach a licensing agreement with the patentee concerned under reasonable commercial terms and conditions within a considerable period of time, the Patent Authority may, upon an application, grant a right of compulsory licensing to the applicant to put the patented invention into practice; provided that such practicing shall be restricted mainly to the purpose of satisfying the requirements of the domestic market. However, if the application for compulsory licensing of a patent right covers semiconductor technology, such application may be allowed only if the proposed practicing is purposed for a non-profit-seeking use contemplated to enhance the public welfare.

II. In the absence of the conditions set forth in the preceding Paragraph, the Patent Authority still may, upon an application, grant to the applicant a compulsory license to practice the patented invention in the event that the patentee has imposed restrictions on competition or has committed unfair competition, as confirmed by a judgment given by a court or a disposition made by the Fair Trade Commission of the Executive Yuan.

III. Upon receipt of a written application for such compulsory licensing, the Patent Authority shall send a duplicate copy thereof to the patentee, requesting that a response be filed within three (3) months. If no response is filed within the specified time limit, the Patent Authority may decide the matter at its own discretion.

IV. The right of compulsory licensing shall not preclude other persons from obtaining the right to practice the same patented invention.

The grantee of the compulsory license shall pay to the patentee an appropriate compensation. In the case of dispute over the amount of such compensation, the amount shall be decided by the Patent Authority.

refers to a “special permission for third party to enforce patent right.” This term is borrowed from the Japanese Law, 日本特許法.<sup>45</sup> The special permission for third party required the third party to apply a permission to enforce the patent without permission of patent holders. It created the same legal effect as the compulsory license (Chinese term 強制授權), but it is a bit different in Chinese meaning. The term “強制授權” means that the government grants a license to third party against the patentee’s will and more like a government contract. The English translated Patent Act did not distinguish these two terms precisely in Article 76, which used “compulsory license” rather than special permission for third party to enforce patent right.” Indeed, the term “un-authorization use” in Article 31 of TRIPS can be used because it is a precise English term, and that it captures the meaning Article 76 intended to convey.

Under Article 76, there are four grounds to exclude the patent:

- (1) The government can grant a compulsory license for non-commercial use grounds on the national emergency
- (2) A compulsory license for non-commercial use grounds on the protections for public interests.
- (3) The third party may apply a special permission against patentee if he/she cannot enter a voluntary agreement with reasonable conditions within reasonable time of negotiation.
- (4) If the anti-competitive practice is confirmed by a judgment given by a court or a disposition made by the Fair Trade Commission of the

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The compulsory license shall be transacted together with the business pertaining to the compulsorily licensing for assignment, trust, inheritance, licensing or pledge creation.

Upon extinguishment of the cause of compulsory licensing, the Patent Authority may terminate the compulsory license upon an application.

<sup>45</sup> See 專利法第七十六條立法理由[The Legislative History of Article 76 of Patent Act].

Executive Yuan.

Article 76.5 requires the third party to pay an appropriate compensation to the patentee. In the case of dispute over how much the compensation that the patentee should pay to the patent owner, the amount will be decided by the Taiwan Intellectual Property Office. This way would drive the patentee to enter a voluntary license within reasonable time and prohibit the unreasonable delay of the entry of generic products.

Compared to the grounds to exclude patent under Article 31(b) of the TRIPS, the grounds under Article 76.1 are essentially the same. In accordance with Article 31(b) and (f) of the TRIPS, without the authorization of the right holder under Article 31 can be applied in any circumstance but should meet three requirements: (1) the use for public interests, (2) the 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, and (3) use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.

The second requirement in Article 31 of TRIPS can be waived if the in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. Likewise, in accordance with Article 76.1 of Patent Act, applicants in the cases of national emergency and non commercial use, are not required to make efforts to obtain permission from the right holder on reasonable commercial terms and conditions within a reasonable period of time. This is the same rationale of Article 31(b) of TRIPS.

Beside the cases other than national emergency and non-commercial use, Article 76.1 allows government could grant a special permission for any purpose if the three requirements are satisfied. First, it requires the grant should be for public interests. Second, a licensee has negotiated with a licensor on reasonable commercial terms and conditions but they could not reach an agreement within a reasonable period of time. Again this arrangement is the same as the article 31(b). With the third requirement, Article 76.1 also imposed the same limitation that the use should be predominately in the domestic market.

Beside three requirements mentioned above, Article 76.2 provides a remedy for anti-competitive practice, determined after judicial or administrative process, which is similar to the Article 31 (k). Overall, the significant difference of Article 76 from Article 31 of the TRIPS agreement is the introduction of a scheme to determine the reasonable compensation when the disputes come form the compensations.

### **5.2.5 The New Draft Amendment of Patent Act**

As a member of WTO, Taiwan government made efforts to comply with the WTO's decisions and polices. After the Doha Declaration and the 2005 Amendment of TRIPS were adopted, the Taiwanese government made effort to implement the WTO's policy to promote access to medicines in the developing countries.

Currently, with respect to pharmaceutical products, the Taiwanese Patent Office drafted the pertinent provisions and had them published to receive opinions from academia and

related industries.<sup>46</sup> The 2008 draft Amendment of Patent Act in relation to the pharmaceutical products is focused on several issues. The first adjustment is to reform current compulsory license scheme in order to produce medicines for countries lack manufacturing capacities. Second, it readjusted the procedure of applying patent extension. The third change is to add another ground to exclude patent that is the experimental and research exception.

Regarding the first adjustment, the reform is focused on the waiver of the requirement that the unauthorized use should be provided predominantly in the domestic market.<sup>47</sup> The 2008 Draft of the Amendment of Patent Act attempted to insert new articles to waive the requirement under Article 76 of Patent Act. As mentioned above, Article 76.1 requires the manufacturer, who has been authorized by a compulsory license, to provide drugs predominantly in the domestic market. Likewise, the full compliance with requirements of TRIPS disables the Taiwanese government to export generic medicines to other countries lack manufacturing capability. The reform loosens the requirements of the compulsory license with certain conditions. First, the qualified disease to waive these requirements is limited to; tuberculosis, malaria, and other infectious disease. Second, the importing countries are not limited to the WTO member, but they should be qualified as the Least Developing Countries (LDCS) under the UN's standard or developing countries

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<sup>46</sup> Taiwan Intellectual Property Office, TIPO to sponsor public hearing for Patent Act draft amendment from March 7, 2008. All circles are welcome to attend, available at <http://oldweb.tipo.gov.tw/eng/press/ne20080304.asp> (last visited Feb. 25, 2009).

<sup>47</sup> TIPO, Reasons to Amend to Article 76 of Patent Act, [http://www.tipo.gov.tw/ch/AllInOne\\_Show.aspx?path=2769&guid=45f2e9ed-6a50-488e-8514-47a78e3cc320&lang=zh-tw](http://www.tipo.gov.tw/ch/AllInOne_Show.aspx?path=2769&guid=45f2e9ed-6a50-488e-8514-47a78e3cc320&lang=zh-tw) (last visited on Feb. 25, 2009).

that are defined under the TRIPS. Third, the importing countries should complete the necessary notifications to the Council to TRIPS.

The second adjustment is with respect to the patent restoration in several aspects. It limited the extension of patent to one time. Second, only pharmaceuticals for human use can be qualified for the extension, and those for animal use are excluded for the extension. Third, it annulled the requirement that the patent extension is applicable only in a case where the registration period is over 2 years. In the 2008 reform, the patent extension will apply to every case where the marketing approval acquired after a patent is granted regardless of whether the registration period is over 2 years. Finally, it attempts to remove the lower limit of patent term. In accordance with Article 52 of Patent Act, the patent term can be granted from 2 to 5 years.<sup>48</sup> The new reform refers to the contemporaneous legislations in the US, Japan and other countries and takes out verbatim limitations.<sup>49</sup> The reform though, neglects to put the caps on the available patent life. This neglect may unreasonably extend the patent and delay the entry of generic medicines.

The third adjustment provides an exception to exclude patent if the use is for research and experimental purposes. For years, Taiwan case law has recognized that the experimental use is permitted under the Patent Act; the 2008 reform is reaffirmed the court's opinion.<sup>50</sup>

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<sup>48</sup> Patent Act, art. 52 (Taiwan).

<sup>49</sup> TIPO, Document No. 09818600080, Feb. 28, 2009, the new update Draft Amendment of Patent Act is available at [http://www.tipo.gov.tw/ch/News\\_NewsContent.aspx?NewsID=3520](http://www.tipo.gov.tw/ch/News_NewsContent.aspx?NewsID=3520), (last visited Mar. 1, 2009)

<sup>50</sup> See TIPO, Patent Act Reform Forum, The Reasons to Amend the Article 57 in 2008 Draft Amendment of Patent Act, available at [http://www.tipo.gov.tw/ch/AllInOne\\_Show.aspx?path=2769&guid=45f2e9ed-6a50-488e-8514-47a78e3cc320&lang=zh-tw](http://www.tipo.gov.tw/ch/AllInOne_Show.aspx?path=2769&guid=45f2e9ed-6a50-488e-8514-47a78e3cc320&lang=zh-tw) (last visited on Feb. 25, 2009).

### 5.3 The Protection of Pharmaceutical Data

The development of concept of protection of pharmaceutical data is highly related to the development of Taiwanese pharmaceutical industry as well as the pharmaceutical registering scheme. The 1993 local clinical requirement built up the local capability of clinical trials and initiated the protection of domestic pharmaceutical data. In 2002 when Taiwan jointed to the WTO, the protection of pharmaceutical data became an issue. At that time, Taiwan stated that the pharmaceutical data are protected under the Trade Secret Act and explained such protection complied with Article 39.3 of TRIPS. The 2005 reform of pharmaceutical law further granted a five-year term of data exclusivity for originators.

#### 5.3.1 The Introduction to Pharmaceutical Registering

##### 5.3.1.1 Western Medicines

The history of pharmaceutical industry in Taiwan has over 60 years, but the legal regime for pharmaceutical industry was not established until early 1980s'.<sup>51</sup> In 1981, the Taiwanese introduced the GMP standard to pharmaceutical industry and assisted local 247 pharmaceutical companies to certify by the standard of GMP.<sup>52</sup> The early development of pharmaceutical industry is focused on how to manufacture good quality of generic medicines. In this stage, the Taiwanese's Department of Health (DOH)<sup>53</sup>

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<sup>51</sup> ITIS, *The Current Pharmaceutical Industry and Trend*, chapter 4: Taiwanese Pharmaceutical Industry, (製藥產業現況與趨勢專題研究), 1996, available at <http://www.itis.org.tw/FreePDF/959878703/國內製藥產業現況分析.pdf> (last visited Feb. 25, 2009).

<sup>52</sup> *Id.*

<sup>53</sup> According to the Department of Health, its mission is to promote medical, health care, and disease prevention, as well as food, drugs, as well as cosmetic management and health insurance affairs. See Mission of DOH, available at [http://www.doh.gov.tw/EN2006/DM/mission.aspx?class\\_no=392&level\\_no=1](http://www.doh.gov.tw/EN2006/DM/mission.aspx?class_no=392&level_no=1) (last visited Feb. 25, 2009).

concerned the inspections of medicines and supervised the manufactures. This situation is demonstrated in the legal regime for the protection of pharmaceutical innovation. The pharmaceutical registration scheme was focused on the capability of manufacturing and even Patent Act before its modification in 1986 protected only the “manufacturing process” of new drugs rather than the end products.

In the 1990s, the protection of intellectual property became a major issue in trade negotiations between the United States and Taiwan. Under the pressure of the US representatives, the Taiwanese government promised to amend the domestic laws to provide a better protection for pharmaceuticals. The first significant modification in 1993 established new requirements for registration of drugs and at the same time initiated the legal regime of protection of pharmaceutical data.<sup>54</sup> Since then, the Taiwanese pharmaceutical industries strengthened the quality of manufacturing as well as devoted to the research and development of new drugs. With respect to pharmaceutical law, many guidelines regarding the clinical trials and registration of new drugs and Chinese Medicines are completed during the period between 1993 and 2002, but the entire reform of regulations of clinical trail since 1993 has not completed. The DOH further introduced the concept of bridging study, which deals with issues of variance of forging clinical trails resulting from the variance of ethnics and populations in 2000.<sup>55</sup> This new

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<sup>54</sup> See *infra* Section 5.3.2.

<sup>55</sup> See *infra* Section 5.3.3.

requirement indirectly promotes the development of capability of clinical trials conducting in Taiwan.<sup>56</sup>

The accession to the WTO in 2002 initiated another legal reform in pharmaceutical law. In 2005, five years of data exclusivity is granted for pharmaceuticals. In the same year, the first new medicine (Chinese traditional medicine) passed the New Drug Application (NDA) and a license was issued to it in June 2005. This was the nation's first new medicine passing the Investigation of New Drug (IND) & NDA examination.<sup>57</sup> This indicates that the Taiwanese pharmaceutical industry would extend its antenna to the development of new drugs rather than the manufacturing of generic medicines. In this way, the protection of pharmaceutical data will be more important than ever.

In 2008, the American Chamber of Commerce in Taipei expressed that Taiwanese government should provide more secured protection of pharmaceutical innovations and proposed three major points regarding the protection of pharmaceutical innovation: (1) the Implementing Separation of Dispensing from Prescribing (SDP), (2) patent linkage with marketing approval of new drugs; and (3) the pricing and reimbursement of new drugs/indications.<sup>58</sup> The issue of patent linkage related to the entire registration of new drugs and another two issues regarding the national health insurance. They are likely to

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<sup>56</sup> ITIS, *supra* note 7 and 8.

<sup>57</sup> Committee on Chinese Medicine and Pharmacy (CCMP), 2005 Achievement of the Commission on Chinese Medicine, <http://www.ccmp.gov.tw/en/public/public.asp?selno=93&relno=93&level=C> (last visited Feb. 25, 2009)

<sup>58</sup> Amcham, White Paper Pharmaceuticals 2008, available [http://www.amcham.com.tw/component/option.com\\_docman/task.cat\\_view/gid,163/dir,DESC/order,date/limit,10/limitstart,10/](http://www.amcham.com.tw/component/option.com_docman/task.cat_view/gid,163/dir,DESC/order,date/limit,10/limitstart,10/), (last visited Feb. 25, 2009).

be the new focus in the next stage of trade negotiations between the US and the government.

### 5.3.1.2 Chinese Medicines

According to 2006 Taiwan Year book, as of December 2005, there were 25 Chinese medicine hospitals, 2,900 Chinese medicine clinics, and 4,610 licensed doctors of Chinese medicine in Taiwan.<sup>59</sup> Chinese medicine is valuable and popular in Chinese society. Indeed, they are enjoying a considerable respect among modern Western medicines. In Taiwan, Chinese herbal medicine is recognized as medicines and subject to the Pharmaceutical Affairs Act. Nevertheless, the approval process for marketing is separate from that for western medicines. The reason for using different surveillance system to the Traditional Chinese medicine is that they are distinguished from modern medicine in many aspects, such as physiological theories, etiology, diagnostics, therapeutics and pharmacology.<sup>60</sup>

There are two branch mainly responsible for the reviewing of Chinese Medicines as new drugs: the Committee on Chinese Medicine and Pharmacy (CCMP) and the Center for Drug Evaluation assists the Committee on Chinese Medicine and Pharmacy (CDE-CCMP).<sup>61</sup> The function of these two agencies is equal to the function of the FDA in the

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<sup>59</sup> 2006 Taiwan Year Book, chapter 16, available at <http://www.gio.gov.tw/taiwan/5-gp/yearbook/16PublicHealth.htm#TraditionalChineseMedicine> (last visited Feb. 25, 2009).

<sup>60</sup> Ruiping Fan, Modern Western Science As a Standard for Traditional Chinese Medicine: A Critical Appraisal, 31 J.L. Med. & Ethics 213, 213 (2003).

<sup>61</sup> Krishna Kaphle et. al., *Herbal Medicine Research in Taiwan*, eCAM 2006;3(1)149–155 doi:10.1093/ecam/nek016, page 151-152 (2006), also available at <http://ecam.oxfordjournals.org/cgi/content/full/3/1/149> (last visited Feb. 25, 2009).

marketing approval of new drugs in the US.<sup>62</sup> The CCMP is responsible for promulgating, revising, and issuing regulations. It is also responsible for the approval, registration, and importation of the Chinese herbal medicines, including determination of the years of exclusivity, and approval of the design and protocol of the clinical trials. The CDE-CCMP is a technical department, which is designed to assist the CCMP in conducting primary and technical reviews for both INDs and NDAs. The CDE-CCMP also assists the CCMP in drafting related guidance.

To regulate the Chinese Medicine, CCMP under the authorization of DOH oversees practices of traditional Chinese medicine. Unlike in the US, Chinese medicines are recognized as medicines rather than the dietary supplements in the US.<sup>63</sup> The difference between the food supplement and medicines is that if the product is recognized as a medicine, then the marketing of Chinese Medicines should apply a permit before they enter the market. In this regard, the CCMP requires the Chinese Medicines to meet certain requirements to obtain the permit before they entered the market.

The current regulation considered some of the Chinese Medicines have been used for thousands of years without adverse effects. Thus, they designed a special reviewing scheme to screen the safety, and quality of the Chinese medicines. This scheme classifies

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<sup>62</sup> Fong Chi et al., *From Chinese Herbal Medicine to Botanical Drug: Regulatory Requirements from Taiwan to a United States IND Submission* (2003), <http://www.cde.org.tw/fileupload/tablename/From%20Chinese%20Herbal%20Medicine%20to%20Botanical%20Drug....pdf> (last visited Feb. 25, 2009).

<sup>63</sup> Yuan Lin ed., *Drug Discovery and Traditional Chinese Medicine: Science, Regulation and Globalization*, page 160 (2004).

the Traditional Chinese Medicines in three groups and determines what requirements should be satisfied in order to obtain marketing approval in each group.<sup>64</sup>

In the first group, a manufacturer of a Chinese herbal medicine claims an indication based on the theory of traditional Chinese medicine as “defined” in five classics of Eastern literature.<sup>65</sup> In this case, the only requirement is that, manufacturing of medicines should comply with GMP. This group of medicines, efficacy and safety data is waived based on long-term human experience with the Chinese herbal medicine.

In the second group, a manufacturer of a Chinese herbal medicine is not defined in five classics of Eastern literature but would like to claim an indication based on the theory of modern medicine. In this case, the Chinese herbal medicines are recognized as a new drug, thus the requirements of manufacturing, testing, and clinical trials to approve the Chinese Medicines are similar to new western medicine. That is to say the manufacturing of a Chinese herbal medicine as a new drug must comply with GMP, and the analytical and animal testing, such as non-clinical pharmacological and toxicological studies, must comply with Good Laboratory Practice (GLP) as well as Clinical trials must comply with Good Clinical Practice (GCP).<sup>66</sup>

Once TCM products are permitted to enter the market, they are protected under the Pharmaceutical Affair Act. The permit to market is five years.<sup>67</sup> This permit is approved

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<sup>64</sup> The Standards of Examination and Registration for Medicines, art. 75 (Revised on September 15, 2005)

<sup>65</sup> Fong Chi et al., *supra* note 62.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

by two stages of processes: the so-called IND stage and the New Drug Application (NDA) stage.

The same logic to decide whether the clinical trial is required is also applied in determining the requirement to approve Chinese herbal medicines. The current law determined how much data should be submitted on the basis of how much understanding of the safety and effectiveness of these drugs. The more understanding and experience of these medicines, the less data would be requested. Apparently, the authority adopts more flexible regulations than west medicine with respect to safety of IND applications for Chinese herbal medicines.<sup>68</sup>

In accordance with Article 40-1 of Pharmaceutical Affairs Act, data submitted to the health agency for marketing approval are protected for five years. In this regard, if the marketing of Chinese Medicine, which is not defined in the five classics of Eastern literature, required applicants to submit data in order to obtain the approval; those data are protected for a five-year term from the date of approval.

### **5.3.2 The 1993 Local Clinical Trial Requirement**

Article 39 of Taiwan Pharmaceutical Affairs stated that manufacturing and importing drugs should be permitted by the DOH.<sup>69</sup> Further, it states that the marketing approval

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<sup>68</sup> For example, if botanical products with little human experience or unknown safety, a full IND is required to start a phase 1 study. In the case of botanical products that are already on the market but where optimal use for the new indication might be beyond previous human experience, or those where safety in the proposed therapeutic dose is not a concern, the data submitted for the approval of marketing is less than new drug.

<sup>69</sup> Article 39 of Taiwan Pharmaceutical Affairs Act [translated text is provided by Taiwan DOH website] reads

should be governed by the Criteria Governing the Review for Registration and Market Approval of Drugs. The Criteria incorporates two sets of procedures for western medicines; one is provided for the approval of new drug and another is for generic drug. Nevertheless, the new drugs registration scheme did not operate until 1993. Before that, most critics argued that the registration scheme is much like a procedure requirement rather than substantial reviewing of clinical trials. The major reason account for this result is that more than half of medicines are imported and they have been tested in other countries. Unless the DOH rejected the results of foreign clinical data, they did not have to make any further review. Consequently, the function of health agency regarding the pharmaceutical administration was focused on regulating pharmaceutical manufacturers rather than substantial reviewing pharmaceutical data. In this stage, there is no special protection for foreign pharmaceutical data unless the act constitutes a breach of contract or a tort.

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1. For the manufacturing and import of drugs, information concerning the ingredients, specifications, functions, summary of manufacturing process, and the specification and method of testing, as well as other related information and certificates, accompanied by labels and use instructions in the original and Chinese languages, and samples, together with the fee paid, shall be filed with the central competent health authority for registration and market approval. No manufacturing or importation of such drugs shall be allowed until a drug permit license is approved and issued.

2. Provisions of the preceding Paragraph shall not apply to application to the central competent health authority for importation of raw materials for the manufacturing. Said application criteria and application fee shall be determined by the central competent health authority.

3. Only the owners of a drug permit license or their authorized persons may apply for import of drugs pursuant to the provisions of the first Paragraph. Application for change or transfer of registration of drug permit license obtained as per for registration and market approval the first Paragraph shall be conducted in accordance with the provisions under Article 46; the issuance of extension of registration, replacement, or new permit license shall be conducted in accordance with the provisions under Article 47. The application criteria, review procedure, approval criteria, and other matters to be complied with shall be established in the Criteria Governing the Review for Registration and Market Approval of Drugs by the central competent health authority available at

[http://www.doh.gov.tw/ufile/Doc/200507\\_Pharmaceutical%20Affairs%20Act.pdf](http://www.doh.gov.tw/ufile/Doc/200507_Pharmaceutical%20Affairs%20Act.pdf), (last visited on Feb 1, 2009)

In 1993, the US trade representatives in Trade and Commerce Agreement meeting highlighted the poor protection of pharmaceutical innovation and required the Taiwanese government to provide better protections for them.<sup>70</sup> Under the pressure of the US representatives, the Taiwanese government amended the regulations of the marketing approval. On July 7, 1993, the DOH issued new regulations in relation to registration of new drug, which was so called the Seventy Seven Announcement.<sup>71</sup> This new regulation is authorized by Article 45 of the Pharmaceutical Affairs Act. The Article declares that the DOH can set a period of time to monitor the imported medicines and required certain information.<sup>72</sup> Under this new regulation, the DOH required that a new pharmaceutical product registering should be mandatory to conduct a domestic clinical trial with a minimum of 40 subjects, except for the submission of relevant documents in accordance with the existing regulations under the Pharmaceutical Affairs Act; if the drug is not developed in Taiwan or clinical trials are not conducted in Taiwan.<sup>73</sup> After approval, marketing exclusivity will be granted to the sponsor for the 7-year safety monitor period.

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<sup>70</sup> The DOH, 七七公告[77 Announcement], DOH document No. 08246232, issued on July 7, 1993, [http://www.cde.org.tw/bse\\_website/report77.html](http://www.cde.org.tw/bse_website/report77.html) (last visited Feb. 25, 2009).

<sup>71</sup> DOH, The History of 77 Announcement, Document No. 8246232, on July 7, 1993. [http://www.cde.org.tw/bse\\_website/english/background.html](http://www.cde.org.tw/bse_website/english/background.html) (last visited Feb. 25, 2009).

<sup>72</sup> Article 45 of Pharmaceutical Affairs Acts (Taiwan):

The central competent health authority may set a specific period of time for monitoring the safety of new drugs approved for manufacturing or import.

The central competent health authority shall establish matters that the pharmaceutical dealers shall adhere to during the safety monitoring period referred to in the preceding Paragraph.

<sup>73</sup> CDE, Background of Bridge Study, available at [http://www.cde.org.tw/bse\\_website/english/background.html](http://www.cde.org.tw/bse_website/english/background.html), (last visited Feb. 25, 2009).

In accordance with Seventy Seven Announcement, the subsequent generic drug should submit the same local clinical trial data as the originator submitted if it plans to manufacture, import the generic version of respective brand name drug within five years from the first date of first registration of brand name drugs. The generic manufacturer can provide either local or foreign bio-equivalence data, if it registered after 5-7 years of the first registration of brand name drug. This regulation though is not a data exclusivity law, but it creates the same legal effect. Such requirements create a marketing exclusive effect for originators for five years, because generic manufacturers cannot enter the market without costly spending in producing pharmaceutical data.

The purpose of 77 Announcement is to encourage the importation of patented drugs and promotion of domestic R&D through drug surveillance system. This system requires any medicine marketing in Taiwan, if it is not developed in Taiwan, to conduct safety surveillance of new drug in designated medical center within seven years from the date of the issuance of marketing approval.<sup>74</sup> In the first five year, no generic application to manufacture or import by a third country (other than Taiwan and the country of origin) will be accepted during this surveillance period unless they can submit the same reports of domestic clinical trials equivalent to those of the original manufacturer. From 5-7 years after the date of issuance of approval, the generic application should submit a report of bioequivalence tests that have been conducted by either domestic or DOH-authorized foreign laboratories.

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<sup>74</sup> See *Id.*

By July 1995, 241 chemical entities and 412 new drug formulations had been placed under surveillance. The DOH believed that new drug safety surveillance did detect some adverse side effects which previous clinical trials may have missed, and expand the clinical capability of local pharmaceutical industry.

However, the adoption of 77 announcements did not stop the reform of Taiwanese Pharmaceutical Registration scheme. Many critics argued that the local clinical requirement of new drug is meaningless for two reasons.<sup>75</sup> First, a sample size of 40 as required would be difficult to demonstrate significant importance clinically or statistically. Second, the study design of the local trial usually only repeated a study that has been done in foreign countries but in a smaller sample size. Therefore, this requirement is wasteful and has no scientific value.

The DOH attempted to relieve the negative impacts after the implementation of July 7 Announcement. Since its adoption, the DOH had issued five announcements regarding the conditions for waiving domestic clinical trials since 1998 and 2000 and these waivers also provide a relief to the unnecessary local clinical trial requirement by 77 Announcement. The early announcements are focused on the waiver for the new drugs containing breakthrough effect and life-saving drugs.<sup>76</sup> The rest of them include orphan drugs, drugs for treatment of AIDS, for use in organ transplants etc.<sup>77</sup>

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<sup>75</sup> Mey Wang and Heng-Der Chern, *Implementation of Bridging Strategy in Taiwan*, available at [http://www.cde.org.tw/03center/write/book02\\_c/Implementation%20of%20Bridging%20Strategy%20in%20Taiwan.pdf](http://www.cde.org.tw/03center/write/book02_c/Implementation%20of%20Bridging%20Strategy%20in%20Taiwan.pdf) (last Feb. 25, 2009).

<sup>76</sup> The first announcement, effective on Mar. 30, 1998 (DOH document no. 87011284), waives clinical trials for four types of medicines: (1) Drugs for Treatment of Acquired Immune Deficiency Syndrome (AIDS); (2) Drugs for Organ Transplant; (3) Ethnic Incentive Cancer Drugs ; and (4) no sufficient number of patients for human trial and no alterative medicines for that specific drug.

### 5.3.3 The Bridge Study and Waiver

In 2000, the DOH found those waivers of July 7 cannot resolve the issue resulting from itself- non-meaningful repetition of local clinical trails. The DOH finally revoked the July 7 Announcement and on December 12, 2000 DOH issued the Bridging Study Announcement (the Double-Twelve Announcement) to substitute for the Double-Seven Announcement.<sup>78</sup> The Double-Twelve Announcement was effective January 1, 2001 and it granted 3 years of transition period. It attempts to avoid the repetition of the clinical trials, and to improve the quality of local clinical trials by introducing guidance ICH-E5.<sup>79</sup> In addition, this Announcement imposed new drug applicants obligation to conduct bridging before submitting the application. The essence of bridge study is to evaluate the impact of ethnical differences on the efficacy and safety of the new drugs through

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The second announcement, effect on June, 19, 1998 (DOH document no. 87040663) waive clinical trials for another three types of medicine: (1) the medicines have "breakthrough" effect for the treatment of life-threatening diseases, such as advanced cases of AIDS etc. , (2) medicine are evidently ethnic insensitive and breakthrough effect, (3) radio medicines for diagnosis.

The third announcement, effected on, waived clinical trials for certain types of vaccine and medicines for treatment for psychiatric medicines and chronic immunity system disease, such as Rheumatoid Arthritis, Systemic lupus erythematosus (SLE), Schizophrenia. Such disease is conditional waive, which means the DOH required the register should provide data to prove ethnic insensitive to waive the domestic clinical trials.

The fourth announcement is focus on the four types medicines: (1) the medicine for single use (2) the same therapeutic effect as the approval new combinations(3) medicines containing local tissues prepared for external use, such as topical skin preparations, ophthalmic preparations, ear preparations. (4) nutrition supplements, such as large-scale of amino acids infusion fluid. (5) Intestine Cleansers used only before the surgery.

See also Ames Gross, *Taiwan: New Pharmaceutical Regulatory Trends*, Pacific Bridge Medical, 2000, <http://www.pacificbridgemedical.com/publications/html/TaiwanMarch2000.htm> (last Feb. 25, 2009).

<sup>77</sup> *Id.*

<sup>78</sup> Hui-Po Wang, *Clinical Trials in Taiwan : Regulatory Achievement and Current Status*, page 6, [http://www.cde.org.tw/03center/write/book02\\_a/Clinical%20Trials%20in%20Taiwan%E2%80%94Regulatory%20Achievement%20and%20Current%20Status.pdf](http://www.cde.org.tw/03center/write/book02_a/Clinical%20Trials%20in%20Taiwan%E2%80%94Regulatory%20Achievement%20and%20Current%20Status.pdf) (last Feb. 29, 2009).

<sup>79</sup> CDE, *supra* note 73.

studying of sets of intrinsic and extrinsic factors.<sup>80</sup> Results from the bridging study evaluation would determine whether foreign clinical trial data could be extrapolated to Taiwanese populations and whether further clinical trials in Taiwan could be waived.<sup>81</sup> In accordance with Double Twelve Announcement, the pharmaceutical industry had to submit data to prove the minimal or no ethnic difference in the efficacy and safety profile of the drug. If the pharmaceutical industry cannot provide evidences to clarify this query, a bridging study will be required to demonstrate the applicable dose regimen in Taiwan.

The implementation of bridge study can be observed in three stages.<sup>82</sup> The first two-year transition period of Announcement began from January 1, 2001 to December 31, 2002. In this transition period, namely the first stage; applicants had options either to conduct a registration trial with a minimum of 40 cases in Taiwan or to present a bridging study evaluation package before new drug application (NDA) submission. Thus, the evaluation as to whether the bridge study is required is optional. Even if pharmaceutical company decided to run a bridge study evaluation in Taiwan, it is flexible to conduct either a bridging study to resolve the ethnic concern or a registration trial directly when the evaluation requires conducting the bridge study.

In the period between January 1, 2003 and December 31, 2003, namely the second stage, all products should go through bridging study evaluation rigidly, unless the conditions of waivers existed. The objective of this stage is to educate all pharmaceutical industries in

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<sup>80</sup> Mey Wang and Heng-Der Chern, *supra* note 75.

<sup>81</sup> *Id.*

<sup>82</sup> DOH, 雙十二公告[Double Twelve Announcement,], Document No. 0890035812, available at [http://www.cde.org.tw/bse\\_website/report33.html](http://www.cde.org.tw/bse_website/report33.html) (last visited Feb. 25, 2009).

Taiwan to prepare and submit the required package for evaluation. In this stage, it is still flexible; applicants can choose a registration trial even after the evaluation. After 2004, namely the third stage, the process of bridging study evaluation remained the same.

However, if the bridging study cannot be waived by registration trial of 40 cases, they have to conduct bridging study.<sup>83</sup> The difference between the second and third stage is before the end of 2003, if a bridging study may not be waived, applicant has the options of either doing a 40-case clinical trial (following the Double-Seven Announcement) or a required bridging study. After January 1, 2004, however, the 40-case trial will no longer be accepted and the sponsor will have to do a required bridging study if not waived.

The DOH also issued two announcements to provide ground to waive the bridge study.<sup>84</sup> Those grounds mainly based on the ethical consideration and risk/benefit assessment; e.g. major therapeutic advance for life-threatening diseases, rare diseases, etc. Moreover, due to the minimal concerns in ethnic sensitivity, a clinical trial can be waived in some categories such as topical-use drugs, which have minimal systemic exposure. For these drugs, the impacts of ethnic difference on efficacy and safety are expected to be negligible.

### **5.3.4 Data Exclusivity**

#### **5.3.4.1 The Background to Incorporate Data Exclusivity**

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<sup>83</sup> Chia-Ling Hsiao et. Al, Algorithm for Evaluation of Bridging Studies in Taiwan, <http://www.cde.org.tw/fileupload/tablename/Algorithm%20for%20Evaluation%20of%20Bridging%20Studies%20in%20Taiwan.pdf>, (last visited Feb. 25, 2009).

<sup>84</sup> The DOH issued the 五五公告[May fifth Announcement], (Document # 0930309777) to waive the bridge test, including, drugs for treatment of AIDS, drugs for use in organ transplants; breakthrough drugs that are diagnostic radio-pharmaceuticals and are proven ethnically insensitive; intestine cleaner etc. also available at [http://www.cde.org.tw/bse\\_website/report33.html](http://www.cde.org.tw/bse_website/report33.html) (last visited Feb. 25, 2009).

The protection of foreign pharmaceutical data became an issue in 2002-2003, after a few papers highlighted the increasing spending in health care after the implementation of the National Health Insurance.<sup>85</sup> This spending, however, did not increase the profits of international pharmaceutical companies. Those multinational pharmaceutical companies, which provide medicines to Taiwan, found that they either sale medicines at low price or sale nothing. Those pharmaceutical companies considered that one reason for this result, perhaps, is because the Taiwanese government did not provide enough protection of pharmaceutical innovation, such as the grant of data exclusivity.

In the 2003 US Commerce Association Annual Report and the EU Commerce Association 2002-2003 report pointed out the Taiwanese government should provide data exclusivity protection to comply with Article 39.3 of the TRIPS agreement. In the 2004 Special 301 report, USTR strongly expressed that they are concerned whether Taiwan made the necessary changes to its relevant laws to prevent unfair commercial use of pharmaceutical and agricultural chemical test data.<sup>86</sup> If not, they would consider put Taiwan in the Special 301 List. Under these economic threats from the US and EU, the Taiwanese government finally incorporated Article 40-1 of Pharmaceutical Affairs to grant the data exclusivity in 2005.<sup>87</sup>

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<sup>85</sup> The Legislative History of Article 40-1 of Pharmaceutical Affair Act (Taiwan).

<sup>86</sup> The 2004 Special 301, available at [http://www.ustr.gov/Document\\_Library/Press\\_Releases/2005/January/US\\_Announces\\_Results\\_of\\_IPR\\_Out-of-Cycle\\_Reviews\\_for\\_Pol\\_Taiwan.html?ht=0](http://www.ustr.gov/Document_Library/Press_Releases/2005/January/US_Announces_Results_of_IPR_Out-of-Cycle_Reviews_for_Pol_Taiwan.html?ht=0)

<sup>87</sup> Article 40-2of Pharmaceutical Affairs Act (Taiwan) reads:

Upon the issuance of license for any new drug, the Central Competent Health Authority shall publicize the relevant patent numbers or file numbers, which are supplied by the applicants and already disclosed to the public.

### 5.3.4.2 Data Exclusivity: Terms and Conditions

In accordance with Article 40-1.1 of Pharmaceutical Affairs Act,<sup>88</sup> all data submitted by a pharmaceutical company, except that which is disclosed to the public by the pharmaceutical company relating to the safety and effectiveness of a drug, is kept confidential by the Department of Health unless they are disclosed to public for public health purpose. Further, Article 40-1.2 provides "data exclusivity" covering safety and effectiveness data submitted by a drug company. Under this law, a generic drug company may not obtain an approval for the same drug within 5 years from the first date of original approval unless it can provide the same data, namely data exclusivity right. This right includes several aspects, some of which even provide protection that is beyond the protection required by TRIPS.

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Within five years after the issuance of a license for new drug of new molecular entity, any other pharmaceutical firm may not apply for evaluation and registration of the same items by citing the data submitted by the licensee without such licensee's authorization.

After three years of the issuance of a license for new drug of new molecular entity, other pharmaceutical firm may apply for registration of drugs of the same substance, the same dosage form, the same dose, and the same dose unit according to this Act and related laws or regulations; the drug license may be issued on the next day to the expiration of five years after the issuance of license to such new drug of new molecular entity.

The second paragraph hereof can only be applicable with the compliance that application for registration of a new drug of new molecular entity shall be made to the Central Competent Health Authority within three years after it is first approved for marketing in any country.

The patent right of the new drug shall not be applicable to researches, teachings, or testing prior to the application for registration by the pharmaceutical firms.

<sup>88</sup> Article of 40-1 Pharmaceutical Affairs Act (Taiwan) reads:

For the public benefit, the Central Competent Health Authority may, if necessary, publicize the drug substances, package insert, or relevant information, which are supplied by pharmaceutical firms in their application for manufacturing or importing medicaments and thus held and kept by such Health Authority. The Health Authority shall keep in confidence any trade secrets in the new drugs application which are under evaluation before registration.

The Central Competent Health Authority shall enact measures governing the extent and method of the publication authorized by the preceding Paragraph.

The first aspect is that this data exclusivity applies both to new drug and new use or dosage, which have been approved for an existing drug.<sup>89</sup> In accordance with Article 39.3 of TRIPS, the protection of data is provided for the new chemical entities.<sup>90</sup> This means that the new chemical entities that is a chemical that has not been used as a registered medicine in human history and did not contain the meaning of new use or new dosage. Compared to TRIPS, the scope of Article 40-2 of Pharmaceutical Affairs Act is new medicines, which covered more than new chemical. Article 7 of Pharmaceutical Affairs Act stated that the term "new drugs" as used in this Act shall refer to drugs which are of the preparations having new compositions, new therapeutic compounds or new method of administration as verified and recognized by the central competent health authority.

The second aspect is that the adoption of data exclusivity. Article 39.3 of TRIPS also established the concept of data protection in international law level, but it leaves a room to decide a measure to protect pharmaceutical data. Apparently, Article 40-2 adopted the US type of data exclusivity to protect pharmaceutical data.

The third aspect is that the adoption of waiting period in the area of protection of pharmaceutical data. In accordance with Article 40-1.2, the foreign originator should register the new drugs to be qualified for the protection of data exclusivity within three years of first foreign registration. After three years from the date of the first registration

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<sup>89</sup> The Article 40-2 state the data exclusivity is applied to all new drugs, According to the article 7 of Pharmaceutical Affairs Act, "the term "new drugs" as used in this Act shall refer to drugs which are of the preparations having new compositions, new therapeutic compounds or new method of administration as verified and recognized by the central competent health authority. " (the translated provisions is provided by the Taiwanese DOH website)Therefore, the data exclusivity can be applied to the new compositions, new therapeutic compounds or new methods of imitations etc.

<sup>90</sup> See Chapter 2.2.2.2

in other jurisdiction, the data exclusivity is forfeited. This is so called the waiting period and a reasonable restriction of the data exclusivity.

Many researchers have appraised the adoption of waiting period in the area of data exclusivity for at least two reasons. First, this measure can encourage the early registration in the countries where the data exclusivity is granted. Second, it would not be unreasonable to delay the entry of the generic medicines if the originators delayed or do not register the new drugs in that jurisdiction.

The fourth aspect is that the structure of exception to pharmaceutical data is incomplete as it should be. In accordance with Article 39.3 of TRIPS there are two basic grounds to exclude the protection of pharmaceutical data; one is for public welfare and the other is for non-commercial, fair use. Article 40-1.1 though states that the health agency can disclose the pharmaceutical data for public interests; it does not provide the exception grounds on non-commercial fair use. In this regard, for certain non-commercial uses such as experimental use, governmental use, and grant of compulsory license to exclude patent, data exclusivity cannot be excluded under the Article 40-1.1. The exceptions set out in Article 40-1 are lack of sufficient flexibilities to increase the access to generic medicines.

Perhaps what could be considered the fifth aspect is that marketing approval is not linked to patent status. In accordance with Article 40-2.1 of Pharmaceutical Affair Act, an applicant should provide the related patent document and license agreement but the drug originator has essentially no recourse to the DOH to prevent approval of a generic version of a drug. That is the DOH does not involve itself in any patent-related issues.

Accordingly, the drug originator cannot take any action against any applicant for a generic drug submission for approval before the DOH. Nevertheless, it might be possible for the originator to take an action before the civil court for patent infringement arising from the act of filing a submission with the DOH for approval of a generic version of a patented drug. This practice is similar to the US FDA.

#### **5.3.4.3 The Exception for Data Exclusivity-The Compulsory License Scheme**

As explained in the previous section the exceptions of data protection are less than what they should be. For instance, the lack of exception grounds on the unfair commercial use makes the compulsory licensing difficult to manufacture patented medicines in the case of emergency.

According to Article 76 of the Patent Act, there are four grounds to exclude patent protection: (1) in order to cope with the national emergencies, (2) to make non-profit-seeking use of a patent for enhancement of public welfare, (3) or in the case of an applicant's failure to reach a licensing agreement with the patentee concerned under reasonable commercial terms and conditions within a considerable period of time; and (4) in the event that the patentee has imposed restrictions on competition or has committed unfair competition, as confirmed by a judgment given by a court or a disposition made by the Fair Trade Commission of the Executive Yuan. However, these exceptions cannot be used to exclude data exclusivity under Article 40-1.

In 2005, during the outbreak of the bird flu, Taiwan's government ruled that Roche had to issue a license to the Department of Health for local production of Tami flu, the drug so

far regarded as the most promising treatment for avian influenza.<sup>91</sup> The decision made Taiwan the first country to employ compulsory licensing to ensure sufficient stockpiles of the drug in the event of a pandemic. Without impediment of the protection of intellectual property, the Taiwanese Intellectual Property Office (TIPO) attached a number of conditions to the compulsory license.<sup>92</sup> The first condition is that Tamiflu medicine should be used up, and then DOH or a local company which authorized by DOH could produce the medicines. The second condition is that compulsory license must be limited to domestic use. The third limitation is that the compulsory license would be effective only until the end of 2007. The fourth condition is that the Department of Health must pay Roche "appropriate" license fees. The final limitation is that the compulsory license can be revoked once the two sides reach an agreement for voluntary licensee. It is not surprising that this case raised the issue of whether the Taiwanese can trigger the national emergency ground to grant a compulsory license. However during this process there was no discussion as to whether such process violated the data exclusivity right. It is clear that the data exclusivity is not excluded by the compulsory license under the current Pharmaceutical Affairs Act. Therefore, the only explanation for this ignorance of the issue of data exclusivity is that DOH took it as granted when the compulsory license is granted; the data exclusivity is also suspended at the same time.

The 2008 reform Draft of Patent resolved a part of issue. It stated that if the compulsory license is granted on the basis of assistance to the developing countries to deal with a

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<sup>91</sup> Kathrin Hille, *Taiwan employs compulsory licensing for Tamiflu*, November 25 2005 <http://www.ft.com/cms/s/0/cebeb882-5dcb-11da-be9c-0000779e2340.html> (last visit Feb. 25, 2009).

<sup>92</sup> *Id.*

health emergency, the patent and pharmaceutical data protection are suspended. In this way this exception, seemingly, is applied for the grant of compulsory license for other needy countries. However, this exception is only applicable in cases where the Taiwanese government manufactures the products to export to countries that having national emergency rather than manufacture for local uses.

## **5.5 Implementation of the Right to Medicines**

### **5.5.1 The Right to Medicines**

Taiwan, though separate territory and separate political and administrative unit is not a UN member; thus, it is not a member to all the important international organizations and agencies. One result of this non-recognition of Taiwan is that many human rights instruments are not open for Taiwan to ratify. However, this does not mean that the right to health is not recognized in Taiwan, because Taiwan is not a member to the ICESCR. To the contrary, the right to health and the right to medicines have been enforced by the adoption of Taiwan National Health Insurance Act.

The legal obligation to implement national insurance scheme is based on Taiwanese Constitution. In accordance with Article 155 of the Taiwanese Constitution "the State, in order to promote social welfare, shall establish a social insurance system." Article 157 of the Constitution further specifies: "The State, in order to improve national health, shall establish extensive services for sanitation and health protection, and a system of public medical service." The obligation to establish a social insurance system is strengthened again in Article 10, Paragraph 5, of the Amendment of the Constitution: "The State shall promote national health insurance . . . ." According to these Constitutional provisions, the

Taiwanese National Health Insurance Act, was promulgated on August 9, 1994, and implemented on March 1, 1995. Later, this implementation was affirmed by Judicial Yuan interpretation No. 472, as a realization of the aforesaid provisions of the Constitution.

#### **5.4.2 Implementation of National Health Care**

Today, the National Health Insurance covers 99 percent of citizens; even some, who live in Mainland China. The NHI program offers comprehensive and equal benefit coverage to every enrollee. This universal coverage includes outpatient services in clinics and hospitals, inpatient hospital service, dental service, Chinese medicine, diagnosis tests and examinations, prescription drugs and certain over the counter drugs, preventive services, day care for the mentally ill and home care.<sup>93</sup> The NHI has been proved one of best universal insurance in the world. Though, the framework of Taiwan National Health Insurance is based on Medicare of the US, it modified the whole idea of medical aid and removed some deficiencies. Bottom line the public health system in Taiwan became an ideal model of universal insurance.

In this system premium service and coverage were offered, beneficiaries paid co-payments of US\$ 2.5 dollar (NT \$ 80 dollar) for every clinic visit or out-patients visit to district hospital, \$ 7 dollar (NT \$240) for an outpatient visit to regional hospitals and only \$11 dollar (NT 360) dollar for an outpatient visits to academic medical center. In every

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<sup>93</sup> DOH, Payment Scope, available at [http://www.nhi.gov.tw/english/webdata.asp?menu=11&menu\\_id=293&webdata\\_id=1881](http://www.nhi.gov.tw/english/webdata.asp?menu=11&menu_id=293&webdata_id=1881) (last visited Feb. 25, 2009).

visit, an outpatient can get the necessary prescription drugs for one or two weeks without extra payment.<sup>94</sup>

The premium is quite low compared to other countries. Basically, it is wage-based premium share by an individual or employer and the government. In the private enterprises, the employee paid 30%, the employer paid 60% and government 10%. The government will subsidize 100 % of the premiums for low-income individuals and veterans. In public sector, the government employee still pays 30% and the government will be responsible for the rest of 70%.<sup>95</sup> The high coverage rates and the comprehensive benefits guaranteed to the citizen the right to medicines.

#### **5.4.3 The Impact of Cost Containment Stage on Pharmaceutical Expenditure**

According to DOH, the pharmaceutical spending is about one quarter of the whole national insurance expenditure.<sup>96</sup> Thus, control of pharmaceutical expenditure became the top priority of National Insurance Bureau. Indeed, the National Health Insurance Act authorizes Bureau of the National Health Insurance (BNHI) to adopt appropriate measures to control pharmaceutical expenditure. In accordance with Article 51 of NHIA,<sup>97</sup> the Insurer, the BNHI,<sup>98</sup> should establish the Fee Schedule for Medical Services

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<sup>94</sup> DOH, *supra* note 3.

<sup>95</sup> Cheng, *supra* note 2.

<sup>96</sup> Lee et al., Impact of Cost Containment Strategies on Pharmaceutical Expenditures of the National Insurance in Taiwan, 1996-2003, *Pharmacoeconomics*, Issue 24 (9), 891, 891-893 (2006)

<sup>97</sup> Article 51 of National Insurance Act (Taiwan) reads:

The Fee Schedule for Medical Services and Reference List for Drugs shall be established jointly by the Insurer and the contracted medical care institutions and reported to the Competent Authority for approval.

and Reference List for Drugs. The payment to the service providers, such as hospitals and clinical are based on the Fee Schedule for Medical Services and Reference List for Drugs.

<sup>99</sup> Since the Bureau of National Health Insurance (BNHI) is the only payer to medical service providers, the formation of Fee Schedule and Reference List for Drugs would affect the choice and price of drugs.

A research pointed out the BNHI adopted many measures to control pharmaceutical expenditure, including adjustment of the List Price downward, setting payment price, limits the payment rate for clinics, implementing the global budget,<sup>100</sup> and conducting the

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The Fee Schedule described in the preceding paragraph shall follow the principle of "equal payment for same illness" and the relative points shall reflect the cost of each medical service. The International Classification of Diseases shall be used as the reference in deciding equal pay for the same illness.

<sup>98</sup> The Taiwan Health Insurance scheme is a Universal Health Insurance Program. The scheme is conducted by a single payer financed through the combination of premiums and taxes.

<sup>99</sup> Article 50 of National Health Insurance Act (Taiwan) reads:

The contracted medical care institutions shall declare to the Insurer the points of the medical services rendered and expense of drugs, based on the Fee Schedule for Medical Services and the Reference List for Drugs.

The Insurer shall calculate the value of each point based on the budget allocated according to in the preceding article and the total points of medical service as reviewed by the Insurer. The Insurer shall pay each contracted medical care institution according to the reviewed points.

The ambulatory care drug expenses shall be paid to the contracted medical care institutions after being examined by the Insurer. In case the payment of expense exceeds the total of drug expense preset according to the preceding article, a certain ratio of the excessive amount shall be deducted from the budget for the ambulatory care for the current season. In such a situation, the Reference List for Drugs shall be adjusted in the following fiscal year.

The ratio of deduction described in the preceding paragraph shall be decided by the Negotiation Committee for Medical Expenses. The Competent Authority shall make decision at its own discretion in case the Negotiation Committee for Medical Expenses does not reach an agreement in time.

Available at [http://www.nhi.gov.tw/english/webdata.asp?menu=11&menu\\_id=295&webdata\\_id=1865](http://www.nhi.gov.tw/english/webdata.asp?menu=11&menu_id=295&webdata_id=1865) (last visited Feb. 25, 2009).

<sup>100</sup> The 2005 Taiwan Year Book, available at <http://www.gio.gov.tw/taiwan-website/5-gp/yearbook/2005/p250.html> (last visited Feb. 25, 2009).

regular marketing price survey to adjust the reimbursement price of medicines.<sup>101</sup> These measures have significant impacts on pharmaceutical expenditures.

Apparently, to adjust pharmaceutical prices this has to be based on several factors:<sup>102</sup> whether the medicine is patented, whether there is a comparable generic version for patented medicine in the market, and whether they are the same bioequivalent medicines. Under such scheme, the BNHI data pointed out new product reimbursement prices in Taiwan have dropped from 80% of the median price (based on the prices in 10 benchmark advanced countries) during the 1996-2002 period to only 56% of the A-10 median in 2006.<sup>103</sup> The price scheme effectively controlled the pharmaceutical spending and reduced the total cost of national health insurance, but it created another problem. This problem, as another research has shown; there are only 15% of new drugs used in the National Health Insurance.<sup>104</sup> This number is lower than most of developed countries. Apparently, the price scheme will avoid the service providers using new drugs and this scheme impedes the access to new medicines, because low reimbursement rate would drive them to use cheaper medicines in order to ensure their profits. In addition, the research showed that an average delay of new medicines, compared to the US is around four years. The price scheme is also a reason to cause this delay. In order to list new

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<sup>101</sup> Lee et al., Impact of Cost Containment Strategies on Pharmaceutical Expenditures of the National Insurance in Taiwan, 1996-2003, *Pharmacoeconomics*, Issue 24 (9), 891, 891-893 (2006).

<sup>102</sup> DOH, Chapter Three Principles on Drug Reimbursement Price Approval of National Health Insurance, available at [http://www.nhi.gov.tw/english/webdata.asp?menu=11&menu\\_id=295&webdata\\_id=2443](http://www.nhi.gov.tw/english/webdata.asp?menu=11&menu_id=295&webdata_id=2443) (last visited Feb. 25, 2009).

<sup>103</sup> Amcham, *supra* note 38.

<sup>104</sup> Institute of Economics and Academia Sinica, Taiwan, The Drug Black Hole, IEAS Working Paper (2005)

drugs covered by the National Health Insurance, the process will take around 13-14 months. This is another negative effect on access to new medicines.

Finally, the price scheme also triggers another trade issue, the violation of national treatment principles in TRIPS. The EU and the US trade representatives concerned that the reimbursement price of medicines and cost containments unreasonably favor the local generic medicines. In their view, this would likely cause unfair competition.

## **5.6 Conclusion**

The implementation of TRIPS raised a global issue of access to medicine, in particular in the developing countries. Taiwan as a member of WTO provides the protections of pharmaceutical innovations. This protection more or less complies with the standard of protection required by TRIPS. Nevertheless, the case of Taiwan is distinguished from other developing countries with respect to access to medicines. That is, the implementation of TRIPS agreement does not create severe negative impacts on the right to access medicines. Perhaps Taiwan is successful because its system comprised three areas; the pharmaceutical patent, the pharmaceutical registering and data exclusivity in one policy, that is, the National Health Insurance Act.

Exploring the Patent Act, the patent is available for pharmaceutical products. The grounds provided under Article 76 of Patent Act to exclude patent basically comply with requirements of Article 31 of TRIPS, which allows states to exclude patent where there is (1) national emergency, (2) an anti-competitive remedy, (3) non-commercial use for public interests and (4) a situation that a voluntary license cannot be entered within reasonable time and terms. These grounds established the exceptions to ensure that the

right to medicines can be realized in Taiwan. A noted case applying the exception to grant compulsory license appeared in 2005, in which, Taiwan granted the compulsory license for Tim-flu. In 2008, Taiwan drafted a reform of Patent Act in order to incorporate the 2005 Amendment. The reform was focused on waivers of requirement that the use of products manufactured by the compulsory license is predominately to be used in domestic market. Thus, it is basically a law to resolve the issue of access to medicines in developing countries.

With respect to the pharmaceutical law, the development of data exclusivity is highly related to the development of pharmaceutical registering scheme in Taiwan. Compared with the US pharmaceutical law, we found the underlying philosophy, basically the same. The desire to develop the pharmaceutical registering scheme in Taiwan, except for ensuring the safety of drugs, may contain another important goal, the promotion of local pharmaceutical industry and nourishing the capability of clinical trials. It is comprehensible why the Taiwanese government should incorporate an additional goal irrelevant to the safety of drugs in pharmaceutical law, if you recognized the features of Taiwanese pharmaceutical market. In general, there are four key features of pharmaceutical market: (1) small capital size, (2) highly relied on technology transfer, (3) half of medicines are imported; and (4) a small pharmaceutical market. These features ensure that the policy in pharmaceutical industry is focused on building capability of manufacturing and conducting clinical trials rather than the development of new drugs. With the strong local capabilities of manufacturing, the affordable medicines can be acquired easily and a competitive pharmaceutical market can be established locally. Under this policy, the health agency is mandated to determine what approaches the

pharmaceutical registering scheme follow and what degree of protection of pharmaceutical data should be implemented.

Overall, the protection of pharmaceutical data has evolved in three separate stages. These three stages, no doubt, stay with the evolution of pharmaceutical registering scheme. The 1993 requirement of local clinical data in pharmaceutical registering, namely the first stage, initiated the development of pharmaceutical clinical trials in Taiwan and also introduced the concept of protection of pharmaceutical data. The protection of pharmaceutical data in this stage is focused on the local clinical data, while the foreign pharmaceutical data is protected only through contracts, torts, and 1997 Trade Secret Act, if they are qualified.

The second stage initiated by Double-Twelve Announcement in 2000. This announcement deregulated the local clinical trial requirement in 1993 and adopted the ICH-E5 standard to comply with the international standard. The purpose of introducing the new standard is to avoid unnecessary repetition of local clinical trials, which were required by 1993 regulation and use the bridge study as the alternative requirement. Apparently, the adoption of bridge test, though still on the basis of boosting the local capability of clinical trial is more logical way to justify the requirement of local data. The essence of bridge study is to deal with the Asian ethnical variance when clinical trails are not conducted in Taiwan. This provides a better ground for health agencies to require such data without violation of national treatment principle in TRIPS. However, this announcement provides the protection data, which covered by bridge study, while the foreign registering pharmaceutical data is protected under this announcement.

The third stage, namely data exclusivity period, began at the adoption of data exclusivity right in 2005. The significance of this stage is that it extended the data exclusivity right from local data to the foreign registering data. This adoption, also, incorporates the measure of waiting period to encourage the early registration of foreign medicines. This measure would incentive the multinational national companies to register in Taiwan within three years after the first foreign registering. However, this adoption lacks certain exception, which are provided under Article 39.3 of TRIPS; namely the fair non-commercial use exception. This incomplete exceptional structure for data exclusivity no doubt will drag Taiwan to a bad position when patent is excluded but the data exclusivity is not. In this regard, the establishing of exceptional structure should take account of the exceptional grounds that provide for patent and make them consistent. Otherwise, the grounds provided under Article 76 of Patent Act finally will be inoperative if the data exclusivity is not excluded. The 2008 Draft of Patent Act Amendment, partially, took account of this issue. The Amendment suspended the data exclusivity when compulsory license is granted to enable Taiwan to export to medicines to eligible countries defined by the WTO. This Draft however did not resolve the issue of basic structure of exceptions of data exclusivity.

The National Health Insurance Act likely is one of key reasons to ensure the citizens right to medicines. In accordance with this Act, BNHI has authority to regulate the pharmaceutical price through appropriate cost containment measures. For a decade now, the cost containment measures indeed had positive impacts on the control of pharmaceutical expenditure. However, the research showed that such control brings other negative impacts on access to “new” medicines. The low reimbursement prices caused

the medical service providers to choose the cheaper generic medicines instead of more effective “new medicines.” On the other hand, the principles to determine reimbursement prices seemingly favor local medicines. This triggers another trade issue, a national treatment principle in TRIPS. Though, recently, the BNHI attempts to relief the issue of insufficient access to the “new medicine’ by commitment to adjust the new drug price upward. So far there is no research to show the impact of this attempt.

The case of Taiwan established an example for developing countries to enable their citizens to realize the right to access medicines by utilizing the flexibilities of TRIPS without breaching their international obligations. In other words, the implementation of TRIPS in flexible way and effective adoption of certain measures fully enable individuals to realize the right to medicines. By adopting appropriate measures into registering scheme, states may build up their local manufacturing capabilities of pharmaceutical industry. This strategy though cannot raise states’ capability to the level as the R&D oriented countries, it should have states acquire certain manufacturing capacities and create a competitive pharmaceutical market. These two prominent results may resolve most of the issues pertinent to the right of access to medicines. The cases of South Africa and Brazil are good examples to demonstrate that even states with their own local capabilities to manufacture generic medicines may still encounter difficulties in access to medicines. Nevertheless, a competitive market may force the pharmaceutical company to provide medicines at reasonable price.

## 6 Conclusions

The era of TRIPS marked that the knowledge itself, though is intangible, is a commercial asset in international trade. It is why medicines can be sold at high price because there is high value of knowledge, which is protected through patent or pharmaceutical data, produced by the pharmaceutical companies. More than \$800 million of developing cost and the 8-12 years of developing period provide an explanation as to why pharmaceutical companies sold new medicines at a high price. Nevertheless, this viewpoint is based on that countries have profitable and well-established pharmaceutical industry and people in those countries have high income to acquire the required medicines. For most of developing countries, medicines seem far and unreachable. In fact medicines come as a second priority in their list because some of these countries' citizens lack food which is much more essential than medicines. This harsh reality did not allow these countries to adopt the same legal standard of protection adopted in the US and other developed countries.

This thesis began with exploring the need of data exclusivity and debate in relation to the protection of pharmaceutical data, discussed the concept of data exclusivity, and surveyed entire exceptions of the protection in current legal regimes. Moreover this thesis sought an answer from the underlying jurisprudence of the right to access medicines and provided a case study to look at how the protection operated without impeding access to medicines.

In chapter 1, we explained that, basically, the concept of protection pharmaceutical data, which originated in the US in 1984 has two main aims: (1) the advance of the entry of

generic medicines; and (2) compensating the lost of originators in clinical trial spending. By merely introducing the concept of data protection at least two urgent controversies had to be confronted and resolved; first, whether pharmaceutical data should be disclosed, and second, whether subsequent applicants for marketing approval regarding respective generic medicine should repeat same clinical trials. In reality, the adoption of data exclusivity in the US expedited the entry of generic medicine and promoted the R&D because the US is the typical R&D countries and more than 80 % of medicines are produced in the US.<sup>1</sup> Therefore, it was not surprising that the US takes a more stringent approach of protection to provide sufficient incentives to promote the industry. However, this same legal principle of protection seemed less suitable to address the question of protection in developing countries. To the contrary, the protection of pharmaceutical data along with the pharmaceutical patent creates un-mounted duel barriers to access generic medicines, in the developing countries.

These competing interests of developed and developing countries are hardly news. A look at the drug market is very revealing.. Global data indicates that the US companies are marketing the largest of new medicines with a 47.2% share and many of them are important global pharmaceutical manufacturers, such as Pfizer, Merck & Co, Johnson & Johnson or Bristol-Myers Squibb, etc.<sup>2</sup> The rest of the new drugs market share is also dominated by companies from powerful countries

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<sup>1</sup> Stuart O. Schweitzer, *Pharmaceutical Economics and Policy*, page 170 (Oxford, 2<sup>nd</sup> ed., 2007)

<sup>2</sup> *Id.*

It legitimate to ask what these companies and their powerful governments behind them would do before the introduction of the concept of data exclusivity to protect their interests. Patent regulations were in place, so one may think that why cannot they keep protecting their interest through patent law, given the fact that patent law in early years provided 20 years of protection? The answer is simple, while patent protect against infringement it is not adequately protective tool when it comes to data protection in today's world. In today's world there exists group and states that have the knowledge and technology to use reverse engineering skills to produce any patented drug and this, technically would not be considered patent infringement. Also another factor that diminished the importance of patent as a tool of protection is that patent law is essentially capital market-oriented tool; thus in early years when it was developing, this law did not take account of other legitimate human interests, namely the human rights law.

Accordingly, there had to be an alternative protection to the well-established patent law. This new alternative is data exclusivity. It keeps generic medicines out the market with fives years. Yet, rightly, many are not happy with new US principle of protection.

In chapter 2, we found that; though, pharmaceutical patent has been recognized as a basic global standard to protect pharmaceutical products in TRIPS, there is no concession concerning how to protect pharmaceutical data. This creates a tension between the US and developing countries. The US came out victorious in this matter. The US was successful in convincing some countries to adopt this concept notwithstanding any other obligations these countries had. The US, accordingly signed treaties with these countries

obliging them to adopt the data exclusivity principle. Eventually the result was that the US was able to provide better protections.

The attitude in TRIPs is, pretty much, neutral compared to the treaties the US made with other countries. These US agreements roughly formed three type of data exclusivity, from conceptual type to comprehensive type. The first generation is the basic type of data exclusivity because it only conceptualizes the term of data exclusivity. The NAFTA, the first regional agreement, began to adopt data exclusivity. The US- Jordan FTA, the first bilateral agreement duplicated the NAFTA model of data exclusivity. These two cases only contain basic elements of data exclusivity, terms and subject matter of protection.

The second generation in the one hand provides clearer terms and develops comprehensive conditions in text through subsequent negotiations of regional and bilateral agreements. On the other hand it creates more barriers for generic medicines. Besides five years terms, this generation often removed the ambiguous terms and defined whether the new use is protected, whether the waiting period is applicable, whether states are allowed to refer data registered in other jurisdiction etc.<sup>3</sup> Of these agreements, the most controversial was the generation that linked marketing approval to patent status. Under the limitation of patent linkage, the subsequent generic manufacturers cannot enter the market without the consent of the originator. One dubious result of this linkage is that in jurisdictions that do not put cap on application periods, the adoption of data exclusivity may delay the entry of the generic medicines more than 10 years. Typically if an originator finds a chance to delay he can apply marketing approval until the last date of

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<sup>3</sup> See chapter 2

five-year term data exclusivity in other jurisdictions and began another five-year term of protection. This unintentionally enables the originator to lock out generic medicines for 10 years from the first registration in the developed countries.

Apparently, the second generation of data exclusivity extremely hindered access to medicines. This approach, no doubts, took few accounts of the citizen's right to access medicines in the developing countries.

It is uncontested that the WTO Doha Declaration and the subsequent Decision in 2003 provide a channel for the US to end the proliferation of the second generation and start the third generation with some adjustments. In 2007, the US incorporated the essence of 2001 WTO Doha Declaration and 2003 Decision into her trade policy. The 2007 US-Peru and the other two agreements incorporated the results of the Doha Declaration and Decision in the agreements and removed patent linkage. Such incorporation initiated new reform of data exclusivity, namely the third generation of data exclusivity. In this new generation of data exclusivity, the most distinguished change is recognition of the right to access medicines. Thus, depending on from what angle you look at it, right to medicines could be seen as a new element that defines the frontiers of data exclusivity, but also the opposite is true; from the other perspective, data exclusivity defines the limit of the right to medicines.

In the domestic level several mechanisms are deployed to deal with the issue of data protection. For instance, the Indian law provides the protection of pharmaceutical data through trade secret law, which is another type of protection other than data exclusivity. The protection through trade secret law indeed is the generic type of protection under

Article 39.3 of TRIPS. In accordance with Article 39.1, pharmaceutical data is protected because it is undisclosed and it contains commercial value. Thus, it is logically possible to protect the pharmaceutical data and avoid the unreasonable linking with patent status. However, protecting pharmaceutical data through trade secrets law has its own repercussions. The pharmaceutical registering scheme for safety reasons require the disclosure of pharmaceutical data to the public in the most of the developed counties. This situation made it difficult to protect pharmaceutical data through the trade secrets, because there is no secrecy after a new drug is registered in one jurisdiction, which unveils the data to the public. In this sense; though, theoretically, there are four types of protection of pharmaceutical data, adopting data exclusivity, arguably, is the reasonable way to go.

Once, we recognized that the data exclusivity is the better model to protect pharmaceutical data; this is an explicit recognition of the policy of promotion of pharmaceutical industry. Then the next step we should ask what kind of elements, terms and conditions should be included in the data exclusivity scheme. Or put it this way, as a safety, any building should have a safety gate for emergency. The adoption of data exclusivity should be based on an assumption that there is a complete set of exceptions for public health purpose. Without this premise, the access to medicines, the one of objectives of this protection, cannot be attained. Thus, in chapter 3, we explored the exceptions of data exclusivity in the global, regional and domestic law level. The several findings regarding the exceptions of pharmaceutical patent and data exclusivity are unpleased. Those exceptions are not flexible as they should be. Fortunately, the Doha meeting initiated a serious of actions to improve this situation.

In the global level, the entire exceptions for patent are based on Article 7, 8, 30 and 31. It seems a complete set of exceptions to exclude patent. Yet, it is not. As the most basic form to protect pharmaceuticals, it is surprising that TRIPS does not provide effective grounds to exclude patents for public health purposes. Basically, the grounds to exclude patent are designed for the use as a goodwill purpose rather than health related purposes. But, most of WTO members before the late 1990s' had an illusionary image that these exceptions and flexibilities in the TRIPS could be used to increase the access to medicines when states encounter health emergencies. The result of 1997 South African case and 1999 Brazil cases awakened these states from this illusion. When these two developing countries used the default exceptions in TRIPS to resolve the issue of access to medicines resulting from the implementation of the TRIPS agreement, there were certain intellectual property infringement suits against them immediately. Soon after these two cases, the WTO members found another severe deficiencies in the compulsory license scheme. The requirements of compulsory license scheme set out in Article 31 of TRIPS restrict developing countries, which lack manufacturing capabilities from importing medicines from other countries, because the grant of compulsory license should provide that the generically licensed medicines should predominately be used in the domestic market. But the problem is countries cannot grant a compulsory license for the use in other countries. This inherent deficiency was unveiled at the moment TRIPS was adopted, because states negligently overlooked the negative impacts of implementation of TRIPS. Indeed, these negative impacts will affect, at least, the interests of two third of members, because only a small portion of countries can manufacture drugs. The profound influence on access to medicines left the WTO members no choices but to resolve this

issue. The emergency of 2001 Doha Declaration and 2003 Decision demonstrates that WTO devoted to a serious of action to satisfy a need to restructure or revise those grounds to exclude intellectual property in cases of health emergency. The results of the WTO actions at least are important in several aspects.

First, the default compulsory license scheme cannot resolve the issue of access to medicines, in particular in developing countries, resulting from the implementation of TRIPS. Second, the flexibilities in TRIPS have little positive effects on resolving the issue of access to medicines if there is no official legal text to support them. It is clear that if there were no substantive grounds for states to exclude pharmaceutical patent and data exclusivity for public purpose, whenever states trigger any flexible measure would have potential risks of law suits against them. The WTO members were aware of this impact; therefore, developing countries attempted to incorporate new texts or new elements into TRIPS. The progress of integrating new text is complicate because it involves fundamental interests between the developing countries and developed countries. The 2005 Amendment of TRIPS represents the final bottom line between the two sides, or the final text that both sides can accept. That is why eventually the WTO decided to put reform in permanent way in 2005.

Turning to the data protection, the situation seems even worst than patent. The exceptions under Article 39.3 of TRIPS are even less complete than patent exceptions. It provides two general grounds to exclude data exclusivity; (1) fair use and (2) the situations are necessary to suspend the protection in order to protect the public. Some researchers have predicted that the adoption of data exclusivity will diminish the legal effect of

compulsory license if data exclusivity cannot be excluded at the same time when the compulsory license is issued to suspend patent protection. These worries are not far from the truth and likely will become another barrier for the generic medicines. Indeed, many regional and bilateral agreements have adopted the strict data exclusivity without adequate exceptions as chapter 2 has pointed out. In the second generation of data exclusivity mentioned, it is noted that the US trade representatives attempted to secure the interest of pharmaceutical industry and even introduced the stricter rules than the US law. In this situation, the generic medicines cannot be marketed, in states that have granted the compulsory licenses to exclude patent, because they are protected by the data exclusivity under the bilateral or regional agreements. Such practice, no doubt, is legally questionable.

The emergence of third generation of data exclusivity is an attempt to improve such negative aspects of data exclusivity and incorporates the texts of Doha Declaration and Decision. Assuming this Amendment can be passed, the exception to exclude the data exclusivity will not only include two grounds under Article 39.3 but also possible flexible measures inconsistent with the TRIPS as well as compulsory license scheme. It is still too early to judge what results these reforms will achieve, but it is true that they provide a better, flexible language to construe the exceptions of data exclusivity for public purpose and access to medicines.

It is noted that the exiting of data protection should not be solely for the profits of pharmaceutical industry. Its existence should carry other social welfare objectives; namely, access to medicines. The question we should ask is why the protection of

pharmaceutical innovation should contain these two objectives. The answer lies in the underlying philosophy of jurisprudence of access to medicines, as demonstrated in chapter 4. Looking more squarely to human rights instruments that embody the right to health and the recent WTO and WHO policies, we found that there is a trend that promises to reconcile these two interests. That is a trend to reconcile the access to medicines and protection of pharmaceutical innovation. Such trend has been developed through three phases; Pre-Doha, Doha and After-Doha phases.

In the Pre-Doha phase, from 2000-2001, we found that though the access to medicines has been recognized in certain human rights instruments for years, this right is not successfully realized. Partially, this unsuccessful realization can be attributed to the lack of operative indicators of health, clear definitions of the scope of the right, and effective evaluation. The ambiguous attitude as to how to implement the right to health, and the right to access medicines affects the WTO's approach to resolve the issue between the protection of pharmaceutical innovations and states' obligation to implement right to health in the early case. In the 2000 Canada Pharmaceutical case, the WTO obviously took more defensive approach against states' right to protect public health and favorable approach to protect pharmaceutical innovations. The adoption of General Comment 14 by ICSCR Human Rights Committee definitely is a turning point in this stage. General Comment 14 furnishes a better and clearer text as to states' obligation to implement the right to health or the right to access medicines and connected the core obligation of this right with the essential medicines. The recognition of the right of "access to essential medicines" being the core obligation imposes on states an obligation to protect this right with maximum efforts to ensure access to essential medicines. This means states should

realize that national policies, in every aspect, should take account of the right to access essential medicines, and this consideration, in turn, impacted the intellectual property law.

The second phase can be marked as the WTO Doha Era (2001-2005), or post Comment 17. In this phase, under the influence of General Comment 14, the WTO members were devoted to reconcile the protection of pharmaceutical innovation and the access to medicines and completed three prominent documents in relation to the TRIPS agreement; (1) 2001 WTO Doha Declaration on Public Health, (2) 2003 Decision to paragraph 6 of Declaration and (3) 2005 Amendment. Indeed, these three documents regardless of how much positive impact they had on the implementation of the right to medicines, they began a new relationship between intellectual property law and human rights law.

In the third phase, after the emergence of 2005 amendment, from international, regional to the domestic level, we found the right to access medicines became the new element of intellectual property as to the protection of pharmaceutical products. In the global level, the Medical Development and Research Treaty had been proposed by NGO and the developing countries to the WTO. The Treaty directly incorporated the access to medicines into the protection scheme.

Finally, we chose Taiwan as a case study in chapter 5 for two reasons. First, Taiwan is a country, which is highly reliant on the importation of pharmaceutical products, but the government adopted the same protection to pharmaceutical innovations as the US does. The second interesting reason to choose this case is the citizens in this island are not suffering from the lack of access to medicines, though the adoption of high level of

protection to IP rights. The case of the Taiwan provides an empirical proof that states may realize the right to health at low cost and at the same provides a high level protection for pharmaceuticals.

The Taiwanese miracle can be unveiled after exploring three areas of law: (1) pharmaceutical patent (2) pharmaceutical law; and (3) National Health Insurance Act. There are several findings in that the Taiwan government protects pharmaceutical innovations though include traditional objective, the promotion of technology but the most important aim is focused on two aspects: (1) strengthening local manufacturing capabilities and (2) prompting the technology transfer. The government has to provide the higher standard of protections for pharmaceutical innovations in order to create a business environment in which foreign companies would like to transfer their high technology and would like to invest in this industry. That is why the Taiwan government does not loosen the protection of pharmaceuticals

Thus, the pharmaceutical patent is available for pharmaceutical products since 1997 reform of Patent Act. The exceptions to exclude Patent under Article 76 of Patent Act are similar to Article 31 of TRIPS with little variance. It is complete enough for Taiwan. The manufacturing of generic medicines is not an issue in Taiwan, once the government can grant the compulsory licenses to exclude patent. In this regard, the 2005 Tamiflu case that Taiwan issued its first compulsory license to manufacture medicines for the treatment of bird flu proves this point.

With respect to pharmaceutical law, the development of protection of pharmaceutical data is highly related to the evolution of pharmaceutical registering scheme. In the early

stage, 1993, the health agency requires only 40 local cases of clinical trials to register data, because its aim was to build up local capabilities. The second breaking point of pharmaceutical registering was 2002. In this stage the government deregulated the local clinical requirement and replaced it by the ethnical variance study, also called bridge study. This incorporation is complied with the standard ICH-E5. This reform provides more judicious reasons to require the local clinical data. Both of these two registering requirements provided five years protection for pharmaceutical data under monitoring period. In 2005 the government, under the pressure of US representatives adopted five years term of data exclusivity in order to protect foreign registered data. The protection of previous two local requirements is focused on the protection of local clinical data, whereas the 2005 data exclusivity is focused on which of pharmaceutical data in the foreign jurisdiction. Through, progressive protection of pharmaceutical data along with pharmaceutical industry policy successfully built up the local clinical and manufacturing ability step by step.

The National Health Insurance scheme plays an important role in ensuring the access to medicines in Taiwan. As the only single payer of Insurance system, Bureau of National Health Insurance can bargain for the price of medicines easily. Further, the National Health Insurance Act authorizes the BNHI to control the price through appropriate measures. As a result, the pharmaceutical prices are 80-90 % less than that of the international median prices. The prices of generic medicines are also reasonable because local companies can produce generic medicines after the expiration of the patent. The strong capabilities of local pharmaceutical manufactures create a competitive pharmaceutical market, which would reduce the price. This approach avoided the

Taiwanese citizens to pay high price for medicines. Here, we found that the Taiwanese government took another approach to increase the access to medicines. By adoption of high-level standards of intellectual property rights, the government wants to use foreign business to inject new blood into the industry to remodel the old and outdated local pharmaceutical industry. Since the resource is constraint, the government spends in upgrading the local manufacturing rather than in pharmaceutical R&D competition. Meanwhile, the R&D will be conducted by governmental institutions or be subsidized by the governmental fund. This approach can direct the R&D toward the neglected disease not high profited disease. The entire package of health policy, including the protection of pharmaceutical innovation still contains some negatives aspects, in that the research found most of prescription drugs used in Taiwan are generic medicines rather than patented medicines. The Taiwanese government still makes efforts to raise the quality of insurance. The Taiwanese citizens are proud of their Health Policy.

Overall, this research takes the protection of the pharmaceutical data as an example to explore the tension between intellectual property and access to medicines. The issue is not new but we found that the international community reconciled these two issues. The international community has recognized the issue of access to medicines is not only resulting from poverty, but it also would happen, inadvertently, because of other human reasons; such as terrorism. A legal protection for any subjects is to make sense; it must be read in the light of some assumed purpose. Thus, if a law merely declaring a rule, with no purpose or objective, this can hardly be called laws as we know it. The protection of data should be construed in accordance with its underlying purpose and policies. Each condition and term should be read in the light of purpose and policy of the rule or

principle in question. Having this in mind, the protection of pharmaceutical is not a purpose in itself; it is rather the social end we want to attain from invoking such a protection. Accordingly, when we talk about protection this should be understood to mean a meaningful protection to a meaningful purpose. And there can never be more meaningful purpose the human being *per se*.

It would be too much to expect that this research, to positively and holistically, cover the entire issue of access to medicines and the issues relating thereby, but it is reasonably expected that it, would at least, add constructively, to the discussion and the debate of this important issue. The lesson learned from the case of Taiwan, is that when a state with no bargaining power in international trade, find itself in a position like Taiwan that the state should use the strong protection to develop its local industry, which is another route to increase the access to medicines. This, indeed not a model answer, and not every state will succeed in following the Taiwanese model, because the answer depends on what the resource the state has and what kind of culture and business features it has, etc. The state should take account of all these factors and develop its policy accordingly.

Therefore it is hereby submitted that the protection of pharmaceutical innovation inevitably raises the price of medicines, but states should also take this price as the cost of developing the industry.

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