WTO Compliance Review: Proposed Amendments to the Intellectual Property Code of the Philippines

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I. INTRODUCTION

The balance between the public's access to medicine and the protection of the rights of intellectual property holders has been the subject of numerous debates and controversies worldwide. The Philippines has not been spared from this debate. Recent developments in the country have exemplified the challenge of balancing these two interests.

The Philippines signed and ratified the Uruguay Round Final Act in 1994 and thus adopting the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[1] In compliance with its

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obligations under the TRIPS Agreement, the Philippines enacted Republic Act No. 8293,[2] otherwise known as the Intellectual Property Code of the Philippines (IP Code), in 1997. On October 13, 2005, Senator Manuel "Mar" Roxas introduced Senate Bill No. 2139[3] (Roxas Amendment) which seeks to amend the IP Code. This bill proposes several amendments to the patent aspect of the IP Code with the goal of lowering the prices of medicines by enhancing government policy tools to influence supply and demand and by promoting greater competition among pharmaceutical companies.[4] The bill has gone through a first reading on October 24, 2005 and has been referred to the Committees on Trade and Commerce and Health and Demography for further study.

On March 1, 2006, Pfizer Limited of the United Kingdom and Pfizer, Inc. (collectively Pfizer) filed a civil case[5] against the Philippine International Trading Corporation (PITC) and the Bureau of Food and Drugs (BFAD) before the Makati Regional Trial Court for patent infringement in connection with *amlodipine besylate*.[6] Pfizer, a multinational company, tried to stop the Philippine government, particularly the state-owned PITC, from

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1. Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results Of The Uruguay Round Of Multilateral Trade Negotiations 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), *available at* http://www.wto.org/english/docs_e/legal_e/final_e.htm (last accessed Sep. 4, 2006) [hereinafter the TRIPS Agreement].
2. An Act Prescribing the Intellectual Property Code and Establishing the Intellectual Property Office, Providing for its Powers and Functions, and for Other Purposes, Republic Act No. 8293 [IP CODE].
3. An Act to Make the Laws on Patents, Tradenames and Trademarks More Responsive to the Health Care Needs of the Filipino People by Allowing the Importation, Early Development of Patented Medicines and Exceptions to the Application of Standard Compulsory Licensing Requirements for Drugs or Medicines to Lower Drug or Medicine Prices by Amending for this Purpose Certain Provisions of Republic Act No. 8293, Otherwise Known as the Intellectual Property Code of the Philippines, S 2139 Explanatory Note, 13th Cong, 2d Sess, October 13, 2005, *available at* http://www.senate.gov.ph/bills/sbn-2139.pdf (last accessed Sep. 4, 2006) [hereinafter Roxas Amendment].
4. *Id.*
5. Pfizer, Inc. v. Philippine International Trading Corporation, Civil Case No. 06-172, (Regional Trial Court, National Capital Region, Branch 61, Makati City, Mar. 1, 2006).
6. *Pfizer asked: Why is medicine 650% higher in RP than in India*, PEOPLE'S JOURNAL ONLINE, March 8, 2006, http://www.journal.com.ph/news.asp?pid=1&sid=1&nid=20760&month=3&day=8&year=2006 (last accessed Apr. 23, 2006).

importing Norvasc (*amlodipine besylate*) – a drug for the treatment of hypertension – and reselling it at a visibly lower price.[7] PITC was planning to import Amlogard, the name under which Norvasc is sold in India, from a Pfizer licensee in India when the patent expires in June 2007.[8]

Although PITC has not yet imported Amlogard for sale, it has applied for a Parallel Import Drug Registration (PIDR) for *amlodipine besylate* from the BFAD. As a requisite, PITC had to submit samples of the drug to the BFAD for testing. By importing and submitting these samples, Pfizer alleged that PITC violated Pfizer's exclusive right to import and use the patented product.[9] In its website, Pfizer claimed that the PITC and the BFAD were "dealing with" the drug that is still under patent. Pfizer also claimed that the drugs that PITC intended to import were counterfeit medicines not sourced from any of Pfizer India's distributors or sub-distributors.[10]

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7. *Senior citizens back import of affordable medicines*, PHILIPPINE TRIBUNE ONLINE, March 13, 2006, http://www.tribune.net.ph/metro/20060313met5.html (last accessed Apr. 4, 2006).

8. *Pfizer sues gov't on import program*, THE MANILA TIMES ONLINE, March 9, 2006, http://www.manilatimes.net/national/2006/mar/09/yehey/business/20060309bus2.html (last accessed Oct. 6, 2006).

9. IP CODE, § 71 states:

> Sec. 71. Rights Conferred by Patent
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> 71.1. A patent shall confer on its owner the following exclusive rights:
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> Where the subject matter of a patent is a product, to restrain, prohibit and prevent any unauthorized person or entity from making, using, offering for sale, selling or importing that product;
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> Where the subject matter of a patent is a process, to restrain, prevent or prohibit any unauthorized person or entity from using the process, and from manufacturing, dealing in, using, selling or offering for sale, or importing any product obtained directly or indirectly from such process.

10. *Pfizer Sues PITC, BFAD for Patent Infringement*, *at* http://www.pfizer.com.ph/corporate/news/main.php?page=release&ID=95 (last accessed Oct. 6, 2006).

Pfizer released the following statement on its website:

> Pfizer's position is that the agencies' dealing with Norvasc (amlodipine besylate) supposedly sourced from India, without the authority of the patent owner, violates the law. The complaint further states that BFAD and its officers induced the violation of Pfizer's patent rights by granting registration approval to PITC.
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> The case Pfizer filed versus PITC and BFAD is not only a trade issue, but a public health concern as well. Products that enter the Philippines through parallel importation may carry health risks associated with

This situation is one of the issues addressed by the Roxas Amendment. Aside from introducing the "Bolar exception" (to be discussed in Part III (B) below), the Roxas Amendment intends to provide legal protection for government officials involved in parallel importations from all kinds of harassment suits and also seeks to shield parallel importations from temporary restraining orders or injunctions.

This article will briefly outline the developments in the World Trade Organization's (WTO) policy on access to medicines. This article will also analyze whether the five major amendments proposed by the Roxas Amendment are consistent with the Philippines' obligations under the WTO, particularly under the TRIPS Agreement. In determining compliance, the author will refer to the practices and experiences of the WTO Members, the principles behind the WTO guidelines on pharmaceutical issues, and the Philippine policies on access to medicine.

II. ACCESS TO MEDICINE UNDER THE WTO

This section will provide a brief background on the developments in the protection of intellectual property. These developments, particularly in patent law, have led to a more liberal attitude of WTO Members, in the face of life-threatening medicines, towards access to medicine.

Protection for intellectual property gained worldwide recognition in the aftermath of World War II. Although the General Agreement on Tariffs and

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counterfeits. Counterfeit medicines may be manufactured in unregulated settings that do not adhere to the rigorous standards of Good Manufacturing Practice (GMP). They may be contaminated, stored improperly, outdated, may not work as claimed or may contain potentially dangerous ingredients. There is no way to ensure that these products adhere to an effective batch tracking and product recall mechanism. Further, there is no Post Marketing Surveillance (PMS) or Adverse Event Reporting system that can indicate possible side-effects not detected in earlier clinical trials.

Pfizer's finding is that none of PITC's sources had been identified by Pfizer India as one of its authorized distributor or sub-distributor. According to the World Health Organization, about 30-40 percent of medicines in the Indian market have been found to be counterfeit. Further, there is no reason to import medicines from India that treat high blood pressure since there are many available treatment options in the Philippine market today.

Respecting patent rights ensures that Pfizer will be able to sustain its mission to innovate and bring new and better lifesaving medicines to more patients. Pfizer is also concerned for the safety of Filipinos since importing medicines from unreliable sources may put patients' health at risk.

Trade (GATT),[11] signed in 1947, did not include a specific agreement on the protection of intellectual property rights (IPRs), the need for their protection was recognized nonetheless. Under Article XX (d) of the GATT, parties are permitted to adopt or enforce measures necessary for "the protection of patents, trademarks and copyrights." When the Convention Establishing the World Intellectual Property Organization (WIPO) was signed in Stockholm in 1967,[12] its objectives included the promotion of intellectual property protection through worldwide state protection and administrative cooperation among the intellectual property unions established by the treaties that the WIPO administers.

During the 1970s, serious violations of IPRs resulted from the trade in counterfeit goods. Several countries, however, were unsuccessful in their attempts to implement measures to create a binding obligation among contracting states to eliminate trade in counterfeit and pirated goods, including the drafting of an Agreement on Measures to Discourage the Importation of Counterfeit Goods and the establishment of a Group of Experts on Trade in Counterfeit Goods.[13]

Historically, protection of IPRs was restricted to traditional forms of intellectual property, namely, copyrights, trademarks, and patents. With the advent of technology, however, more and more intangible properties were considered appropriate subjects of IPRs entitled to protection. Thus, protection was also extended to cover databases, plant varieties, and integrated circuits, among others.

The expansion of intellectual property protection, however, was not without consequences. The most controversial effect of this expansion was

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11. General Agreement on Tariffs and Trade 1994, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, The Legal Texts: The Results Of The Uruguay Round Of Multilateral Trade Negotiations 17 (1999), 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) [hereinafter GATT].

12. It must be noted though that protection of IPRs already existed back in the 1800s based upon the conclusion of the Paris Convention for the Protection of Industrial Property and the Berne Convention for the Protection of Literary Works. Previously, these Conventions were administered by separate bureaus which were eventually united in 1893 and replaced by the International Bureau in 1970 through the WIPO Convention. A discussion about the WIPOs origins can be accessed at the WIPOs website. *See* Summary of the Convention Establishing the World Intellectual Property Organization (WIPO Convention), *at* http://www.wipo.int/treaties/en/convention/summary_wipo_convention.html (last accessed Oct. 6, 2006).

13. Daniel J. Gervais, The TRIPS Agreement: Drafting History and Analysis 7-8 (2003).

the potential curtailment of the access to medicine. With the rise in epidemics, particularly HIV-AIDS, issues on intellectual property veered toward patents, mainly on pharmaceutical drugs and essential medicines.

When the WTO was established in 1995, one of the obligations imposed on its Members was automatic accession to the TRIPS Agreement. The TRIPS Agreement has been generally recognized as a compromise between the interests of intellectual property-originator countries and of recipient countries. Although TRIPS recognizes that "intellectual property rights are private rights" and lays down minimum standards for their protection, the "special needs" of developing and least developed countries for flexibility in the implementation of certain provisions were also recognized. Articles 65 and 66 of the TRIPS Agreement permit developing and least developed countries to delay the application of the TRIPS Agreement for a period of five and ten years,[14] respectively.

A. The Doha Declaration

The balance between access to medicine and protection of IPRs remains a very contentious issue. Recognizing the gravity of health problems affecting developing and least developed countries, the Ministerial Conference of the WTO adopted the Declaration on the TRIPS Agreement and Public Health (Doha Declaration).[15] The Doha Declaration establishes that the TRIPS 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 medicine for all."[16]

The Doha Declaration likewise reaffirmed the flexibility of the TRIPS Agreement and instructed the TRIPS Council to find a solution to the difficulties faced by the WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector in effectively making

14. According to the WTO, the transition period for least-developed countries have been further extended until January 1, 2016 for protection to pharmaceutical patents and July 1, 2013 for protection of other IPRs. *See* Press Release 426, World Trade Organization, *Members OK amendment to make health flexibility permanent*, December 6, 2005 (on file with the author), *available at* http://www.wto.org/english/news_e/pres05_e/pr426_e.htm (last accessed Sep. 23, 2006).

15. World Trade Organization, Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, November 20, 2001, *available at* http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (last accessed Sep. 4, 2006) [hereinafter Doha Declaration].

16. *Id.*, ¶ 4.

use of compulsory licensing[17] under the TRIPS Agreement. A condition imposed by the TRIPS Agreement for the grant of a compulsory license is that the patented drug should be predominantly used for the domestic market of the Member who granted such compulsory license. As a result thereof, numerous Members were unable to take advantage of compulsory licenses since manufacturing Members could not export them to the international market. The deadline for fulfilling the mandate to find a solution, set on December 31, 2002, was not met due to disagreements concerning the scope of disease coverage.[18]

B. The August Decision

On August 30, 2003, the WTO General Council adopted a decision on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health (August Decision).[19] This decision was considered the "final piece of the jigsaw" to enable "poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people."[20] On one hand, non-governmental organizations and developing countries who were producers of generic drugs were less enthusiastic and argued that the complexity of the arrangement would be unworkable in practice.[21] On the

17. The WTO defines "compulsory licensing" to include situations "when a government allows someone else to produce the patented product or process without the consent of the patent owner." Although the TRIPS makes no specific mention of compulsory licensing, it has been generally recognized to be permitted under Article 31 of the TRIPS Agreement. *See* TRIPS and Health: Frequently Asked Questions, Compulsory Licensing of Pharmaceuticals and TRIPS *at* http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last accessed Oct. 6, 2006).

18. Intellectual Property: Following TRIPS/Medicine Impasse, USTR Announces Implementation of Plan, 20 BNA'S INTERNATIONAL TRADE REPORTER 7 (2003).

19. World Trade Organization, Decision of August 30, 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Doc. WT/L/540, September 2, 2003, *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last accessed Sep. 4, 2006) [hereinafter the August Decision].

20. Press Release 350/Rev. 1, World Trade Organization, *Intellectual Property: Decision removes final patent obstacle to cheap drug imports*, August 30, 2003, *available at* http://www.wto.org/english/news_e/pres03_e/pr350_e.htm (last accessed Sep. 4, 2006), (quoting Director-General Supachai Panitchpakdi).

21. Frederick M. Abbot, The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health, 99 AM. J. INT'L L. 317 (2003).

other hand, representatives from the pharmaceutical industry welcomed the August Decision and saw it as a "balanced agreement"[22] since it considered the patent interests of the developed Members as well as the access interests of the developing and least-developed Members. The August Decision was considered a temporary solution, and the TRIPS Council was tasked to prepare an amendment incorporating a permanent solution into the TRIPS Agreement.[23]

Before the August Decision, a Member who wanted to issue compulsory licenses had to comply with the conditions provided in Article 31[24] of the

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22. *Intellectual Property: Developing Countries Prepared to Use New WTO Accord to Import Cheap Medicines*, September 3, 2003, BNTA WTOR d10 (quoting Dr. Harvey E. Bale, Jr., director-general of the International Federation of Pharmaceutical Manufacturers Associations [IFPMA]).

23. August Decision, *supra* note 19, ¶ 11.

24. The relevant portions of Article 31 of the TRIPS Agreement are as follows:

> Article 31 - Other Use Without Authorization of the Right Holder
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> Where the law of a Member allows for other use 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:
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> x x x
>
> (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 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;
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> (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;
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> x x x
>
> (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
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> x x x

TRIPS Agreement. The August Decision offered a waiver of obligations laid under Article 31(f) and (h) of the TRIPS Agreement under certain conditions as the solution to the problem raised in the Doha Declaration. Under this waiver, drugs created under the compulsory license need not be marketed solely to the domestic market but can be sold to eligible importing Members.[25] Furthermore, once the exporting Member has paid adequate remuneration, the importing Member need not pay the same provided that the economic value to the importing member has been considered in the computation of the adequate remuneration paid by the exporting Member.[26] The August Decision likewise obliged the Members to take reasonable measures to prevent re-exportation of the products as well as provide effective legal means to prevent diversion.[27] The Philippines, however, was concerned about the terms of this Decision since, in its bilateral discussions with the United States, the Philippines was believed to have adequate pharmaceutical manufacturing capacity and would not qualify as an importing country under the system.[28]

C. *The December Amendment*

On December 6, 2005, WTO Members approved the proposed changes to the TRIPS Agreement – the first time that a core WTO agreement was amended.[29] The Decision on the Amendment of the TRIPS Agreement (December Amendment)[30] transforms the August Decision into a permanent

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

25. August Decision, *supra* note 19, ¶ 2.
26. *Id.*, ¶ 3.
27. *Id.*, ¶¶ 4 & 5.
28. Abbot, *supra* note 21, at 337 (citing WTO Doc. IP/C/M/40, ¶ 52).
29. *See* WTO Press Release 426, *supra* note 14.
30. World Trade Organization, Decision of December 6, 2005 on the Amendment of the TRIPS Agreement, WT/L/641, December 8, 2005, *available at*

amendment. The ratification of at least two-thirds of the WTO's one hundred forty-nine members,[31] however, is still necessary for the amendment to take effect.[32] In the meantime, the waivers under the August Decision remain in effect.

The December Amendment was a result of more than two years of negotiations between developed and developing countries on how to incorporate the August Decision into a permanent and legally binding part of the TRIPS Agreement.[33] The December Amendment was considered by the WTO leadership as a confirmation of the Members' intent to "ensure [that] the WTO's trading system contributes to humanitarian and development goals."[34] The pharmaceutical industry also welcomed the December Amendment and believed that it permitted poorer members to respond to local health emergencies while preserving the protection granted to IPRs.[35] The conclusion of this negotiation was considered timely since in January 2005, India's patent law took effect thereby providing patent protection to pharmaceutical products, in compliance with its WTO obligations. India did not previously provide any patent protection to drugs and had been the leading exporter of cheap generic drugs worldwide. On the contrary, certain sectors believed that the December Amendment turned out to be a bad deal that further exacerbated the access struggle. There are arguments to the effect that the December Amendment burdens poor countries with a lengthy and complex process and is considered as "anti-consumer, anti-competition and anti-free trade."[36]

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docsonline.wto.org/imrd/directdoc.asp?DDFDocuments/t/WT/L/641.doc (last accessed Sep. 4, 2006) [hereinafter December Decision].

31. Saudi Arabia became the 149th member of the WTO on December 11, 2005.

32. *See* art. X, ¶ 3 of the Marrakesh Agreement Establishing the World Trade Organization, April 15, 1994, The Legal Texts: The Results Of The Uruguay Round Of Multilateral Trade Negotiations 4 (1999), 1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994).

33. Daniel Pruzin, *WTO TRIPs Council Set to Incorporate 2003 Medicines Deal Into TRIPs Accord*, BNA's International Trade Daily, December 6, 2005, *available at* Westlaw 12/6/2005 BTD d19.

34. Daniel Pruzin, *WTO Members, Industry Welcome Deal Incorporating TRIPs/Medicines Agreement*, BNA's International Trade Daily, December 7, 2005, *available at* Westlaw 12/7/2005 BNA WTOR d10 (quoting WTO Director-General Pascal Lamy).

35. *Id.*

36. *WTO generics deal slammed by activists; World Trade Organization; opposed by non-governmental groups*, PHARMA MARKETLETTER, December 19, 2005, 2005 WLNR 20715834 (quoting James Love of Consumers International's Consumer Project on Technology).

Under the December Amendment, an importing Member has to give notification to the TRIPS Council with the following specifications: (1) the name of the drug and expected quantities needed; (2) a confirmation that it lacks manufacturing capacity; and (3) its intention to grant a compulsory license.[37] The exporting Member must likewise notify the TRIPS Council and issue a compulsory license limiting production to the amount specified in the importing Member's notification and providing special identification marks on the subject products.[38] It must be noted that, as of this writing, no importing or exporting Member has made any notification to the TRIPS Council.[39] Some Members[40] have also indicated that they will not use the system as importing Members while others have said that they will only use the system in situations of national emergency or other circumstances of extreme urgency.[41] Whether the December Amendment is a viable solution to the access to medicine problem can be determined only after the system has been tested.

III. WTO COMPLIANCE REVIEW OF THE PROPOSED AMENDMENTS

The Philippines, despite having the status of a developing country, has been protective of IPRs and has, in fact, enacted a number of intellectual property laws several years before the TRIPS Agreement deadline. As early as 1947, the first patent law, Republic Act No. 165,[42] was already enacted. Other IPRs were also protected under separate laws.[43] As a result of its accession to the WTO, the Philippines enacted the IP Code, consolidating all laws

37. December Decision, *supra* note 30, Annex to the TRIPS Agreement, ¶ 2(a), WT/L/641.

38. *Id.*, ¶ 2(b).

39. Notifications made to the TRIPS Council may be accessed at TRIPS and public health: dedicated webpage for notifications, http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm (last accessed Oct. 6, 2006).

40. These countries are Australia, Canada, the European Community, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.

41. These countries are Hong Kong, China, Israel, Korea, Kuwait, Macao (China), Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and the United Arab Emirates.

42. An Act Creating a Patent Office, Prescribing Its Powers and Duties, Regulating the Issuance of Patents, and Appropriating Funds Therefore, Republic Act No. 165 (1947).

43. *See* An Act to Provide for the Registration and Protection of Trade-Marks, Trade-Names and Service-Marks, Defining Unfair Competition and False Marking and Providing Remedies Against the Same, and for Other Purposes, Republic Act No. 166 (1947).

protecting IPRs. The IP Code has also been amended in response to technological developments.[44]

Several new amendments, mostly focused on the high pharmaceutical drug prices that limit the Filipinos' access thereto, are pending hearing and discussion in the Philippine Congress. These proposed amendments have originated from both the lower house (House of Representatives) and the upper house (Senate).[45] Other bills aside from Senate Bill No. 2139 have also been introduced relating to the price of pharmaceutical drugs.[46]

In Philippine legislative practice, important legislation is often introduced in both houses through companion identical bills to expedite the legislative process by allowing both houses to consider the bill simultaneously. Furthermore, the introduction of several bills dealing with the same subject usually emphasizes "the importance or urgency of the issue and show broad support for the legislation."[47] The numerous bills seeking to reduce drug prices that have been introduced in both houses in the past two years show the exigency of expanding the access to medicines for Filipinos. Among these bills, Senate Bill No. 2139 has received the most support and is the version most likely to be considered.

A. *Curtailing Evergreen Patents*

The current IP Code defines a *patentable invention* as "any technical solution of a problem, in any field of human activity, must be new, involves an inventive step, industrially applicable and may be or may relate to a product or process or an improvement of the foregoing."[48] The Roxas Amendment

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44. *See* An Act Providing for the Protection of Layout-Designs (Topographies) of Integrated Circuits, Amending for the Purpose Certain Sections of Republic Act No. 8293, Otherwise Known as the Intellectual Property Code of the Philippines and for Other Purposes, Republic Act No. 9150 (2001).

45. Generally, members of either house can introduce bills for adoption. Exceptions are appropriation, revenue or tariff bills, bills authorizing increase of the public debt, bills of local application, and private bills, which must originate exclusively in the lower house. *See* PHIL. CONST. art VI, § 24.

46. The other bills introduced include: House Bill No. 00305 or the "Drug Price Act;" House Bill No. 00498, which seeks to enable the government to control the prevailing price schemes of drug companies and to support the fledging local drug industry and decrease the patent period of drugs from 20 years to 10 years; House Bill No. 00499 or the "Drugs Act of 2004; and House Bill No. 03830 or the "Drug Prices Regulation Act of 2005."

47. For a detailed discussion of the legislative process of the Philippine Senate *see* Senate of the Philippines: Legislative Process, http://www.senate.gov.ph/about/legpro.htm (last accessed Oct. 6, 2006).

48. IP CODE, § 21.

adds the following definition to be considered as part of the original patent: "new uses or molecules or compounds of a patented invention shall be deemed as included in the original patent and shall not be allowed to be covered by a new and separate patent." This amendment seeks to prevent the issuance of new patents for previously patented drugs or processes to cover newly discovered benefits and thus curtailing the so-called "evergreen patents."

1. Definition of Evergreening

Evergreening occurs when patent holders[49] file new patent applications on updates, new uses, or attributes of the patented drug to effectively extend their patent monopoly.[50] The European Generic Medicines Association[51] has enumerated an increasing list[52] of drug properties that has been the subject of evergreen patents.

Several strategies are employed by pharmaceutical companies to obtain evergreen patents.[53] For example, a drug company, with a patent over Drug A (composed of Ingredients 1, 2 & 3) may seek to obtain a subsequent patent over Drug B (composed of Ingredients 1 & 2, but essentially has the same effects as Drug A). Another strategy is where the pharmaceutical company

49. Patent holders and patent owners are used interchangeably in this article.

50. *Evergreening* has been described as "protection that reinforces basic compound patents covering a product [that] is frequently obtained through patents on new formulations and patents on new uses of the product." *See* Jean O. Lanjouw, *A New Global Patent Regime for Diseases: U.S. and International Legal Issues*, 16 HARV. J. LAW & TEC 85, 94 (2002).

51. The European Generic Medicines Association (EGA) is the official body and represents over 500 companies and their subsidiaries from throughout Europe, either directly or through national associations. The organization is committed to "providing high-quality affordable medicines to millions of Europeans and stimulating competitiveness and innovation in the pharmaceutical sector." More information about the EGA is available at their website: European Generic Medicines Association, http://www.egagenerics.com (last accessed: Oct. 6, 2003).

52. This list has increased to 18 to include aspects such as field of use, dosage regimen, range and route, combinations, chemistry methods, biological target and mechanism of action. *See* Evergreening, http://www.egagenerics.com/gen-evergrn.htm (last accessed Oct. 6, 2006).

53. *See* CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES, 20-24, 51-57 (2000), *available at* http://www.southcentre.org/publications/publichealth/publichealth.pdf (last accessed Oct. 6, 2006) (thoroughly discussing the *evergreening* strategies employed by pharmaceutical companies).

subsequently discovers a new use for its patented Drug A and obtains another patent for this second use.[54]

Pharmaceutical patent holders pursue evergreen patents to obtain "legitimate protection of the fruits of costly research"[55] since it is widely known that patent protection on drugs and medicine usually ends even before the pharmaceutical companies are able to recoup expenses for costly research.[56]

Although the TRIPS Agreement does not prohibit evergreen patents, the issue of "evergreening" affects the requirement of inventive step or novelty. One commentator has noted that there is no universal rule for novelty.[57] One of the basic principles of patent law, however, is that a product or process which is already known cannot be patented. Under this principle, any new properties of the product, for instance, a chemical compound, cannot be patented, where the compound itself is already known.[58]

2. Developments in the United States Jurisprudence[59]

Under United States law, a patent is granted to whoever invents or discovers any new and useful process or any new and useful improvement thereof.[60] The definition of *process* includes the new use of a known process, machine,

54. The Roxas Amendment only addresses *evergreening* strategies based on new uses, compounds, or molecules but not on selection patents, polymorphs, active metabolites, or prodrugs. *See id.*

55. Dan Robrish, *GlaxoSmithKline to Pay $14M to States,* March 28, 2006, ASSOCIATED PRESS, http://news.corporate.findlaw.com/ap/f/66/03-28-2006/fc3f00136e4586ac.html (last accessed Apr. 23, 2006).

56. Stuart Nightingale, M.D., Associate Commissioner for Health Affairs of the U.S. Food and Drug Administration's Public Health Service, Statement at the Subcommittee On Patents, Copyrights And Trademarks, Committee On The Judiciary of the United States Senate (Aug. 1, 1981) (discussing the reason given for the enactment of the United States' Patent Term Extension Act) (on file with the author), *available at* http://www.fda.gov/bbs/topics/SPEECH/SPE00001.htm (last accessed Oct. 6, 2006).

57. GERVAIS, *supra* note 13, at 221.

58. Jonathan Q. Perez, *The Clever Art of "Evergreening,"* (on file with the author), *available at* http://www.iplaw.ph/bnu2_ipviews_evergreening.asp (last accessed Sep. 4, 2006).

59. A review of the practice jurisprudence and law in the United States is instructive as these cases have illustrated the creative utilization of *evergreening* strategies and how the courts have responded to them.

60. 35 U.S.C. § 101 (1952).

manufacture, or composition of matter or material.[61] Thus, under the United States law, new process patents may be granted on a new method of treatment, even if the same drug has already been used for another purpose.[62] Arguments have been propounded to the effect that this provision was necessary to stimulate continuous research on a drug that may lead to numerous other benefits or uses.[63]

The foregoing discussions establish that the United States does not prohibit evergreen patents. Instead, the United States resorts to other measures such as anti-trust to "catch" patent holders who abuse the rights granted to them. United States courts have also established a double patenting doctrine known as non-statutory or "obviousness-type" double patenting which seeks "to prevent claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive rights would effectively extend the life of patent protection."[64] For example, where Patent A was previously granted for the use of Vitamin C in a cosmetic topical skin treatment, Patent B cannot be granted for the method of applying Vitamin C to prevent sunburn, because the latter is merely a variant of the treatment covered by Patent A.[65]

Another relevant development in United States jurisprudence is the *inherency doctrine*.[66] Under this doctrine, "if the public already benefits from

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61. 35 U.S.C. § 100 (1952)tent Act sed at the WIPO'

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62. Rebecca S. Eisenberg, *Pharmaceutical Innovation and Cost: An American Dilemma*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 717, 724 (2005) (citing In re *Marshall*, 578 F.2d 301, 304 [C.C.P.A. 1978]).

63. Michael Z. Untalan & Karen O. Amurao-Dalangin, *Observations on Proposed Amendments to Patent and Trademark Laws*, (on file with the author), *available at* http://www.iplaw.ph/bnu2_ipviews_observations.asp.

64. Perricone v. Medicis Pharmaceutical Corporation, 432 F.3d 1368, 1373 (Fed. Cir. 2005).

65. *Id.* at 1372-75 (discussing the validity of the patents covering the use of Vitamin C for skin treatment).

66. A subsequent invention is considered inherent in prior art where "it is the natural result flowing from' the explicit disclosure of the prior art." *See generally* Schering Corporation v. Geneva Pharmaceuticals, 339 F.3d 1373, 1379 (Fed. Cir. 2003) (citing *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 970 [Fed. Cir. 2001]); *In re* Kratz, 562 F.2d 1169, 1174 (CCPA 1979). Thus, "the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's function, does not render the old composition patentably new to the discoverer." *See* Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001).

the invention, even if they [do not] know why, the invention is inherent in the prior art."[67] For instance, a patent on sprouts referring to a new method of preparing food products to induce enzymes that detoxify potential carcinogens was not permitted since the applicant merely recognized properties already existing in certain prior art sprouts and did not introduce anything new.[68]

3. Arguments under the TRIPS Agreement

The TRIPS Agreement classifies patentable subject matter as "products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[69] Based on this definition, the proposed Roxas amendment to patentable subject matter under the IP Code cannot be considered in violation of the TRIPS Agreement. The TRIPS Agreement merely lays down the basic parameters for patentability of products or processes. There is no mention of the protection of "new uses" nor is there any indication that this is included under products or processes. Furthermore, experts have argued that patents on new uses do not fulfill the requirement of novelty for patentability under the TRIPS Agreement.[70] In any event, such new uses can arguably also be rejected under the double patenting or inherency doctrines discussed above.

Review of the relevant provisions of other developing countries will reveal similar limitations existing in their intellectual property laws. India, for instance, likewise disallows patents on "the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant."[71] The amendments to India's Patent Act took effect in 2005 and this provision was inserted to "allay domestic fears of evergreening of patents."[72] The Andean Community also

67. "Inherency" is a term coined by Professors Dan L. Burk and Mark A. Lemley. This concept is extensively treated in their article, *Inherency*, 47 WM. & MARY L. REV. 371, 374 (2005).

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

69. The TRIPS Agreement, *supra* note 1, art. 27(1).

70. *See* Correa, *supra* note 53, at 21. *See also* Jayashree Watal, Intellectual Property Rights in the WTO and Developing Countries 104 (2001).

71. India, The Patents Act, 1970, No. 39, Acts of Parliament, 1970, *available at* http://www.wipo.int/clea/docs_new/pdf/en/in/in004en.pdf (last accessed Sep. 4, 2006).

72. KG Narendranath, *Centre to curb evergreening of patents in amended Bill*, THE FINANCIAL EXPRESS (New Delhi), March 22, 2005, http://www.financialexpress.com/fe_full_story.php?content_id=85839 (last accessed Oct. 6, 2006).

does not grant patents for previously patented products or processes on the "sole ground of having been put to a use different from that originally contemplated by the initial patent."[73]

An argument against the Roxas Amendment is that it will stifle subsequent research that may be conducted resulting in second medical uses.[74] Aspirin, for example, which was originally used for headaches and fever, was found to have beneficial effects on heart disease patients. Admittedly, one danger is its capacity to include "genuine" new uses in its coverage. Certainly, this will discourage pharmaceutical companies from conducting research on other benefits of medicines and drugs already out in the market.

Nonetheless, this amendment is necessary particularly in the Philippine context to prevent abuses by patent holders in their attempts to gain market monopoly, as shown in the case of Pfizer versus PITC. Studies[75] have shown that Philippine consumers have been constantly paying what has been touted as the highest drug prices in Asia.[76] With about 40 percent[77] of the population living below poverty level, the need to reduce prices of medicines cannot be overemphasized. This will be a matter of balancing two interests and given the current state of law and economic situation, protecting the health of the Filipino public and ensuring their access to medicine is of paramount importance.

This argument is further bolstered by the TRIPS Agreement that recognizes that Members may not only "adopt measures necessary to protect public health and nutrition" but also measures "needed to prevent the abuse of IPRs by right holders or the resort to practices which unreasonably

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73. Decision 486: Common Intellectual Property Regime, art. 21, 2000 (Andean Community), *available at* http://www.comunidadandina.org/INGLES/normativa/D486e.htm (last accessed Sep. 4, 2006).

74. Untalan & Amurao-Dalangin, *supra* note 63.

75. Roxas Amendment, *supra* note 3, Explanatory Note.

76. The drug involved in the PITC and Pfizer controversy, Norvasc, is being sold at P44.75 per 5 mg tablet and P74.57 per 10 mg tablet while the same medicine can be bought in India for P8.74 per 5 mg tablet, and P17.09 per 10 mg tablet and in Pakistan for P5.98 per 5 mg tablet and P8.96 per 10 mg tablet. *See* Francis Earl A. Cueto, *PITC bares high cost of medicines produced in RP*, THE MANILA TIMES, *available at* http://www.abs-cbnnews.com/storypage.aspx?StoryId=33755 (last accessed Oct. 6, 2006). The Peso-Dollar Exchange Rate as of October 6, 2006 is $1 = Php 49.97.

77. Caesar B. Cororaton et al., *Doha Scenarios, Trade Reforms, and Poverty in the Philippines: A CGE Analysis*, *in* POVERTY AND THE WTO: IMPACTS OF THE DOHA DEVELOPMENT AGENDA, Figure 13.1, 382 (Thomas W. Hertel and L. Alan Winters, eds., 2005).

restrain trade or adversely affect the international transfer of technology."[78] Based on the foregoing, there is no reason to prevent the exclusion of new uses under the definition of patentable subject matter as this provision is consistent with the Philippines' WTO obligations.

4. Looking Forward

(a) *Australian FTA Experience*

Should this provision be expunged from the Roxas Amendment, the Philippines can learn from the Australian approach of solving abuses made through evergreen patents, which was a controversial issue in the Australian-US Free Trade Agreement (FTA) negotiations. Australia's enabling legislation[79] implementing the FTA was passed on August 16, 2004 and included provisions intended to eliminate *evergreening*, which had been introduced by the opposition before they allowed the passage of the legislation.[80]

In line with the enabling legislation, an amendment to Australia's Therapeutic Goods Act 1989 (TGA) required pharmaceutical patent holders seeking to commence patent infringement proceedings to certify that the proceedings are brought "in good faith," with "reasonable prospects of success," and will be "conducted without reasonable delay."[81] The submission of a false or misleading certificates may result in penalties of up to AU$10,000,000.00. The amendment to the TGA has been considered as the means to prevent pharmaceutical companies from undertaking spurious tactics to extend their patents and prevent the entry of generic drugs.[82] A similar regulation can be adopted by the Philippines to ensure that

78. The TRIPS Agreement, *supra* note 1, art. 8.

79. An Act to Implement the Australia-United States Free Trade Agreement, and for Other Purposes (2004) (Austl.) *available at* http://scaleplus.law.gov.au/html/comact/12/6876/pdf/1202004.pdf (last accessed Sep. 4, 2006) [hereinafter US FTA Implementation Act].

80. David Wilson & Andrew McRobert, *Legal update: US FTA-Pharmaceutical patents and evergreening*, November 11, 2004, *at* http://www.deacons.com.au/NewsUpdates/Newsroom/LegalUpdates.cfm?objid=5102 (last accessed Oct. 9, 2006).

81. US FTA Implementation Act, *supra* note 79, at 87-88.

82. *See* Patricia Ranald, *Australia must hold line on evergreening*, AUSTRALIAN FINANCIAL REVIEW (2006), *available at* http://afr.com/articles/2006/01/12/1136956265010.html (last accessed Apr. 25, 2006). *See also* David Wroe, *Drug price alert on trade pact*, THE AGE, January 4, 2006, *available at* http://www.theage.com.au/news/national/drug-price-alert-on-trade-pact/2006/01/03/1136050442061.html (last accessed Sep. 4, 2006).

pharmaceutical companies do not file spurious suits with the intention of extending their monopoly in the drug market.

(b) *Response of the Pharmaceutical Companies*

Meanwhile, should the amendment be approved, a strategy that the pharmaceutical companies may take is to seek a narrow interpretation of the "new use" exception to patentability. It has been said that the definition of a patentable subject matter under the TRIPS Agreement "establish[es] a general principle of eligibility," and thus, any exclusion from patentability restrictively interpreted, with the goal of eventually eliminating such exclusions.[83] In *EC Measures Concerning Meat and Meat Products*, however, the Appellate Body explicitly declared:

> Merely characterizing a treaty provision as an "exception" does not by itself justify a 'stricter' or 'narrower' interpretation of that provision than would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in the light of the treaty's object and purpose, or, in other words, by applying the normal rules of treaty interpretation.[84]

Hence, there is no obligation under the TRIPS Agreement to narrowly interpret exceptions from patentability and the Philippines can arguably thwart the attempts of pharmaceutical companies to impose such interpretation based on the foregoing ruling of the Appellate Body.

(c) *Limitations of the Amendment*

Finally, it must be emphasized that the Roxas Amendment, as worded, will only curtail *evergreening* strategies that pertain to new uses of the patented drug. As previously discussed, there are other methods which pharmaceutical companies will employ to effectively extend their drug monopoly. It is recommended that a more careful study of these strategies be conducted to determine whether the Roxas Amendment must be reworded to address all these other strategies. Experts have recognized that evergreening strategies through patenting of new (second) uses are generally weak[85] and as a result, may be least likely used by pharmaceutical companies. Thus, the current amendment may not actually fully serve the best interests of the citizenry.

B. *Regulatory Review Provision*

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83. GERVAIS, *supra* note 13, at 220.

84. Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, ¶ 104, WT/DS26/AB/R & WT/DS48/AB (Jan. 16, 1998).

85. Interview with John R. Thomas, Professor, Intellectual Property in the World Trade Organization, Georgetown University Law Center, in Washington, D.C. (Apr. 24, 2006).

Another amendment sought is the inclusion of the *Bolar exception*. This exception was first introduced in a US statute[86] enacted to reverse the ruling in a federal court decision,[87] which declared that performing tests for purposes of obtaining marketing approval constitutes infringement and cannot be excused by the "scientific use" exemption under the United States' patent law. A recent United States Supreme Court case[88] has affirmed that the use of patent products in preclinical studies will be permitted where such use is for the purpose of obtaining regulatory approval. Other countries that have adopted similar legislation or interpretations of existing patent law include Argentina, Australia, Hungary, Israel, Japan, and Portugal.[89]

1. Changes under the Roxas Amendment

Under the current law, the relevant exceptions that permit the derogation of the patent holder's rights include the following: (1) acts done privately and on a non-commercial scale for a non-commercial purpose that does not significantly prejudice the patent holder's economic interests and (2) acts that consist of making or using exclusively for the purpose of experiments.[90] The

86. 25 U.S.C. § 271(3) which provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

87. Roche Products, Inc. v. Bolar Pharmaceutical Co., Inc., 733 F.2d 858 (C.A.F.C. 1984).

88. Merck KGAA v. Integra Lifesciences I, Ltd., 125 S.Ct.3372 (2005).

89. Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, ¶ 7.42, WT/DS114/R (Mar. 17, 2000) (*adopted* Apr. 7, 2000) [hereinafter Canada Pharmaceutical].

90. IP CODE, § 72. The limitations to the patent holders' rights are enumerated in § 72:

> Sec. 72. *Limitations of Patent Rights.* The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 hereof in the following circumstances:
>
> 72. 1. Using a patented product which has been put on the market in the Philippines by the owner of the product, or with his express

Roxas Amendment revises Section 72.3 and inserts a new Section 72.4 in the IP Code. The amended provisions will read as:

> 72.3. Where the act consists of making or using exclusively for experimental use of the invention for scientific purposes or for commercial purposes that do not unreasonably conflict with a normal exploitation of the patent and that do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of such third parties.
>
> 72.4. Where the act includes testing, using, making or selling the invention including any data related thereto, solely for purposes reasonably related to the development and submission of information required under any law of the Philippines or of another country that regulates the manufacture, construction, use or sale of any product.

Under the foregoing provisions, generic manufacturers can already commence using the patented drugs or medicines, even before the patent expires, for the purpose of obtaining regulatory approval. The Roxas Amendment seeks to prevent future cases similar to Pfizer and PITC. The amendment to Section 72.3 is almost entirely copied from Article 30 of the TRIPS Agreement and uses the limited exceptions rule granted therein. Article 30 of the TRIPS Agreement provides:

> 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

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> consent, insofar as such use is performed after that product has been so put on the said market;
>
> 72.2. Where the act is done privately and on a non-commercial scale or for a non-commercial purpose: Provided, That it does not significantly prejudice the economic interests of the owner of the patent;
>
> 72.3. Where the act consists of making or using exclusively for the purpose of experiments that relate to the subject matter of the patented invention;
>
> 72.4. Where the act consists of the preparation for individual cases, in a pharmacy or by a medical professional, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;
>
> 72.5. Where the invention is used in any ship, vessel, aircraft, or land vehicle of any other country entering the territory of the Philippines temporarily or accidentally: Provided, That such invention is used exclusively for the needs of the ship, vessel, aircraft, or land vehicle and not used for the manufacturing of anything to be sold within the Philippines.

not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

The excepted use in Section 72.3 is further clarified by succeeding paragraphs, including the amendment of Section 72.4 which is referred to as the "regulatory review provision." The validity of the regulatory review provision under Article 30 has been interpreted in the Panel Decision in *Canada – Patent Protection of Pharmaceutical Products*.[91]

2. Interpretation of Article 30 by the WTO Panel

In the case brought by the European Communities (EC) against Canada, one of the provisions that the Panel reviewed was Canada's regulatory review provision, which provides an exception against infringement for the making, constructing, using, or selling for the "development and submission of information."[92] This provision effectively cuts off an extra one to two and a half years of market exclusivity enjoyed by the patent holder after the expiration of the patent since it permits generic manufacturers to commence the process of obtaining government marketing approval during the term of the patent.[93] As a result of the early development of the generic drug, generic manufacturers could immediately enter the market as soon as the patent expires.

The provision was found to be a violation of Article 28.1[94] of the TRIPS Agreement on the exclusive rights of patent holders. Canada, however, sought to justify it by resorting to the Article 30 exception. The

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91. Canada Pharmaceutical, *supra* note 89.

92. Canadian Patent Act, Section 55.2(1) (1985):

> It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product.

See id. ¶ 2.1.

93. *Id.*, ¶ 7.2.

94. Article 28.1 of the TRIPS Agreement, *supra* note 1, provides:

> A patent shall confer on its owner the following exclusive rights: (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent form 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.

Panel laid down three cumulative conditions that must be independently met to qualify under the exception: "(1) the exception must be 'limited'; (2) the exception must not 'unreasonably conflict with normal exploitation of the patent'; and (3) the exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.'"[95]

The Panel interpreted the first condition to mean "a narrow exception – one which makes only a small diminution of the rights in question."[96] The regulatory review provision complied with this condition as long as it was "confined to conduct needed to comply with the requirements of the regulatory approval process, [such that] the extent of the acts unauthorized by the right holder that are permitted by it will be small and narrowly bounded."[97]

In defining "normal exploitation" under the second condition, the Panel referred to exploitation as the "commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patent" and normal as the combined meanings of what is "common within a relevant community and of a normative standard of entitlement."[98] Thus, normal practice of exploitation by patent holders is the exclusion of "all forms of competition that could detract significantly from the economic returns anticipated from a patent's grant of market exclusivity."[99]

Although the Panel rejected Canada's argument – the market exclusivity occurring after the expiration of the patent term, as a result of the regulatory review lag time should not be regarded as normal – it accepted that the post-expiration market exclusivity "is an unintended consequence of the conjunction of the patent laws with product regulatory laws, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity to the enforcement of certain patent rights."[100] The resulting market exclusivity was recognized as not a "natural or normal consequence of enforcing patent rights" and that the lengthy regulatory review herein required does not apply to a majority of patented products.[101] Therefore, the second condition was complied with and there was no conflict with the normal exploitation of the patent.

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95. Canada Pharmaceutical, *supra* note 89, ¶ 7.20.

96. *Id.*, ¶ 7.30.

97. *Id.*, ¶ 7.45.

98. *Id.*, ¶ 7.54.

99. *Id.*, ¶ 7.55.

100. *Id.*, ¶ 7.57.

101. Canada Pharmaceutical, *supra* note 89, ¶ 7.57.

Finally, the Panel proceeded to the third condition and defined "legitimate interest" as "a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms."[102] The Panel rejected the EC's argument that the impairment of the patent holder's rights under Article 28 as a result of the regulatory review exception amounts to prejudice since legal interests was not equivalent to legitimate interests.[103] On the EC's argument that the reduction of the effective market exclusivity period entitled the patent holders to impose a similar period of delay for the generic manufacturers,[104] the Panel found that the patent holders' interest in the reduction of the effective period of market exclusivity due to delays in marketing approval was "neither so compelling nor so widely recognized that it could be regarded as a 'legitimate interest' within the meaning of Article 30 of the TRIPS Agreement" and concluded that no prejudice on the legitimate interests of affected patent holders resulted from the regulatory review provision.[105]

3. Compliance with the TRIPS Agreement

Based on the foregoing interpretation, Section 72.4 complies with the Article 30 exception since it satisfies the "narrow exception" rule as the act is solely for the purpose of development and submission of information to obtain regulatory approval. Similarly, the additional period of market exclusivity that patent holders in the Philippines enjoy after the expiration of their patents is a result of the government's regulatory process given that it usually takes about eighteen months for the BFAD to evaluate drug applications for generic drugs. Finally, the reduction of the effective market exclusivity period is not prejudicial to legitimate interests of patent holders.

4. Looking forward

The inclusion of the regulatory review or the *Bolar* provision into the IP Code is an ultimate necessity as reflected in the ongoing case between Pfizer and PITC. The adoption of a regulatory review provision is necessary to offset the harmful effect of drug patent monopolies by hastening the release of affordable alternatives to expensive essential drugs or medicines.

The passage of the Roxas Amendment may lead the pharmaceutical companies to develop strategies to temper the effects of the regulatory review provision, such as the imposition of a patent term restoration, which

102. *Id.*, ¶ 7.69.

103. *Id.*, ¶ 7.73.

104. *Id.*, ¶ 7.74.

105. *Id.*, ¶ 7.82 - 7.83.

extends patent life as compensation for marketing time lost while developing the product and awaiting government approval.[106] The passage of this concession, however, is not an obligation under the TRIPS Agreement and thus, the Philippines can choose to ignore such attempt. Furthermore, patent term extensions are not considered workable for developing countries as they are appropriate for countries whose consumers can afford expensive patented medicines.[107]

C. *Shift to International Exhaustion*

Exhaustion is a limitation on the patent holder's exclusive right of importation.[108] Note that not all IPRs are affected by the doctrine of exhaustion. Under the TRIPS Agreement, a patent holder has the right to prevent unauthorized third parties from using its patented process or from making, using, offering for sale, selling, or importing its patented product or the product obtained from its patent process.[109] Effectively, the exhaustion doctrine limits the rights of the patent holder to "control the disposition of an article after the article has been sold by or under the authority of the IP owner."[110] Thus, even if a patent holder has exhausted its IPRs over a particular product, it can still prevent unauthorized third parties from making its patented product or from using its patented process to make the product. Note further that exhaustion attaches only to the specific item that has been sold and bought but does not affect other identical items still under the patent holder's possession.[111]

1. Types of Exhaustion

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106. The US has provided a patent term extension under its Patent Term Restoration Act (21 C.F.R. §60 [1988]).

107. Frederick M. Abbot, *Managing the Hydra: The Herculean task of ensuring access to essential medicines, in* INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 406 (Keith E. Maskus & Jerome H. Reichman, eds., 2005).

108. The TRIPS Agreement, *supra* note 1, art. 28(1)(a), n. 6 (which subjects the right of importation to the provisions of Article 6 on exhaustion). *See also* Peggy B. Sherman & Ellwood F. Oakley, III, *The World Trade Organization's Efforts to Balance Pharmaceutical Patents and Access to AIDS Drugs*, 41 AM. BUS. L.J. 353, 373-75 (2004) (explaining the issue of exhaustion of intellectual property rights under the TRIPS Agreement).

109. The TRIPS Agreement, *supra* note 1, art. 28.

110. James B. Kobak, Jr. *Exhaustion of Intellectual Property Rights and International Trade*, 5 GLOBAL ECONOMY JOURNAL No. 1, Art. 5 at 1 (2005).

111. Prof. John R. Thomas, Georgetown University Law Center, Lecture on Intellectual Property in the WTO (Apr. 19, 2006).

There are three systems of exhaustion imposed by Member-States: national, regional, and international. The Philippines currently has *national exhaustion*, whereby once a product has been put on the market in the Philippines by the patent holder or with his consent, the patent holder cannot control the resale of said product anywhere within the Philippines.[112] Thus, Buyer A can buy 30 Norvasc pills in a Metro Manila pharmacy which Pfizer has supplied and subsequently sell these pills at any price in any part of the Philippines.

Regional exhaustion currently exists in the European Community. This resulted from the European Court of Justice's interpretation of Article 30[113] of the European Community Treaty whereby national exhaustion systems were considered restrictions on trade between Community members, preventing the free movement of goods within the European Union.[114] Under this regime, the members of the European Community are

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112. IP CODE, § 72.1.

113. Article 30 of the European Community Treaty provides:

> The provisions of Articles 28 and 29 [prohibiting quantitative restrictions on imports and exports] shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. Such prohibitions or restrictions shall not, however, constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.

Eur-Lex, Selected Instruments Taken from the Treaties, *available at* http://europa.eu.int/eur-lex/en/treaties/selected/livre207.html (last accessed Sep. 4, 2006).

114. The leading case dealing with the exhaustion doctrine is *Centrafarm v. Sterling Drug* (Case 15/74, European Court Reports, vol. 1974, 1147), where the Court declared:

> In fact, if a patentee could prevent the import of protected products marketed by him or with his consent in another Member State, he would be able to partition off national markets and thereby restrict trade between Member States, in a situation where no such restriction was necessary to guarantee the essence of the exclusive right flowing from the parallel patents.
>
> The question referred should therefore be answered to the effect that the exercise, by a patentee, of the right which he enjoys under the legislation of a Member State to prohibit the sale, in that State, of a product protected by the patent which has been marketed in another Member State by the patentee or with his consent is incompatible with the rules of the EEC Treaty concerning the free movement of goods within the common market.

considered to be a single market and, thus, the patent holder cannot control the movement of the protected goods through the national boundaries of the members of the Community once the product has been put into the market.[115] For example, when Drug A has been put into the market in Denmark, the patent holder cannot stop Buyer A, who purchased 100 pieces of this drug, from bringing these items into Germany for subsequent sale.

Finally, under *international exhaustion*, the entire world is treated as one single market such that once the patent holder puts the product on the market in any part of the world, he cannot prevent the sale or redistribution of that particular product into any other country by means of his IPRs. Countries which provide for the international exhaustion of patent rights include Argentina, Canada, Singapore, and Venezuela.[116]

It is important to note that in countries where patent protection to pharmaceuticals was not granted until January 1, 2005, it is not clear whether patent rights have been exhausted once the patent holder puts its drugs or medicine out in the market since there were no patent rights to begin with. Furthermore, in all of these systems, exhaustion applies only where the products bought have been legitimately placed on the market by the patent holder. Thus, exhaustion does not apply to counterfeit goods, in which case, the patent holder can still enforce his rights against these goods.

2. Changes under the Roxas Amendment

The Roxas Amendment seeks to impose international exhaustion of rights for drugs or medicines, such that the limitation on patent rights applies upon market introduction anywhere in the world by the patent holder or anyone else he authorizes. For the rest of patent products, however, national exhaustion of IPRs still applies. Under the new system for drugs and medicines, Pfizer cannot prevent PITC from buying Norvasc from India or Pakistan and importing them to the Philippines for subsequent sale, since Pfizer has already put Norvasc in the Indian and Pakistani markets. The amended provision reads as follows:

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115. Commission Communication On Parallel Imports Of Proprietary Medicinal Products For Which Marketing Authorizations Have Already Been Granted, COM (2003) 839 final, December 30, 2003 (reaffirming the principle of free movement for the pharmaceutical sector and defined the limits of parallel imports), available at http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=COMfinal&an_doc=2003&nu_doc=839 (last accessed Sep. 4, 2006).

116. Posting of James Love, love@cptech.org, to hague-jur-commercial-law@lists.essential.org, December 14, 2001 (on file with author).

> Sec. 72. Limitations of Patent Rights. – The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 [referring to the rights of a patent holder over its patented products or process] hereof in the following circumstances:
>
> 72.1. Using a patented product which has been put out on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been put on the said market; provided that, with regard to drugs or medicines, the limitation on patent rights shall apply after a drug or medicine has been introduced anywhere in the world by the patent owner, or by any party authorized to use the invention.

The shift from a national exhaustion system to that of international exhaustion was included in the Roxas Amendment to pave the way for the legitimization of parallel imports of drugs and medicines since the "right of importation has to follow the exhaustion regime."[117] The concept of parallel importation and the proposed changes to the Philippine law as a result of the shift to international exhaustion will be discussed in Part III (D) below.

3. Compliance with the TRIPS Agreement

The TRIPS agreement mandates that the availability of patents and patent rights shall be without discrimination as to the "field of technology."[118] The discriminatory treatment in this provision refers to the exhaustion of IPRs which the TRIPS has explicitly excluded from being a subject of dispute resolution.[119] The Doha Declaration likewise provided that each Member is "free to establish its own regime for [the] exhaustion [of intellectual property rights] without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4."[120] Thus, each Member can establish a separate regime on exhaustion of patent rights only for pharmaceutical products without fear of being challenged in a WTO dispute.[121] From the foregoing, there is no basis to prevent the shift to international exhaustion as the proposed amendment to Section 72.1 does not violate the TRIPS Agreement.

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117. Christopher Heath, *Legal Concepts of Exhaustion and Parallel Imports, in* PARALLEL IMPORTS IN ASIA 23 (Christopher Heath, ed. 2004).

118. The TRIPS Agreement, *supra* note 1, art. 27.

119. *See Id.*, art. 6, which provides that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights," except national treatment and the most favored nation treatment clauses.

120. Doha Declaration, *supra* note 15, ¶ 5(d).

121. World Health Organization & World Trade Organization, *WTO Agreements & Public Health*, ¶ 185 (2002) [hereinafter WHO-WTO Study].

4. Looking Forward

The Philippine legislature must carefully study the application of this provision on drugs imported from countries where patent protection over pharmaceuticals had not been previously granted. Although unpatented drugs or medicines were legitimately released by the drugs companies in the market, these companies may argue that since there had been no grant of patent, they have not exhausted their patent rights over the specific drug or medicine (even under international exhaustion) and are still entitled to the patent protection within the Philippine jurisdiction. There has been no definitive ruling on this issue and experts are in disagreement whether such an argument can be made.[122] This is a very important concern that must be addressed, particularly since the Philippines' primary drug source is India, which just granted patent protection for pharmaceuticals in 2005.

D. *Exception for Parallel Importation*

The WTO has defined *parallel imports* as products made legally (not pirated) abroad and are imported without the permission of the intellectual property right-holder (for example, the trademark or patent holder).[123] As discussed in Part III (C), whether such importation is an infringement of IPRs depends on the Member's exhaustion regime. As a result of the proposed shift from national to international exhaustion of patent rights for drugs and medicines, the Roxas Amendment seeks to permit parallel importation for drugs or medicines after the filing of an *ex parte* notice before the Intellectual Property Office and exempting the same from the compulsory licensing requirements.

Under the WTO, a *compulsory license* is defined as a license issued by the authorities (usually the government) permitting companies or individuals other than the patent holder to use the rights of the patent (to make, use, sell or import a patented product or a product made by a patented process) without the permission of the patent holder.[124] Although this term does not exist in the TRIPS Agreement, it is generally accepted to fall under Article 31 entitled *Other Uses Without Authorization of the Right Holder* and is one of the flexibilities on patent protection included in the TRIPS Agreement.[125] Although the TRIPS Agreement requires the fulfillment of certain

122. Interview with Prof. Thomas, *supra* note 111.

123. WTO Glossary, http://www.wto.org/english/thewto_e/glossary_e/parallel_imports_e.htm (last accessed Oct. 9, 2006).

124. *Id.*, http://www.wto.org/english/thewto_e/glossary_e/compulsory_licensing_e.htm (last accessed Oct. 9, 2006).

125. World Trade Organization, *TRIPS and Health: Frequently Asked Questions*, http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last accessed Oct. 9, 2006).

procedures and conditions before issuing compulsory licenses, no specific grounds are enumerated, leaving the Members free to determine their own grounds.[126]

1. Parallel Importation under the Current Rules

The current IP Code permits the government or its agent to exploit the invention even without the consent of the patent holder under two circumstances: (1) when an appropriate agency determines that public interest (national security, nutrition, health or development of other sectors) requires it, or (2) when it has been determined by a judicial or administrative body that the manner of exploitation by the patent holder is anti-competitive.[127] Government use, however, has to be subject to the conditions of compulsory licensing set forth in the IP Code.[128]

Before the compulsory license is issued, the government must establish that the applicant has made efforts to obtain an authorization from the patent holder on reasonable commercial terms and conditions but such efforts have not been successful within a reasonable period of time.[129] Note that this requirement does not apply in situations of national emergency, or other circumstances of extreme urgency, or where the purpose of the exploitation is public non-commercial use.[130] However, in both instances, the patent holder must be informed of such use.[131]

Furthermore, the compulsory license is limited by certain terms and conditions. The scope and duration should be limited to the purpose for which it was authorized and the license itself shall be non-exclusive and non-assignable and should be terminated upon cessation of the circumstances leading to its grant.[132] Adequate remuneration must be paid to the patent holder and the products manufactured under the license shall be devoted predominantly for the Philippine market.[133]

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126. Doha Declaration, *supra* note 15, ¶ 5(b).

127. IP CODE, § 74.1.

128. *Id.*, § 74.2.

129. *Id.*, § 95.2 & The TRIPS Agreement, *supra* note 1, art. 31(b).

130. The TRIPS Agreement, *supra* note 1, art. 31(b). Although the TRIPS Agreement does not require a showing of effort to obtain authorization from the patent holder in cases of a judicial or administrative determination of anti-competitive practice, this exception is not included in the IP Code.

131. INTELLECTUAL PROPERTY CODE, §§ 95.3 & 95.4. *See also* The TRIPS Agreement, *supra* note 1, art. 31(b).

132. Intellectual Property Code, §§ 100.1-100.3 & 100.5.

133. *Id.*, §§ 100.4 & 100.6. It is interesting to note that the IP Code also provides that these limitations do not apply where the license was granted as a result of

2. Changes Proposed under the Roxas Amendment

The Roxas Amendment will permit the government to commence parallel importation for drugs or medicines immediately upon the filing of an *ex parte* notice with the Intellectual Property Office. Further, the importation of medicines or drugs is treated as an exception to the compulsory licensing requirements under the IP Code – although the importation is subject to the direct supervision and control of the Departments of Health and Trade and Industry. The amended provision states:

> Sec. 74. Use of Invention by Government.
>
> x x x
>
> 74.3. Subject to the control, supervision and determination of the respective Secretaries of the Department of Health and Department of Trade and Industry, the importation, including parallel importation, or manufacturing or sale or distribution by the government or any of its authorized representatives of drugs or medicines to protect public health shall be immediately executory only upon filing of an *ex parte* notice before the Intellectual Property Office (IPO). This procedure shall be an exception to the application of the standard requirements of compulsory licensing. Any drug or medicine procured, as provided herein, shall be evaluated and approved for public consumption by the Bureau of Food and Drugs (BFAD) after proper laboratory testing for safety, efficacy and quality. It is provided further, that the sale and distribution of such drugs or medicines shall only be made by persons who are duly licensed by both the Department of Health to engage in the sale and distribution of drugs or medicines and authorized by the Department of Trade and Industry to be official distributors or retailers of the drugs or medicines subject of the said procurement.
>
> All importations, manufacturing, sale or distribution of drugs or medicines shall be undertaken by the government or any of its authorized representatives through the coordinated regulatory efforts and subject to the approval of the Departments of Health and Trade and Industry.
>
> x x x

Parallel importation shall refer to the importation and resale of drugs or medicines in the Philippines, whether patented or not and without the consent of the patent holder, by the government or any of its authorized representatives based upon the joint determination of the Secretaries of the Department of Health and the Department of Trade and Industry for the purpose of protecting public health. Drugs and medicines approved and

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the judicial or administrative determination of the anti-competitive practice of the patent holder. Note, however, that the anti-competitive practice exception is permitted by Article 31 of the TRIPS Agreement as an exception only for the requirements of conducting reasonable efforts and supplying the domestic market but not for the payment of adequate remuneration.

imported for this purpose shall not be considered as counterfeit drugs as defined by applicable laws.

The Roxas Amendment does not change any of the procedures for compulsory licensing laid down in the IP Code. Instead, it seeks to liberalize the compulsory licensing procedures for medicines or drugs by creating an exception such that the government need not follow the procedure for the issuance of compulsory licensing required under the IP Code. It must be determined whether these two exceptions – exception for drugs or medicines and the exception to the compulsory licensing procedures – do not violate the TRIPS Agreement.

(a) *Exception for Drugs or Medicines*

A compulsory license is recognized as an exception to the rights of a patent holder that can be granted only on certain conditions. The Roxas Amendment creates an exception to the fulfillment of conditions only for drugs or medicines. Although the TRIPS Agreement permits Members to create exceptions to the rights of a patent holder, such exception must not be discriminatory "as to the place of invention, the field of technology and whether products are imported or locally produced."[134] The WTO Panel laid down this interpretation in *Canada Pharmaceutical*, where the Panel declared that the non-discrimination rules apply both to Articles 30 and 31.[135]

Note however that the foregoing Panel Decision was issued before the Doha Declaration, the August Decision, and the December Amendment. These three documents extended the flexibilities under the TRIPS Agreement only for pharmaceutical products. The exceptions to the requirements of compulsory licensing (for example, adequate remuneration, supply only for the domestic market) under these documents are specifically for pharmaceutical products. Arguably, this has resulted to an exception to the non-discrimination clause as to fields of technology under Article 27.1 for pharmaceutical products on the issuance of compulsory licenses.

Although the Roxas Amendment may be considered to be discriminatory under the Panel ruling, it may be argued that the exception created is permissible under the August Decision and the December Amendment. The drugs or medicines exception under the Roxas Agreement is limited to the requirements of compulsory licensing which are explicitly given special treatment under the August Decision and the December Amendment. Thus, on this issue, the exception to drugs or

134. The TRIPS Agreement, *supra* note 1, art. 27(1).

135. Canada Pharmaceutical, *supra* note 89, ¶ 7.91.

medicines under the Roxas Amendment is not in violation of the TRIPS Agreement.

(b) *Exception from the Compulsory Licensing Requirements*

Next, it must be determined whether the exception from the compulsory licensing requirements for drugs or medicines complies with the December Amendment. Note that the Members have until December 1, 2007 to ratify this amendment[136] and, as of this writing, the Philippines has not yet adopted the amendment.

As discussed in Part II (C), the December Amendment transforms the August Decision into a permanent Amendment. The obligation under Article 31(f) of the TRIPS Agreement is waived, such that an exporting Member who grants a compulsory license need not limit the production of the resulting pharmaceutical product for the domestic market.[137] Furthermore, the importing Member need not pay adequate remuneration upon the grant of the compulsory license waiving its obligation under Article 31(h) of the TRIPS Agreement, provided that the pharmaceutical product is sourced from an exporting Member which has paid the adequate remuneration (taking into account the exports to be made to the importing Member).[138]

Under this procedure, the Philippines can obtain a compulsory license for Pfizer's Norvasc to import 1,000 capsules it needs from India. Meanwhile, India obtains a compulsory license to manufacture 3,000 capsules (2,000 for its domestic consumption plus 1,000 for export to the Philippines). India will have to pay adequate remuneration to Pfizer for 3,000 Norvasc capsules. When the Philippines imports the 1,000 Norvasc capsules from India, it need not pay Pfizer any remuneration since India has already paid the same.

To participate in this arrangement, however, the Member must be an *eligible importing Member* since an exporting Member can only export pharmaceutical products to the former.[139] An *eligible importing Member* is any least-developed Member or any other Member that has made a notification, which does not need to be approved, to the TRIPS Council of its intention to use the system.[140] The notification must likewise indicate whether the

136. *See* WTO Press Release 426, *supra* note 14.

137. December Decision, *supra* note 30, Annex to the Protocol Amending the TRIPS Agreement, art. 31*bis*(1).

138. *Id.*, art. 31*bis*(2).

139. *Id.*, Annex to the TRIPS Agreement, ¶ 1(c).

140. *Id.*, ¶ 1(b). The TRIPS Council has a webpage enumerating notifications which have been made and is *available at* http://www.wto.org/

Member intends to use the system as a whole or only in limited cases, such as national emergencies, extreme urgency, or for public non-commercial use.[141] The Philippines and India must have both notified the TRIPS Council of their intention to use the system before they can issue their respective compulsory licenses on Pfizer's Norvasc.

The wording of the Roxas Amendment results in two possible government acts: (1) issuance of a compulsory license for the importation, manufacture, sale or distribution of the drugs or medicines without complying with the requirements and (2) parallel importation of drugs or medicines.

The issuance of a compulsory license without complying with the requirements is considered a violation of the TRIPS Agreement, even under the December Amendment. The importation, manufacture, sale, or distribution of drugs or medicines is permitted immediately upon *ex parte* notice to the Intellectual Property Office (IPO) and subject only to the control, supervision, and determination of the heads of the responsible government agencies. It does not consider the procedure that must be followed under the December Amendment. For instance, there is no procedure for making a notification with the TRIPS Council and the only justification under this exception is the protection of public health. It must be emphasized that the TRIPS Agreement and the December Amendment permit the issuance of compulsory licenses (including government use) only upon the fulfillment of certain conditions. Thus, exceptions to the fulfillment of these conditions will be in violation of the TRIPS Agreement.

Parallel importation following the international exhaustion of the patent holder's rights, however, will not be considered a violation of the TRIPS Agreement. As discussed in Part III (C) above, international exhaustion of rights results in the loss of the patent holder's right to control the disposition or resale of its patented product or product obtained from its patented process. In this case, as long as the drug or medicine was legitimately placed by the patent holder in the market of any country in the world, the Philippines can import the same since the patent holder has already exhausted his IPRs in the Philippines. Hence, the government's parallel importation under the Roxas Amendment will be acceptable under the TRIPS Agreement.

3. Looking forward

To issue compulsory licenses, the Philippines may take advantage of the flexibilities under the December Amendment. However, the Roxas

english/tratop_e/trips_e/public_health_e.htm. No importing or exporting Member-State has made a notification as of this writing.

141. *Id.*

Amendment must be reworded to consider the conditions and requirements imposed by the December Amendment. The arbitrary grant of compulsory licenses without complying with the established procedures, a violation of the TRIPS Agreement, will surely result in complaints from other WTO Members.

Nevertheless, a reworded Section 74.3 must still be included as it may serve as an incentive for pharmaceutical companies to lower drug prices to avoid being subjected to this exception. This has been proven in the experience of Brazil and South Africa.

Brazil imposed a "local working" requirement subjecting a patent to compulsory license if it is not "worked in Brazil."[142] Although this was challenged by the US, which challenge was eventually settled, Brazil has successfully used the threat of compulsory licensing to secure more favorable terms in its negotiations with pharmaceutical companies in at least two instances.[143]

Meanwhile, in South Africa, a suit filed by pharmaceutical companies against the government to block a law that empowered the Minister of Health to authorize and prescribe conditions for the parallel importation of patented drugs was eventually withdrawn, with the pharmaceutical companies paying for all costs of litigation and the government reiterating its commitment to uphold its obligations under the TRIPS Agreement.[144]

The foregoing experiences will be instructive in the application of the Roxas Amendment. It has been recognized that the threat of issuance of a compulsory license strengthens the government's hand during drug supply negotiations.[145] Thus, Section 74.3 may not even be utilized by the government but instead may simply exist as a sufficient threat to induce drug companies to lower the prices in the Philippines.

E. *Trademark Exception for Protection of Public Health*

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142. Request for the Establishment of a Panel by the United States, *Brazil - Measures Affecting Patent Protection - Request for the Establishment of a Panel by the United States*, WT/DS199/3 (Jan. 9, 2001) & Notification of Mutually Agreed Solution, *Brazil – Measures Affecting Patent Protection - Notification Of Mutually Agreed Solution*, WT/DS199/4, G/L/454, IP/D/23/Add.1 (Jul. 19, 2001).

143. WHO-WTO Study, *supra* note 121, ¶ 197.

144. *Id.*, ¶ 200.

145. WORLD HEALTH ORGANIZATION, PUBLIC HEALTH – INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 135 (Apr. 2006), http://www.who.int/intellectualproperty/documents/thereport/en/index.html (last accessed on Oct. 9, 2006).

At the onset, it must be established that patent rights are separate from trademark rights. Further, trademark rights are likewise subject to national, regional, or international exhaustion, depending on the laws of the relevant Member and, as such, the rules on the parallel importation of trademarked goods follow the exhaustion regime of the importing Member.

Under the TRIPS Agreement, the owner of a registered trademark has the "exclusive right to prevent all parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion."[146] The same right is reproduced in Section 147.1[147] of the IP Code. To protect this right, the IP Code prohibits the importation of merchandise that copies or simulates the following: (1) the registered name of any domestic product, or manufacturer, or dealer; (2) any other registered mark; or (3) a mark or tradename calculated to mislead the public as to its origin, and is permitted into the Philippines.[148]

The Philippines currently has a national exhaustion regime for trademark rights. Even if the patent over a branded drug has expired, the trademark owner can prevent its importation into the Philippines since its rights to the trademark have not yet been exhausted over the particular drugs, which it did not place in the Philippine market.

1. Changes under the Roxas Amendment

To remedy this situation, the Roxas Amendment seeks to include a limited exception to the foregoing prohibition for government procured medicines. The proposed amendment reads:

> 166.2. The importation, manufacturing, sale or distribution by the government of drugs or medicines with trademarks and tradenames for the protection of public health as provided in Section 74.3 of this Act shall be a limited exception to the rights conferred by trademarks and/or tradenames; provided further, that such drugs or medicines procured by the government or any of its authorized representatives under this provision shall not be

146. The TRIPS Agreement, *supra* note 1, art. 16.1.

147. IP CODE, § 147.1.

> Section 147.1. The owner of a registered mark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs or containers for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use, of an identical sign for identical goods or services, a likelihood of confusion shall be presumed.

148. *Id.*, § 166.1.

> subject to any temporary restraining order or injunction and no suit of any kind related to such may be filed against the relevant public officials or other persons acting under the direction of the Secretaries of the Department of Health and the Department of Trade and Industry for anything which is in good faith done or intended to be done in the execution or purported execution of this provision.

Under the amendment, the products imported or manufactured, sold or distributed by the government pursuant to Section 74.3 (see Part III (D) above) will not be subjected to the trademark owner's rights but will be justified as a limited exception to the rights of the trademark holder. The limited exception rule[149] is provided under the TRIPS Agreement and has been interpreted by the Panel in *EC – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*.[150]

2. Interpretation of the Limited Exception Rule

A limited exception was considered to be a narrow derogation from the rules and to permit only a small diminution of rights and must take into account the legitimate interests of the trademark owner and third parties.[151] The European Communities' regulation, which permitted uses of certain trademarks as geographical indications, satisfied this requirement since the curtailment of rights was only to a limited number of goods, against a limited number of third parties and a limited number of signs.[152] The Panel also found that the EU satisfied the proviso of the limited exception rule since it took account of the interests of: (1) the trademark owner, by providing several ways to raise objections against the use of the geographical indications to preserve the distinctiveness of the mark[153] and (2) the consumers, by preventing the registration of geographical indications likely to mislead the consumer.[154]

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149. The TRIPS Agreement, *supra* note 1, art. 17, stating "[m]embers may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties."

150. This case was brought by Australia and the United States and the Panel issued separate reports for each complaint. *See* Panel Report, *EC – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS290/R (Mar. 15, 2005) [hereinafter Australia Panel] & Panel Report, *EC – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS174/R (Mar. 15, 2005) [hereinafter US Complaint].

151. Australia Panel, ¶ 7.650 & US Panel, ¶ 7.650.

152. Australia Panel, ¶¶ 7.655-7.657 & US Panel, ¶¶ 7.655-7.657.

153. Australia Panel, ¶ 7.665 & US Panel, ¶ 7.665.

154. Australia Panel, ¶ 7.677 & US Panel, ¶ 7.677.

3. Compliance with the TRIPS Agreement

Based on the foregoing ruling, the Roxas Amendment cannot fall under the limited exception rule of the TRIPS Agreement. The Roxas Amendment allows the government to import, manufacture, sell, or distribute drugs or medicines with protected trademarks and tradenames – acts that the trademark owner can validly withhold. This is a very broad exception that diminishes the rights of trademark owners. Also, the Roxas Amendment does not set any standards for the curtailment of the trademark owners' rights to drugs or medicines but is merely justified by the protection of public health. Furthermore, by creating the exception, the Roxas Amendment effectively takes away the trademark owner's right to sue for infringement for acts relating to the unauthorized use of its trademark. Finally, since the notification to the IPO is *ex parte*, there is no opportunity for trademark owners to raise objections on the potential diminution of their rights.

4. Looking Forward

To comply with the TRIPS Agreement, the Philippines is recommended to shift to an international regime of trademark rights for drugs or medicines. Similar to the exhaustion of patent rights, once the product is sold under the specific mark anywhere in the world, the trademark owner's rights are deemed exhausted and it cannot prevent the entry of the trademarked product into the Philippines. Note that the procedure for compulsory licensing of trademarks related to drugs or medicines is not an option since the TRIPS Agreement expressly prohibits compulsory licensing of trademarks.[155]

V. CONCLUSION

The Philippines was a strong supporter of the amendment to the TRIPS Agreement pursuant to the Decision on TRIPS and Public Health of August 2003. The Philippines believes that "an essential component of a health policy includes measures to promote the rational use of drugs and ensure the availability of medicines of adequate quality at a reasonable price."[156] In the 2001 State of the Nation Address, Philippine President Gloria Macapagal-Arroyo made a commitment to reduce the prices of drugs and medicine usually bought by the public by fifty percent.[157] The Department of Health

155. The TRIPS Agreement, *supra* note 1, art. 21.

156. Sec. Peter Favila, Philippine Secretary for Trade and Industry, Statement at the Sixth Session of the WTO Ministerial Conference, WT/MIN(05)/ST/107 (Dec. 16, 2005).

157. The transcript of the 2001 State of the Nation Address is *available at* http://sona.inq7.net/previousaddresses/2001.php. The original statement of President Arroyo is "*Bababa din ang presyo ng gamot. Sa loob ng isang taon hahatiin*

has embarked on a project called "GMA 50" to ensure the constant availability of affordable, high quality, safe, and effective drugs and medicines, especially to the poor.[158] To achieve this goal, the PITC was tasked to import drugs and medicines at affordable prices.

The prices of medicines in the Philippines are among the highest in Asia. In 2001, the Philippine pharmaceutical market was estimated to have a value of $960 million, sixty nine percent of which is controlled by multinational companies.[159] Although the country has enacted the Generics Law of 1998, a majority of doctors still continue to prescribe branded drugs without indicating the generic name, effectively preventing Filipinos from purchasing a cheaper brand.

The main reason of the pharmaceutical companies for respecting patent rights and keeping drug prices high is the promotion of research, development, and innovation.[160] Commentators have noted that stronger patent protection does not always result in innovation for drugs essentially needed by developing and least-developed countries.[161] It has also been shown that there is a strong link between the expansion of profit opportunities and increase in research and development investments.[162] These divergent points of view reveal the balancing act that the government must face in order to respond to the interests of affected parties.

It must be emphasized that Members can adopt measures necessary to protect public health and nutrition as long as these measures are consistent with the TRIPS Agreement. It has also been recognized that the TRIPS Agreement provide flexibility and its interpretation and implementation should be supportive of the Member's right to protect public health and promote access to medicines.[163] Thus, in deliberating over the Roxas Amendment, legislators must be aware of these basic principles and

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natin ang presyo ng gamot na madalas bilhin ng madla." This can be roughly translated as saying, "The prices of medicine will go down. Within one year, we will slash the prices of commonly-bought medicines."

158. Philippine Department of Health, *GMA 50%*, http://www.doh.gov.ph/pharma50/pharma50.htm (last accessed Oct. 9, 2006).

159. *Philippines: A tight fight with titans Thursday*, PHARMABIZ.COM, April 22, 2004, http://www.pharmabiz.com/article/detnews.asp?articleid=21492&sectionid=50&z=y (last accessed Oct. 9, 2006).

160. See Pfizer sues PITC, supra note 10.

161. Ruth Mayne, *The TRIPS Agreement and Access to Medicines: an NGO Perspective*, *in* THE WTO AND DEVELOPING COUNTRIES 155 (Homi Katrak & Roger Strange, eds., 2004).

162. WHO-WTO Study, *supra* note 121, Box 14.

163. Doha Declaration, *supra* note 15, ¶ 4.

flexibilities, and utilize them to create a regime that sufficiently addresses the needs of the Filipino people.