INTELLECTUAL PROPERTY AND PUBLIC HEALTH: TWO SIDES OF THE SAME COIN[*]

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ABSTRACT

Intellectual property (IP) protection has been blamed as one of the main sources of the public health challenge facing society. The high prices of patented drugs causes a low rate of access to medicine in poor countries. Public health and human rights advocates propose to abandon pharmaceutical patents or impose a legal duty on pharmaceutical companies to make essential medicines accessible. This article investigates the monopoly rights and practices in the pharmaceutical field, the gravity of the public health problem and the status of patenting and medicine access in least-developed countries (LDCs) and developing countries (DLCs), and the legal and policy schemes tailored to increase medicine access. Based on the analyzes of the findings from the investigation, the article argues that a patent is a minor factor for medicine access in LDCs, and an important factor in DLCs. But compulsory licensing or other practical solutions can reduce its impact, and intellectual property and public health, as an integral part of each other or two sides of the same coin, are inseparable and mutually dependent. IPR provide necessary incentives in drug discovery and development for public health, the IP system in turn benefits from public health related drug discovery R&D and commercial activities.

[*] This article is revised based on a paper submitted for presentation in "2011 Conference on International Health and Trade: Globalization and Related Health Issues," held on Aug. 5-6, 2011 at College of Law, National Taiwan University. The author is grateful for the enlightening comments from the conference participants, particularly from Professors Chang-fa Lo, Shin-yi Peng and Thomas Alured Faunce, and from an anonymous article reviewer.

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The relationship between the two should be perceived and constructed in a positive, forward looking and pragmatic way, rather than mutual condemnation and destruction. Scholars and practitioners in both fields should collaborate to have an in-depth understanding of the issues, objectives, schemes and practices in the two fields, and an objective assessment of the impact each has exerted, efforts to reconcile, and positive outcomes achieved.

KEYWORDS: *intellectual property rights, patents, access to essential medicines, public health, compulsory licensing, Doha Declaration*

I. INTRODUCTION

Before the World Trade Summit in Doha in 2001, the Ministers of Health of South Africa and Belgium issued a strong statement noting that "[I]t is a crime against humanity for poor people to die because lifesaving medicines are too expensive."[1] Many, particularly public health advocates, claim that patents are responsible for such a crime because patented essential medicines are too expensive and thus not affordable to the poor people living in developing countries (DLCs) and least-developed countries (LDCs).[2] Is the patent truly a factor contributing to the public health disaster, and, if so, is it the sole or main factor? Are IPRs and public health irreconcilable enemies? In other words, must we abandon pharmaceutical patent in order to protect public health, or *vice versa*, is public health doomed to suffer at the cost of the existence of patents? Are there any positive aspects about the relationship between IPRs and public health, and ways to change and improve the negative aspects? In short, can IPRs and public health co-exist, as the two sides of the same coin? This article argues that IPRs and public health are the two sides of the same coin and can co-exist to promote the healthy lives of mankind, if we perceive their relationship positively, assess the effects of patents on medicine access objectively, and strive to find workable solutions to use IPRs to promote public health.

To support the above arguments, this article will examine the legally available monopoly rights in the pharmaceutical field and how pharmaceutical companies exercises or abuse these rights to maintain their market exclusivity. The article will then identify major public health problems such as HIV/AIDS, malaria, tuberculosis and other epidemics in the world, and investigate how pharmaceutical patents interact with or affect public health by separately exploring patenting status and medicine access in LDCs and DLCs. This will be followed by a study on legal and policy schemes aiming to reduce the impact of pharmaceutical patents on medicine access to promote generic competition such as no-patent protection, experimental use and Bolar-exception, compulsory licensing, and parallel importation. The article then analyzes the findings from the investigations in preceding sections, assesses the relationship between

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[1] Mary Ann D. Lansang, Access to Medicines: Reorienting the Research Agenda, http://www.novartisfoundation.org/platform/content/element/278/access_research_agenda.pdf (last visited Sept. 25, 2011).

[2] For example, Médecins Sans Frontières [hereinafter MSF] states in its website, "Many medicines, in particular those that are still relatively new such as HIV medicines are too expensive for use in poor countries. Patent protection has increased in developing countries and this pushes prices up because patents provide a monopoly for the originator company for up to 20 years, blocking competition." *See* Campaign for Access to Essential Medicines: About Us, http://www.msfaccess.org/about-us/ (last visited Sept. 28, 2011).

patents and public health, and explores practical solutions to improve the relationship of the two sides and to use intellectual property to promote public health.

II. IP AND MONOPOLY IN THE PHARMACEUTICAL FIELD

A. An Overview

Patents provide a patent holder a 20-year monopoly right to exclude others from using the invention he or she patented. As long as the patent holder does not grant authorization, or refuses to license, no one can use the invention, except where a compulsory licensing is granted. There are typically two kinds of patents: product patents and process patents. Product patents confers more powerful protection as it is difficult to invent around a product once it is patented, while process patents are easier to be infringed as there are multiple routes to produce the same product. Neither the Paris Convention nor the Agreement on Trade-Related Intellectual Property Rights (TRIPS) clearly lists patentable subject matter, except broadly stating that a patent is available for "any inventions, whether product or processes, in all fields of technology."[3] Presumably, pharmaceutical products and processes are protected by patent because discovery of new drugs should be considered a field of technology. Indeed, pharmaceutical products and processes are protected in most WTO member states. However, under special transitional arrangements in the TRIPS agreement,[4] some DLCs and LDCs within the WTO have delayed their patent protection for pharmaceutical products for 10 or more years. For example, India only started to protect pharmaceutical products in 2005, 10 years after TRIPS entered into force, and LDCs are allowed to delay until 2016. We will further discuss these special transitional arrangements and their impact on developing countries in the latter part of this paper. It is sufficient to know that pharmaceutical patents are only effective in the countries where

[3] Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

[4] TRIPS Agreement article 65(4) provides, "To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years." TRIPS article 66(1) provides, "In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period."

pharmaceutical patents are protected and granted, and have no effect in countries that are not. For example, since pharmaceuticals were not protected by patent in India prior to 2005, India was free to produce generic versions of the patented antiretroviral (ARV) drugs for a long time. In the same way, if some ARV drugs are not filed for patent protection in LDCs, these countries are also free to produce these ARV drugs without fear of infringement lawsuits.

B. Patent Term Extensions

In countries that do have patent protection for pharmaceutical products and processes, pharmaceutical companies must obtain authorization or licenses from the patent holder to produce the patented drugs, or else they may face a lawsuit for patent infringement. Pharmaceutical patent holders, mostly multinational pharmaceutical corporations (MPCs), typically file as many patents as possible for their new inventions, and fiercely guard against any infringement because developing a new drug is both extremely expensive and time-consuming. It is estimated that "of every 5,000 new chemical entities (NCEs) screened, on average, only five are tested in clinical trials and only one of those is approved for patient use,"[5] and the cost for putting a new drug on the market is somewhere from US$500 million to US$800 million, but only about 30% of the patented drugs on the market are profitable.[6] It shall be noted, though, that opponents of pharmaceutical patents argue that the figures are exaggerated and many of the research projects are funded by public institutions.[7] In the meantime, the time spent on drug discovery and marketing approval is notoriously lengthy. About 8-12 years will be spent on clinic trials and the marketing approval process before a new drug can be put on the market.[8] In effect, the pharmaceutical companies suffer a significant reduction of the 20 years patent term as they typically file their patent applications at a pre-clinical stage to protect their new ideas. To compensate for such a loss in patent

[5] Meir Perez Pugatch, *Intellectual Property and Pharmaceutical Data Exclusivity in the Context of Innovation and Market Access*, ICTSC-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines Bellagio, at 9 (Oct. 12-16, 2004), http://www.iprsonline.org/unctadictsd/bellagio/docs/Pugatch_Bellagio3.pdf (last visited Sept. 25, 2011).

[6] *Id.*

[7] For example, the discoveries of 15 out of 21 drugs (71%) introduced between 1965 and 1992 were publicly funded. *See* Prayas & Jan Swastha Abiyan, *Medicine Pricing and Universal Access to Treatment Fact Sheet*, http://www.oxfamindia.org/sites/www.oxfamindia.org/files/Factsheet-_Universal_access_to_medicine.pdf (last visited Sept. 25, 2011).

[8] Clinical trials normally include five stages: a pre-clinical stage and four clinical stages. The pre-clinical stage involves the isolation of new chemical compounds, safety tests on animals and other studies. The clinical stages involve safety and efficacy trials on human volunteers, and regulatory and post-marketing studies. Pharmaceutical companies typically file their patent applications at the pre-clinical stage to protect their inventions. *See* Pugatch, *supra* note 5, at 4.

term, the U.S., EU, Japan and Australia adopted legislation to restore the patent term up to five years. To illustrate, EU's Supplementary Protection Certificate (SPC) system and the U.S.' Hatch-Waxman Act are explained below.

The SPC system was created by Council Regulation (EEC) No. 1768/92 for medicinal products published on July 2, 1992, was codified under Regulation (EC) No. 469/2009, and came into force on July 6, 2009. SPC provides an extension of five years of market exclusivity after a patent has expired, or 15 years for a designated medicinal product, subject to the following conditions: (1) the medicinal product must be authorized for marketing; (2) the SPC relates to that medicinal product only, not process or other claims in the original patent; (3) the application must be made within six months of the grant of the marketing authorization.[9]

In 1984, the U.S. Congress passed the Drug Price Competition and Patent Term Restoration or Hatch-Waxman Act to give generic companies considerable leverage in drug market competition and patent litigation by creating a "Bolar exception," which we will discuss later. As a balance, the Act also grants patent holders a period of additional market exclusivity by restoring the time lost during the regulatory approval. Specifically, it grants an extension up to five years, but the total patent term (including the restoration period) following FDA approval cannot be longer than 14 years. So when the regulatory review period for a new drug is five years, a five-year restoration period may be granted. However, if the remaining term of a patent is 10 years, only a four-year restoration period is allowed even if the review period is five years.

C. Data Exclusivity

In addition, pharmaceutical companies also arguably receive extra market exclusivity through the protection of test data exclusivity. Test data exclusivity is a form of protection given to clinical test data that are used to prove safety and efficacy of new pharmaceutical or agricultural chemical products. During the period of exclusivity, ranging from 5-10 years depending on national legislation,[10] no generic applicant can rely on the data for marketing authorization. Under TRIPS Article 39(3), the data submitted for the purpose of marketing approval are protected against unfair commercial use or disclosure.[11] It is arguable that this article has

[9] Intellectual Property Office, Supplementary Protection Certificate: Guide for Applicants (2009), *available at* http://www.ipo.gov.uk/spctext.pdf (last visited Sept. 25, 2011).

[10] U.S.: 5 years for new pharmaceutical chemical entities; 3 years for new indications of drugs, and 12 years for biological products. EU: 8 years (+2 years market exclusivity +1 year for new indication). China: 6 years; and Taiwan: 3 (or 5) years.

[11] TRIPS Agreement article 39(3) provides: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new

provided the data holder exclusive right over the test data because, under this article, it will be very difficult for a generic company to argue that its use of the data is not for commercial purpose, although it may make a case that the commercial use is not "unfair." Since generic companies are financially and technically unable to create the test data, the data exclusivity may prevent them from entering into the market, as such they often complain that data exclusivity is another extension of the pharmaceutical patent term.[12] For instance, the European Generic Association argues, "data exclusivity merely extends the originator company's market monopoly over a product by not allowing the authorities to process an application for marketing authorization."[13] However, a study by IMS Health found that "very few high-selling drugs gain further marketing monopoly from the provision afforded by data exclusivity" and that "only drugs that do not have granted Supplementary Protection Certificates or took an exceptionally long time to traverse the R&D process gain significantly from the data exclusivity provisions."[14] The reason for this is that market exclusivity protected by patent is normally longer than the data exclusivity.[15]

D. "Authorized Generics" and "Reverse Payment" Settlement

In recent years, generic companies have become more "strategically proactive and successful" in challenging the patents of original drugs.[16] For example, India's Ranbaxy Laboratories challenged the patent of Pfizer's Lipitor in Australian court and invalidated one of its patents, although it was held to have infringed the basic patent covering atorvastatin.[17] To retaliate against generic companies challenging their patents, MPCs adopted a strategy of "authorized generics" which grants another "friendly" generic company a license to produce a generic version of the original drug.[18] For instance, a generic company Mylen Pharmaceuticals challenged the validity of a patent for Macrobis (for the

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chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use."

[12] Pugatch, *supra* note 5, at 12.

[13] European Generic Association: Data Exclusivity, http://www.egagenerics.com/gen-dataex.htm (last visited Sept. 25, 2011).

[14] Pugatch, *supra* note 5, at 13.

[15] For detail discussion on this point, *See id.* at 13-14.

[16] *Id.* at 11.

[17] Partial Win for Ranbaxy in Lipitor Case v. Pfizer in Australia, http://www.financialexpress.com/news/partial-win-for-ranbaxy-in-lipitor-case-vs-pfizer-in-australia/315685/ (last visited Sept. 25, 2011).

[18] Pugatch, *supra* note 5, at 11.

treatment of urinary tract infections) and therefore was entitled to the 180-day market exclusivity. The patent holder Procter & Gamble then licensed another generic company Watson Pharmaceuticals to manufacture a generic version of the drug, thereby stopping Mylen's 180-day market exclusivity. Mylen sued the FDA for failing to enforce the 180-day market exclusivity, but later withdrew the case.[19]

MPCs also frequently reach settlements with a generic competitor to delay generic competition. Specifically, when facing a patent validity challenge, the MPCs agree to pay a generic competitor a certain sum of money, in return, the generic competitor agrees to delay the date of market entry. It is called a "reverse payment" settlement, because in this kind of settlement, the patentee pays the alleged infringer, which is opposite to a normal settlement scenario where an accused infringer, e.g., generic competitor, pays the patentee. Several cases involving "reverse payment" settlement have been challenged for antitrust law violations. For example, in *Louisiana Wholesale Drug Co. v. Bayer AG* (On Petition for a Writ of Certiorari 2011), reverse payment settlements are being challenged as unlawful under the Sherman Act. Courts are divided on the issue whether these kind of settlements are legal. So far, the 2nd Circuit and Federal Circuit held that it is legal *per se*,[20] while the 11th Circuit held that they should be treated under the rule of reason, and the 6th Circuit ruled that they are illegal *per se*.[21] A group of more than 80 law professors lead by Prof. Mark Lemley filed a friend-of-the-court brief to request the Supreme Court to hear the case, as they believe that the holding of "*per se* legality" is wrong.[22]

E. Patents for New Use of Known Substances and "Evergreening" Patents

New use (or new therapeutic use or second use) of known substances is a practice of pharmaceutical companies to file patents for a new therapeutic use discovered from a chemical compound that was used or known for another therapeutic purpose. For example, AZT, the first ARV drug for HIV/AIDS, was first discovered for the purpose of treating cancer in 1964, but it was patented as a drug treating HIV/AIDS in 1985. Another example

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[19] *Id.*

[20] They held that the settlement has no antitrust problem unless: (1) patent was obtained by fraud, (2) infringement suit has no basis, (3) restrains competition beyond the scope of patent. *See* CCH 2010-1 Trade Cases 76,989, *Arkansas Carpenters Health & Welfare Fund v. Bayer AG*, 604 F.3d 98 (Apr. 29, 2010).

[21] Reverse Payment Settlements Return to the Supreme Court, http://www.patentlyo.com/patent/2011/01/reverse-payment-settlements-return-to-the-supreme-court.html (last visited Sept. 25, 2011).

[22] *Id.*

of new use is Viagra (treating erectile dysfunction) over sildenafil citrate treating high blood pressure. It is said that new use can substantially reduce R&D costs and the risk of unexpected side effects, and that about 40% of Pfizer's compounds in the development pipeline have a prior known use.[23] Obviously, patenting a new use can allow a pharmaceutical company to maintain market exclusivity over one chemical compound for two or more patent terms. Whether this is allowed and justified, TRIPS gives no guidance and national laws are widely divided. Generally, it is supported in the developed countries and is suspected or resisted in developing countries. In the U.S., inventors can claim a method of use for the novel therapeutic use of a known compound under 35 U.S.C. § 287.[24] In Europe, a special novelty exception and a legal construction "Swiss claim" were created to allow the first and the second use of known substances.[25] In developing countries, some countries, like South Korea, allow new use patents; some countries, such as Brazil and Argentina, are not clear, and others, like Kenya and Andean community, specifically prohibit new use patents.[26] The U.K. Commission on Intellectual Property Rights (CIPR) report recommends, "Most developing countries, particularly those without research capabilities, should strictly exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products."[27]

While patenting new use for known substances may be considered as legally acceptable, "evergreening" patents are generally perceived as patent abuse because the former normally involves a novel use that significantly differs from prior use but the latter only involves minor modifications of an existing chemical compound. According to a critique, "Evergreening refers to different ways wherein patent owners take undue advantage of the law and associated regulatory processes to extend their IP monopoly particularly over highly lucrative blockbuster drugs by filing disguised/artful patents on an already patent-protected invention shortly before expiry of the patent term."[28] A patent application for imatinib mesylate filed by Novartis in India was rejected by the Indian patent office.

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[23] Richard A. Castellano, *Patent Law for New Medical Uses of Known Compounds and Pfizer's Viagra Patent*, 46 IDEA 283, 285(2006).

[24] *Id*. at 293.

[25] Pascale Boulet et al., *Drug Patents Under the Spotlight: Sharing Practical Knowledge About Pharmaceutical Patent*, at 15 (2003), *available at* http://apps.who.int/medicinedocs/pdf/s4913e/s4913e.pdf (last visited Sept. 25, 2011).

[26] *Id.*

[27] Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy, at 50 (2002), *available at* http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf (last visited Sept. 25, 2011).

[28] Inderjit Singh Bansal et al., *Evergreening: A Controversial Issue in Pharma Milieu*, 14(4) J. INTELL. PROP. RIGHTS 299, 299 (2009).

This decision was upheld by the Indian court on the ground that Novartis's patent application lacked "significant therapeutic advances" over the previous version, imatinib, pursuant to amended Indian Patent Law section 3(d).[29]

III. PATENTS AND ACCESS TO ESSENTIAL MEDICINES

There have been many complaints that the cost for accessing medicines essential for public health is too high and people in developing countries and particularly LDCs cannot afford to purchase the drugs protected by patents.[30] As a result, people suffering HIV/AIDS or other infectious diseases have no choice but to wait and die. Take, for example, the price for patented ARV combination therapy for AIDS treatment. It used to cost more than US$10,000 per patient per year on average, but a generic version costs only US$168 per patient per year.[31] But on the other hand, "significant progress has been made in recent years in increasing access to HIV treatment in the developing world. Between 2002 and 2010, the number of people in developing countries receiving ARV therapy increased by more than 2,100%, from fewer than 300,000 to 6.6 million."[32] How does one evaluate these two conflicting phenomena? Is the patent the sole or main source of the problem in medicine access? Before answering these questions, we examine the gravity of public health problems first, and then the patenting status of essential medicines in LDCs and DLCs respectively.

A. The Gravity of the Public Health Problem

"Public health" is defined in Webster's Medical Dictionary as "the approach to medicine that is concerned with the health of the community as a whole."[33] The Dictionary also lists three core functions of public health:

- "The assessment and monitoring of the health of communities and populations at risk to identify health problems and priorities;
- The formulation of public policies designed to solve identified local and national health problems and priorities;

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[29] Prayas & Abhiyan, *supra* note 7. *See also* the discussion in IV-C of this article.

[30] MSF, The Impact of Patents on Access to Medicines, http://www.msfaccess.org/content/impact-patents-access-medicines (last visited Sept. 25, 2011).

[31] Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20(2) BERKELEY TECH. L.J. 1031, 1033 (2005).

[32] Gilead Press Release, Gilead Expands Access Program for Medications in Developing World, http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsarticle&id=1584101 (last visited Sept. 25, 2011).

[33] MedicineNet.Com, Definition of Public Health, http://www.medterms.com/script/main/art.asp?articlekey=5120 (last visited Sept. 24, 2011).

- To assure that all populations have access to appropriate and cost-effective care, including health promotion and disease prevention services, and evaluation of the effectiveness of that care."[34]

The public health problems that were identified by the WTO in its Doha Declaration on the TRIPS Agreement and Public Health [hereinafter Doha Declaration] include HIV/AIDS, tuberculosis, malaria and other epidemics, which particularly afflict developing and LDCs.[35] In order to assess how IP affects public health, we must first understand how grave the medicine access problem is in these areas.

1. HIV/AIDS. — According to UNAIDS' statistics, in 2009, the number of people living with HIV was 33.3 million among which 22.5 million were living in Sub-Saharan Africa, and 4.1 million living in South and South-east Asia.[36] "Since the beginning of the epidemic, more than 60 million people have been infected with HIV and nearly 30 million people have died of HIV-related causes."[37] The disease is treated by Highly Active Anti-retroviral Therapy (HAART), which is not a cure but reduces infection and prolongs life. However, HAART is very costly and not widely available outside of developed countries. Among 25 million HIV-positive Africans, only about 25,000 or just one in 1,000 receive one ARV drug.[38] In 2009, 5.2 million people with HIV in low- and medium-income countries had access to ARV drugs, up from 700,000 in 2004, but 10 million still do not have access.[39]

2. Tuberculosis. — It is estimated that one-third of the world's population is currently infected with the TB bacillus, and 5-10% of people who are infected with TB bacilli become sick or infectious.[40] Sub-Saharan Africa has the largest population of TB patients, with over 350 cases per 100,000 people, and the South-east Asia region comes in second, with 35% of the global cases in 2008.[41] It was estimated that 1.7 million people died

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[34] *Id.*

[35] Ministerial Conference, Doha Declaration on the TRIPS Agreement and Public Health, art.1, WT/MIN(01)/DEC/W/2 (Nov. 14, 2001) [hereinafter Doha Declaration].

[36] Joint United Nations Programme on HIV/AIDS [hereinafter UNAIDS], The Global AIDS Epidemic, http://www.unaids.org/en/media/unaids/contentassets/documents/factsheet/2010/20101123_FS_Global_em_en.pdf (last visited Sept. 25, 2011).

[37] *Id.*

[38] Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286(15) JAMA 1886, 1890 (2001).

[39] UNAIDS, *supra* note 36. In 2009, in Sub-Saharan Africa, only 3.9 million HIV infected were receiving ART, while 10.6 million were still in need of ART.

[40] WHO, Tuberculosis, http://www.who.int/mediacentre/factsheets/fs104/en/index.html (last visited Sept. 25, 2011).

[41] *Id.*

from TB in 2009, of which mostly are people in Africa.[42] The increase of TB was partly cause by the emergence of HIV as the virus weakens the immune system. The two most powerful anti-TB drugs are isoniazid and rifampicin, but more and more patients started to become resistant to both of them due to inconsistent or partial treatment.[43] The drug resistance can be treated with chemotherapy and second-line anti-TB drugs that are more expensive. Right now, the WHO has launched The Global Plan to Stop TB 2010-2015, which set targets to reduce TB prevalence and death rates by 50% by 2015 and eliminate TB as a public health problem by 2050.[44]

3. Malaria. — The WHO estimated that, in 2008, there were 247 million cases of malaria and nearly one million deaths, mostly among African children, of whom one will die of malaria every 45 seconds.[45] It is also estimated that 59% of the world's clinical malaria cases occur in Africa, 38% in Asia and 3% in the Americas.[46] Malaria can decrease GDP by as much as 1.3% in countries having high levels of transmission, and health costs are up to 40% of public health expenditures.[47] Although curable, the disease could be fatal if not treated promptly. The best available treatment is artemisinin-based combination therapy (ACT). However, artemisinin has increasingly become resist, which may cause a serious health crisis "as no alternative antimalarial medicines will be available in the near future."[48] The 2002 statistics show that the cost for the treatment with antimalarial drugs in Sub-Saharan Africa was well below US$1, and the cost of ACTs was in the range US$1-3.50 per adult treatment.[49] But the price difference between a brand name product and its generic version is huge. For example, per-tablets prices of mefloquine varied from a low of US$0.54 for a generic product in Uganda to US$8.10 for a brand-name product in the United Republic of Tanzania, and the private sector prices for artemisinin monotherapy compounds in Kenya ranged between US$5 and 7 per adult treatment.[50] A new antimalarial drug, malrone, has been launched for prophylaxis and treatment, but it is not affordable for most of malaria endemic countries in Sub-Saharan Africa.[51]

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[42] *Id.*
[43] *Id.*
[44] *Id.*
[45] WHO, Malaria: Fact Sheet (2010), http://www.who.int/mediacentre/factsheets/fs094/en/ (last visited Sept. 25, 2011).
[46] WHO, World Malaria Report 2005, *available at* http://whqlibdoc.who.int/publications/2005/9241593199_eng.pdf.
[47] WHO, *supra* note 45.
[48] *Id.*
[49] WHO, Improving Access to Antimalarial Medicines: Report of the RBM Partnership Meeting (2002), http://www.emro.who.int/rbm/background%20documents/egy04/acess.pdf (last visited Sept. 25, 2011).
[50] *Id.*
[51] Lansang, *supra* note 1.

Malaria has been eliminated in many countries such as the United States, but the effort to eradicate it in Africa has been a failure. The best way to reduce malaria transmission, as the WHO suggested, is vector control such as insecticide-treated mosquito nets and indoor spraying with residual insecticides.[52] However, mosquitoes too have developed resistance to insecticides over time, and developing new, alternative insecticides is an expensive and long process.[53]

B. Patent Status and Medicine Access in Least-developed Countries

From the above statistics, we know that the access rate for drugs treating HIV/AIDS, tuberculosis and malaria in LDCs is extremely low. The question is whether this low access rate is caused by patent or by other factors. According to a study by Attaran and Gillespie-White, among the 15 antiretroviral drugs treating AIDS which are patented by MPCs such as GSK, Roche, BMS, Merck, BI, Abbott and Agouron, only very few (e.g., 4) are patented in most of African countries, with one exception that 13 out of 15 drugs were filed for patents in South Africa, and among total 795 patents filed, only 172 (21.6%) actually exist.[54] They concluded that patent is not to be blamed for the lack of access to ARV drug treatment in most African countries, because the "scarcity of treatment cannot rationally be ascribed to antiretroviral patents that are few – or nonexistent – in most African countries. Other factors, and especially the ubiquitous poverty of African countries, must be more to blame."[55] They further listed the non-patent barriers for access to antiretroviral treatment in Africa as: insufficient finances to purchase; lack of political will; poor medical care and infrastructure; inefficient drug regulatory procedures that exclude competing products from the marketplace; and high tariffs and sales taxes.[56]

The authors of the above study emphasized that their conclusion only applies to ARV drugs in Sub-Saharan Africa,[57] but not to other types of drugs in other regions. Indeed, even in Sub-Saharan Africa, there is one exception to the general rule as the authors pointed out, that is, MPCs had

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[52] WHO, *supra* note 45.
[53] *Id.*
[54] Attaran & Gillespie-White, *supra* note 38, at 1887.
[55] *Id.* at 1890.
[56] *Id.*
[57] For the purpose of discussion, this article use LDCs and Sub-Saharan Africa interchangeably because most Sub-Saharan African countries are in the category of LDCs which are classified by the UN as countries average GNI per capita is less than US$750. *See* The United Nations Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and the Small Island Developing States [hereinafter UN-OHRLLS], The Criteria for the Identification of the LDCs, http://www.un.org/special-rep/ohrlls/ldc/ldc%20criteria.htm (last visited Sept. 25, 2011).

filed and received many patents in South Africa. This resulted in a legislation of South Africa's Medicines Act 1997 authorizing the Minister of Health to revoke patents on HIV/AIDS medicines and to allow broad compulsory licensing to produce generic version of HIV/AIDS drugs and parallel importation for the cheapest patented medicines. In response, the South African Pharmaceutical Manufacturers Association and 39 MPCs sued the South Africa government in February 1998, seeking to revoke the Act on the ground that it has violated the South African Constitution and the TRIPS Agreement. Three years later in March 2001, the lawsuit was withdrawn under tremendous international condemnation.

C. Patent Status and Medicine Access in Developing Countries

In other regions, such as Asia and South American countries, the situation may be different. The MPCs do seek patent protection in the countries of these regions that are mostly developing countries with manufacturing capacity for producing generic drugs.

For example, in July 1992, Bristol-Myers Squibb (BMS) filed a patent application for formulation of an ARV drug didanosine in Thailand and received the patent in January 1998. Only three months after the patent was granted, Thailand's Government Pharmaceutical Organization (GPO) launched a generic didanosine 150mg tablets. In May 2001, the AIDS Access Foundation and two patients with HIV-1 in Thailand filed a lawsuit against BMS in the Thai Central IP and International Trade Court on the ground that BMS' patent application for didanosine had intentionally omitted the dose restriction. The court ruled in favor of the plaintiffs in October 2002. The central issue in the case was whether an individual has the right to challenge a patent. BMS argued that the plaintiffs "do not have the objective to manufacture didanosine, and can choose other medicines to cure the disease, and are therefore not injured or interested parties."[58] The court in its final verdict, however, ruled that "medicine is one of the fundamental factors necessary for human beings, as distinct from other products or other inventions that consumers may or may not choose for consumption," that "injured parties . . . are not limited to manufacturers or sellers of medicines protected by patent." Those in need of the medicine are also interested parties to the granting of the patent, and that TRIPS should be "interpreted and implemented so as to promote the rights of members to protect public health, especially the promotion and support of access to medicines."[59] It was believed that "the ruling has set an important precedent that essential drugs are not just another consumer product but a

[58] Nathan Ford et al., *The Role of Civil Society in Protecting Public Health over Commercial Interests: Lessons from Thailand*, 363(9408) THE LANCET 560, 561 (2004).
[59] *Id.*

human right, and that patients are injured by patents."[60]

Another patent for ARV drug was also filed and met opposition in Thailand. GSK had attempted several times (in 1997 and 2006 respectively) to patent its ARV drug, Combid, in Thailand, but had to withdraw its application due to opposition from HIV/AIDS advocates.[61] Thailand's GPO has been producing a generic version of Combid known as Zilarvir, and about 4,000 out of the 100,000 HIV-positive people in the country each paid $38 monthly for the generic version.[62] In fact, GPO had been producing seven generic ARV drugs that are 2-25 times cheaper than the brand equivalents.[63]

In Brazil, the government launched a program to provide universal access to antiretroviral therapy in the late 1990s. In 2008, a patent application filed by Gilead Sciences for the drug tenofovir disproxil fumarate (TDF) was rejected by the Brazilian Patent Office on the ground that it lacked inventiveness.[64] This decision was considered very important for Brazil's AIDS patients because there were about 31,000 people receiving TDF under the government's treatment program, and TDF was produced by India's generic companies at a tenth of the price for the brand equivalent: US$158 for one patient yearly, compared to the US$1,387 charged by Gilead in Brazil.[65] Without patent protection in Brazil, TDF can be freely produced by local generic companies or imported from India.

India represents a very interesting case on medicine access. The country has the second highest number of HIV infections in the world, and is one of the few countries enjoying low drug pricing due to the lack of product patent protection for drugs prior to 2005, and yet "access still remains denied to the large number of HIV positive persons."[66] "Healthcare expenditure is the second greatest cause of rural indebtedness in India today . . . between 1999-2000, 32.5 million patients fell below the poverty line after just a single hospitalization . . . WHO estimates that 65% of India's population lacks regular access to essential medicines."[67] A commentator attributes the inaccessibility to factors such as "poverty,

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[60] *Id.* at 560.

[61] GSK Withdraws Application Seeking Patent for Antiretroviral Drug Combid in Thailand, http://www.medicalnewstoday.com/releases/50050.php (last visited Sept. 25, 2011).

[62] Henry J. Kaiser Family Foundation, HIV/AIDS Advocates in Thailand Protest GSK's Application Seeking Patent for Antiretroviral Drug Combid (Aug. 9, 2006), http://www.thebody.com/content/art7778.html (last visited Sept. 24, 2011).

[63] Ford et al., *supra* note 58, at 562.

[64] European AIDS Treatment Group, Brazil Rejects Patent on an Essential AIDS Medicine, http://www.eatg.org/eatg/Global-HIV-News/Access-to-treatment/Brazil-rejects-patent-on-an-essential-AIDS-medicine (last visited Sept. 25, 2011).

[65] *Id.*

[66] Salvi S, *Access to Medicine and Treatment in India*, http://gateway.nlm.nih.gov/MeetingAbstracts/ma?f=102254781.html (last visited Sept. 25, 2011).

[67] Prayas & Abhiyan, *supra* note 7.

existing public health policies, the drug pricing regulation, obligations under TRIPS to amend the patent laws and lack of knowledge of the fundamental right to health." Take pricing as an example, it was said that the Indian Government had been reluctant to have price control over drugs arguing that generic competition should be adequate to lower prices, as a result, "prices can remain quite high even for 'generic medicines,' with [generic] companies still able to skim enormous mark-ups from bulk to individual retail price."[68] The situation may be worsened by the 2005 amendment to the patent law introducing product patents for drugs. To ensure its generic competition right after patent expiration and to prevent "everygreening" medicines, India amended section 3(d) in its 2005 patent law, requiring patents to represent significant therapeutic advances over previous versions of a medicine.[69] This provision was applied by the Indian Patent Office (Chennai Patent Office) to reject a patent application filed by Novartis for imatinib mesylate, a blood cancer treatment drug based on an earlier version imatinib. Novartis challenged this decision, as well as the constitutionality of section 3(d), at the Madras High Court. Novartis claimed that section 3(d) was not in compliance with Article 27 of TRIPS because it gave unguided discretionary powers to the Patent Controller to reject the patent applications on the ground that there was no invention. The court did not accept Novartis' contention.

According to an MSF's study, China also faces the problem of access to essential medicines due to drug choice restrictions, lack of availability of key second-line drugs and the inability to take advantage of voluntary differential pricing.[70] China has about 840,000 HIV positive people, 80,000 of whom are living with AIDS by a 2005 estimation.[71] The government has been able to provide free antiretroviral drugs to these patients since 2003 thanks to domestic generic production. But these drugs (d4+, ddl and NVP) have high toxicity and the WHO recommended the use of lamivudine (3TC) which was available in 2004 when China reached a supply agreement with GSK, the patent holder of 3TC.[72] But the supply

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[68] *Id.*

[69] Section 3(d) amended in 2005 provides that the following are not "inventions": "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or 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."; Shamnad Basheer & T. Prashant Reddy, *The "Efficacy" of Indian Patent Law: Ironing out the Creases in Section 3(d)*, 5(2) SCRIPTED 232, 238 (2008), http://www.law.ed.ac.uk/ahrc/script-ed/vol5-2/basheer.pdf (last visited Sept 25, 2011).

[70] MSF, Access to Essential Medicines and the WTO: Case Study China, http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_WTOMinisterialConference6_HongKong_ENG_2005.pdf (last visited Sept. 24, 2011).

[71] *Id.*

[72] *Id.*

still could not satisfy the need. In addition, the effective fixed-dose combination (FDC) of d4T/3TC/NVP could not be manufactured or sold in China because of the patent on 3TC.[73] Many second-line antiretroviral drugs (tenofovir, lopinavir/ritonavir, saquinavir, nelfinavir, and ritonavir) which can solve the resistance problem of first-line drugs are also not available in China because the patent holders of these drugs do not market them in China.[74] As a lower-middle income country, China does not have the privilege to enjoy "differential pricing" as the LDCs do.[75] MSF attributes the access problem in China mainly to patents, but another study by a group of Chinese researchers shows that the obstacle is created by the Chinese pharmaceutical companies' reluctance to produce essential medicines as these medicines are not perceived as profitable because of low demand and price and mark-up controls.[76] For example, manufacturers in Shangdong and Gansu provinces choose not to produce 40% of the essential drugs listed on the 2004 NEML (National Essential Medicine List) even though they are licensed to produce these essential medicines. Hospitals also store and prescribe less essential medicines due to their lack of clinical use and profitability compared to other medicines such as antibiotics.[77]

IV. SCHEMES LIMITING MONOPOLY RIGHTS

Intellectual property in essence is a kind of monopoly right and this right, if not restrained, could be abused as shown in the above section. Therefore, for centuries international organizations and national governments have been seeking ways to restrict IPRs within certain limits, and counter-balance measures to prevent the abuses of IPRs. Particularly in the pharmaceutical and public health areas, these measures include: not protecting product patents, experimental exceptions or "Bolar exception," compulsory licensing, and parallel importation.

A. No-patent Protection for Pharmaceutical Products

Prior to the implementation of the TRIPS agreement, most developing countries did not provide patent protection to pharmaceutical products. A study of WIPO in 1988 showed that of the 98 state parties to the Paris

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[73] *Id.*
[74] *Id.*
[75] *Id.*
[76] Wen Chen et al., *Availability and Use of Essential Medicines in China: Manufacturing, Supply, and Prescribing in Shandong and Gansu Provinces*, http://www.biomedcentral.com/1472-6963/10/211 (last visited Sept. 25, 2011).
[77] *Id.*

Convention, 49 excluded pharmaceutical products from patent protection.[78] The TRIPS agreement required all WTO member states to provide 20 years of patent protection to any inventions, both products and processes. However, minding the economic gap between developed countries and less-developed countries, the agreement made special transitional arrangements for DLCs to delay product patent protection for an additional 10 years, and for LDCs to delay until 2016.[79] This arrangement, however, can be taken away by some TRIPS-plus arrangements such as FTAs and the U.S. threats of trade retaliation. For example, China, Brazil and Thailand were forced to amend their patent laws to provide patent protection for pharmaceutical products before the due date of their special transitional period. But India is a good example of taking advantage of this arrangement to allow its generic drug companies to produce a generic form as soon as a new brand-drug is put on the market and to not only meet its domestic demand of access to medicines but also export to countries with similar demand.

B. Experimental Use and Bolar Exception

Research and experimental use is allowed under the TRIPS agreement[80] and patent laws in many countries[81] because early disclosure enabling the public to learn about newly discovered technology is the trade-off of a patent holder for receiving the monopoly granted by the government. Not allowing research and experimental use will eventually stifle the original purpose of the patent system. As a report remarks, "a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public."[82]

Referring to the public health area, the WHO's 2008 Global Strategy

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[78] K. Balasubramaniam, *Access to Medicines and Public Policy Safeguards Under TRIPS*, *in* TRADING IN KNOWLEDGE: DEVELOPMENT PERSPECTIVES ON TRIPS, TRADE AND SUSTAINABILITY 135, 140 (Christophe Bellmann et al. eds., 2003).

[79] TRIPS Agreement art. 66; Doha Declaration, para. 7.

[80] 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 not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

[81] For example, Article 43(II) of Brazil's Law No. 9279/96 allows unauthorized acts of third parties for experimental purposes, in connection with scientific or technological studies or research. Section 47(3) of the Indian Patent Act provides that acts that constitute "merely of experiment or research" are exempted from patent infringement.

[82] Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, ¶ 7.69, WT/DS114/R (Mar. 17, 2000).

and Plan of Action on Public Health, Innovation and Intellectual Property had also specifically recognized that a research exception could help to address public health needs in developing countries.[83]

Most countries exempt research and experimental use for non-commercial purpose from patent infringement. For example, a U.S. court held in *Peppenhausen v. Falke* that "no doubt is now well settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the right of the patentee."[84] In 2002, the U.S. Court of Appeals for Federal Circuit (CAFC) ruled in *Madey v. Duke University* that experimental research, using a patented product without patent holder's consent, constitutes patent infringement where the use was to further "the infringer's legitimate business" interests.[85] In the U.K., the High Court of England and Wales (patent court) held in *CoreValve Inc. v. Edwards Lifesciences AG & Anor* that it is when the preponderant purpose of the research is to generate revenue, that the claim of infringement cannot be avoided. For example, when the user of the patented invention starts to sell samples of his product for profit, his use is not exempted under the research and experiment exception.[86]

From the above cases, we can see that the courts in different jurisdictions have been trying to differentiate commercial and non-commercial uses when applying the research and experimental use exception. However, the following exception concerns the situation when the use is for pure commercial purposes, but the marketing of the product only starts after the patent term expires. As mentioned above, the Hatch-Waxman Act not only extend patent monopoly rights by restoring the patent term for the patent holders, but also created a "Bolar exception" for generic companies to give the latter more leverage in market competition. Specifically, this exception allows generic companies to use the patented invention to obtain marketing approval without the patent holder's permission so that they can market their product as soon as the patent expires.

The exception is called the "Bolar exception" because it was developed based on a case, *Roche Products v. Bolar Pharmaceutical*, 733 F.2d 858 (Fed. Cir. 1984). In this case, Bolar, a generic drug manufacturer, used Roche's patented chemical, Valium, in its experiments to decide whether its generic product was a bioequivalent to Valium in order to obtain FDA approval. Roche sued Bolar for patent infringement, but Bolar argued that

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[83] Evans Misati & Kiyoshi Adachi, *The Research and Experimentation Exceptions in Patent Law: Jurisdictional Variations and the WIPO Development Agenda*, 7 POL'Y BRIEF 1 (Mar. 2010).

[84] Peppenhausen v. Falke, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11,279).

[85] Madey v. Duke University, 307 F.3d 1351 (Fed. Cir. 2002), cert. denied 539 U.S. 958, 123 S. Ct. 2639, 156 L.Ed.2d 656 (2003).

[86] CoreValve Inc. v. Edwards Lifesciences AG & Anor [2009] EWHC 6 (Pat.) [Eng.].

its use of the patented product was under the experimental use exception of the U.S. patent law. Bolar also argued that public policy favors the availability of generic drugs immediately following patent expiration, thus justifies the experimental use of the patented chemical to determine the bioequivalence of the generic version, and denying such use would extend patent holder's monopoly beyond the patent term. The Court of Appeals for the Federal Circuit (CAFC) rejected Bolar's arguments and held that the experimental use exception does not apply when the use is for commercial purpose. Since Bolar intended to sell its generic product in competition with Roche immediately after Roche's patent expired, the exception does not apply. The CAFC also held that the policy issue whether the public policy favoring the availability of generic drug immediately after patent expiration justifies Bolar's use should be decided by Congress, rather than by court. Shortly after the case, the U.S. Congress did pass the law, the Hatch-Waxman Act, to allow use of patented products in experiments for the purpose of obtaining FDA approval. The law was codified as Section 171(e)(1) of the Patent Act. It reads, "[i]t shall not be an act of infringement to make, use, offer to sell within the United States or import into the U.S. a patented invention . . . solely for uses related to the development and submission under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological product."

In addition, the Hatch-Waxman Act also grants 180 days of market exclusivity to generic drugs, based on successful patent challenges.[87] Between 1998 and 2001 the FDA granted 180 days of market exclusivity to more than 31 generic drugs.[88] This 180-day exclusivity, however, can be offset by the "authorized generic" arrangement between patent holder and another generic company, as discussed in II-D above.

C. Compulsory Licensing

A compulsory license is a license granted by the government allowing the use of an intellectual property right without the IP holder's consent. Compulsory licenses are normally used for copyright and patents, not for trademarks, and require payment of certain amounts of royalties from licensees to IP holders. Compulsory licenses are granted only under certain conditions such as "for public non-commercial use," "to correct anti-competitive practices," "for the demand of domestic market," "national

[87] Section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act grants 180 days of marketing exclusivity to the first generic applicant, who in the course of submitting an abbreviated new drug application (ANDA) to the FDA, is able to challenge the validity of the patent of the original drug.

[88] Federal Trade Commission, Generic Drug Entry Prior to Patent Expiration: An FTC Study, at 57 (July 2002).

emergency" and "extreme urgency."[89] In the case of public health, compulsory licenses can be granted only when there is a public health crisis, and "public health crises including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency."[90] This was confirmed in the Doha Declaration on the TRIPS Agreement and Public Health [hereinafter Doha Declaration] adopted at the WTO Ministerial Conference on November 14, 2001.

1. "Doha Declaration" and "Paragraph 6 System." — The Doha Declaration was adopted specifically for dealing with public health problems faced by developing and least-developed countries. Paragraph 1 of the declaration "recognize[s] the gravity of the public health problem afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." Paragraph 4 further affirms 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 medicines for all." The historical significance of the declaration reflected not only in its recognition of the gravity of the public health problems in those countries, but also in its recognition of the problem that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing," and its instruction for the TRIPS Council to find "an expeditious solution" to the problem.[91]

Following this instruction, in August 2003, a TRIPS Council adopted a system to implement the instructions under Doha Declaration paragraph 6, and was thus called the "Paragraph 6 system."[92] Specifically, this system works in the following way: it waives the obligation in TRIPS Article 31(f) that requires that the production of pharmaceutical products under compulsory license must be "predominantly for the supply of the domestic market," therefore allowing countries which have manufacturing capacity to export the drugs produced under compulsory license to countries which do not have manufacturing capacity. This waiver in theory could solve the problem stated in Doha Declaration paragraph 6 that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing." In practice, however, the system may not have worked as ideally as its creator expected. So far, only one pair of countries has utilized the "Paragraph 6

[89] TRIPS Agreement art. 31.
[90] Doha Declaration, para. 5(c).
[91] Doha Declaration, para. 6.
[92] Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (2003).

system" since its adoption in 2003, that is, Canada as an exporting country and Rwanda as an importing country, for the medicine of Apo-TriAvir, an HIV antiretroviral drug.[93] Some attribute the under-use of the system to the complexity of its procedures.[94] For example, Canada passed the Jean Chretien Pledge to Africa Act[95] to implement Canada's Access to Medicines Regime (CAMR), which allows Canada to export essential medicine produced under a compulsory license to countries without manufacturing capacity. But when MSF placed an order with a Canadian generic company to produce Triple FDC-AZT/3TC/NVP for exporting purposes, they encountered some difficulties: (1) no eligible importing country was willing to notify the TRIPS Council because the drug was already available from India at a cheaper price and it is difficult to for these countries to get a compulsory license, (2) lengthy and troublesome dealings with the Canadian health authorities as well as the generic company. In the end, no pills were exported.[96] However, Canada, the first and the only user of the system, defended the system in its "intervention" to the WTO TRIPS Council relating to the review of the Paragraph 6 system delivered on October 27, 2010. After describing how the system worked in the Canada-Rwanda case and confirming that Canada's CAMR and WTO's Paragraph 6 system are "efficient, effective and timely,"[97] the Canadian "intervention" attributes the under-use of the system to the fact that there have been more options available to importing countries since the adoption of the system, e.g., "the international environment for procurement of drugs has changed significantly with the introduction of a variety of global mechanisms and alliances now offering greater choice to countries to obtain medicines."[98] In fact, the Canadian "intervention" calls for future evaluation of the role of the "Paragraph 6 system" in a "broad global context", and consider it as "a part of broader international strategy to

[93] For the details of the case, *see* Knowledge Ecology International, Canada's Intervention to TRIPS Council: Experience Using the System (Apotex – Rwanda Case), http://keionline.org/node/1000 (last visited Sept. 25, 2011); *see also* WTO: 2010 News Item, Members Ask: Is the "Par. 6" System on Intellectual Property and Health Working?, Mar. 2, 2010, http://www.wto.org/english/news_e/news10_e/trip_02mar10_e.htm (last visited Sept. 24, 2011).

[94] First of all, a country intending to import a pharmaceutical produced under compulsory license must be qualified as an "eligible importing member," that is, an LDC or any other member that has made a notification to the TRIPS Council of its intention to use the system as an importer. The notification must confirm that the eligible importing member: (1) has insufficient or no manufacturing capacities and, (2) has granted or intends to grant a compulsory license. In the meantime, the exporting country must also do the following: (a) Issue a compulsory license meeting certain conditions. (b) Notify the TRIPS Council of its grant of the compulsory license and other information about the exportation.

[95] In full, "An Act to amend the Patent Law and the Food and Drug Act." It claims that the Act is "the use of patents for international humanitarian purposes to address public health problems."

[96] Hu Yuanqiong, *Implementation of Paragraph 6 System: Some Practical Experiences and Observations*, http://www.unescap.org/tid/projects/trips_hu.pdf.

[97] Knowledge Ecology International, *supra* note 93.

[98] *Id.*

combat diseases that impact developing country." The above cases involving MSF and Canada – Rwanda indicate that, although the system could work well theoretically, its role in practice is limited. It was not as "expeditious" as required in the declaration as it took the Canadian generic company, Apotex, three years to supply the medicine, even though the Canadian government claimed that the system was "efficient" and "effective".[99] As one commentator put it, "the ["Paragraph 6"] system could only play a supportive role in the wider effort to improve access to essential medicines."[100]

Interestingly, although paragraph 8 of the declaration requires that the TRIPS Council conduct an annual review of the functioning of the system, and the annual review had been dutifully conducted,[101] little has been found about why the system has been used only once in eight years since its introduction. In general, developing countries such as India and Brazil attributed the under-use to the troublesome procedure of the system without providing more concrete evidence, while developed countries such as Canada and Australia insisted that the fact that the system has been used once should not imply a failure of the system since there were other ways to obtain medicines.[102] Indeed, since the system is "demand-driven," it was suggested that more studies were needed to find why potential importers did not procure under its auspices.[103] It seems that "a wider discussion on legal, procedural, commercial or other obstacles to the 'effective operation' of the Paragraph 6 system," as asked by India government, is certainly a must.[104]

Notwithstanding the under-use of the "Paragraph 6 system," the waiver of the "domestic market" requirement for the production of generic medicine under compulsory license has been made permanent in TRIPS Article 31bis by the Protocol amending the TRIPS Agreement in 2005. The amendment will come into force after the ratification by two-thirds of WTO members. The deadline for the ratification has been postponed several

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[99] *Id.*

[100] WTO: 2010 New Item, *supra* note 93, Part "The 12 February Consultation on TRIPS and Public Health: What the Chairperson Reported."

[101] Normally in October each year. For example, on October 27, 2010, the TRIPS Council spent the whole day reviewing national experiences focusing on the following topics: "actual experiences in using the system and any obstacles confronted, various legal aspects such as any domestic legislation needed and the international treaty process of accepting the TRIPS Agreement amendment, capacity building, alternative ways of achieving access to medicines, and what to do next," *see* WTO: 2010 New Item, Little-used "Par. 6" System Will Have Its Day, WHO Tells Intellectual Property and Health Review, http://www.wto.org/english/news_e/news10_e/trip_26oct10_e.htm (last visited Sept. 25, 2011)

[102] WTO: 2010 New Item, *supra* note 100.

[103] *Id*.

[104] Text of Indian Statement on Generics Seizure Before TRIPS Council, http://indiainthewto.wordpress.com/2009/03/11/text-of-indian-statement-on-generics-seizure-before-trips-council/ (last visited Sept. 24, 2011).

times from 2007, 2009, and lastly, December 31, 2011. By May of 2011, only 34 member states (22% of the total) have ratified. Thirteen members have amended their IP laws to implement the TRIPS amendment.[105] The slow ratification process indicates that the majority of WTO members are still not ready to make a commitment to the new system. In fact, an interest group, Treatment Action Campaign (TAC), urged the South African Parliament not to ratify the amendment, arguing that the new system is "deeply flawed, and arguably incapable of properly solving the problem identified in paragraph 6 itself;" and that "it is unclear what benefits, if any, arise from formal ratification of the proposed amendment to the TRIPS agreement."[106]

2. Post-Doha Development. — Although "Paragraph 6 system" is not widely used, countries do issue compulsory licenses to produce generic medicines. Brazil and Thailand are said to be one of the few developing countries that have achieved universal access to antiretroviral therapy through compulsory licensing or other means.[107] The success was attributed to the following three factors: legislation for free access to treatment; public sector capacity to manufacture medicines; and strong civil society support for government initiatives to improve access.[108]

"Price negotiations, backed by the threat of compulsory licensing and local generic production" have been Brazil's main strategy to lower the price of antiretroviral drugs.[109] As early as 2001-2003, the Brazilian government already used compulsory licensing as a threat to negotiate price reduction for antiretroviral drugs. As a result, price reductions were obtained at 73% for efavirenz, 56% for kaletra (lopinavir/ritonavir) and 74% for nelfinavir.[110] On June 24, 2005, Brazil announced it would issue a compulsory license to produce kaletra, which led to a price negotiation with Abbott to reduce the price to US$1,380 per patient per year for the old version and US$1,518 for the heat-stable version. In return, the Brazilian government agreed to limit the use of compulsory license, and to have a moratorium on future price negotiations until 2011.[111] This concession was challenged by civil society groups in a lawsuit asking for the grant of compulsory licenses, but the case was prevented from moving forward by

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[105] They are: Norway, Canada, India, EU, Hong Kong, Switzerland, Philippines, Singapore, Albania, Croatia, China, Rep. of Korea.

[106] The Pharmaceutical News, Groups Urge South African Parliament Not to Ratify WTO Paragraph 6 Decision (May 27, 2011), http://thepharmaceutical-news.com/groups-urge-south-african-parliament-ratify-wto-paragraph-6-decision (last visited Sept. 25, 2011).

[107] Nathan Ford et al., *Sustaining Access to Antiretroviral Therapy in the Less-developed World: Lessons from Brazil and Thailand*, 21(suppl. 4) AIDS S21 (2007).

[108] *Id.*

[109] *Id.* at S24.

[110] *Id.* at S25.

[111] *Id.* at S26.

the judges on the ground that a compulsory licensing will result in the U.S. retaliation while Brazil does not have the capacity for local production.[112] Then on April 25, 2007, the Brazilian government issued its first compulsory license for efavirenz. But the patent holder, Merck, was only willing to offer a 2% discount on the current price (US$580 per patient/year). Therefore, Brazil decided to buy a generic version of efavirenz from India at less than US$170 per patient/year at first, and then start local production later.[113]

In the meantime, Thailand also issued compulsory licenses for efavirence, kaletra and plavix. As a result, Sanofi-Aventis offered Thailand a "special access program" to provide a cheaper version of Plavix, but Thailand awarded a contract for two million pills of a generic version of Plavix to an Indian drug company, Emcure. Sanofi responded to this deal by threatening to sue Emcure for patent infringement if the pills were imported into Thailand.[114] However, at the time of writing, no action by Sanofi has been taken. In addition, Thailand also threatened to issue compulsory licenses for another four drugs: Glivec, Femara, Tarceva and Taxotere, for the purpose of negotiating prices with MPCs. The Thai government required that the price of patented drugs cannot be more than 5% over the generic cost. It is arguable that Thailand had used the threat of compulsory licensing too broadly because whether cancer may be qualified as public health problem and justified for using compulsory licensing is questionable. The EU trade commissioner, Peter Mandelson, in a letter addressed to Thailand's Minister of Commerce, said that such a policy "would be detrimental to the patent system and so to innovation and the development of new medicines," and "neither the TRIPS nor the Doha Declaration appear to justify a systematic policy of applying compulsory licences wherever medicines exceed certain prices."[115]

D. Parallel Importation

In addition to compulsory licensing, TRIPS also allows parallel importation of patented products under the Doctrine of Exhaustion.[116] It is recommended that the latter is a better solution to the drug access problem

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[112] *Id.*

[113] *Id.*

[114] Managing Intellectual Property Weekly News – September 24, 2007, More Drugs Under Threat in Thailand, http://www.tginfo.com/sites/default/files/drugs_under_threat_TH.pdf (last visited Sept. 25, 2011).

[115] Letter from Peter Mandelson, to Krirk-krai Jirapaet, Thailand's Minister of Commerce (July 10, 2007), *available at* http://www.wcl.american.edu/pijip_static/documents/mandelson07102007.pdf?rd=1 (last visited Sept. 25, 2011).

[116] TRIPS Agreement article 6 provides that: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

because it works for developing countries and LDCs without domestic manufacturing capacity; it is legally allowed without extra conditions imposed; it does not require government's approval; and it is exempted from a WTO dispute settlement challenge.[117] The only problem with parallel imports is the difficulties in finding low-priced drugs.[118] The "Paragraph 6 system" was designed to solve this problem as the generic companies of a foreign country can produce and export, under a compulsory license, the low-priced drugs to a country without manufacturing capacity. However, as discussed above, the "Paragraph 6 system" has only been used once since its creation. Therefore, how to use the parallel importation to solve medicine access problem still requires further research.

V. DISCUSSION

A. IPRs and Public Health: Two Sides of the Same Coin

The IP system was created originally not to promote public interests, but primarily to protect the private property rights of inventors/manufacturers. This is manifested by the fact that early IP laws mostly only granted the IP holder exclusive rights in using his/her IPRs without paying much attention to public interest. This position was justified by various theories. For instance, natural right theory justifies IPRs as a man's natural property right in his own idea which is exclusive and inalienable; labor theory justifies IPRs as a reward for the labor invested by inventor in the invention; personality theory justifies IPRs as personhood of the inventor; utilitarian theory justifies IPRs as incentives for innovation,[119] and economic analysis of law justifies IPRs as a way to address the problem of market failure in stopping "free-riding" of invisible knowledge.[120] Although there were limitations such as compulsory licensing in earlier IP regimes like the Paris Conventions, it was not until the TRIPS agreement that public interest started to receive serious attention. On the one hand, TRIPS emphasizes that IPRs are "private rights," and there is a "need to promote effective and adequate protection of intellectual

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[117] Krithpaka Boonfueng, *Parallel Imports in Pharmaceuticals: Increase Access to HIV Drugs*, Thailand Law Forum, http://www.thailawforum.com/articles/hivdrugs1.html (last visited Sept. 25, 2011).

[118] *Id.*

[119] William Fisher, *Theories of Intellectual Property*, *in* NEW ESSAYS IN THE LEGAL AND POLITICAL THEORY OF PROPERTY 168, 168 (Stephen Munzer ed., 2001).

[120] Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 609-26 (Universities-National Bureau ed., 1962).

property rights."[121] On the other hand, it also recognizes "the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives."[122] It further sets out objectives noting that "the protection and enforcement of intellectual property rights should [be] . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations,"[123] and posits that "members may . . . adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development."[124] The Doha Declaration and "Paragraph 6 system" provide practical ways to make the compulsory licensing system more workable to solve the problem of access to essential medicines and public health, albeit not very successful.

Therefore, it may be appropriate to say that public interest has become an integral part of the IP system. Applying this thought to the context of this paper, we could say that public health is also an integral part of the IP system, or put it in another way, public health and IP are two sides of the same coin, which can not only co-exist but must be mutually dependent. On the one hand, the patent system is crucial to provide necessary incentives to invest in discovery of essential drugs for public health as there is a long lead time, high investment and entry barriers in the drug discovery process. Without patents, many essential drugs may have never been discovered in the first place, and thus public health may have even suffered more severely. In fact, it was suggested that the Doha Declaration, the "Paragraph 6 system" and sharp cuts to patent-protected prices for HIV/AIDS medicines in developing countries have "threatened the erosion of patent rights," which "leads to the deterioration of pharmaceutical companies' incentives to further develop HIV/AIDS medicines," and "pharmaceutical firms would shift their emphasis of research and development to higher-profit medicines for affluence-related diseases such as rheumatism."[125] Actual decrease of patent filing at USPTO for HIV/AIDS drugs post-Doha Declaration has been recorded, e.g., 319 were filed in 2002, while only 276 were filed in 2003.[126] Specifically as to discovery of new drugs for tuberculosis, the situation is very worrying. A study conducted in 2000 by D. Chang Blanc and P. Nunn for the WHO shows that in the 28 years prior to 2000, only one new anti-tuberculosis

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[121] TRIPS Agreement Preamble.
[122] *Id*.
[123] TRIPS Agreement art. 7.
[124] TRIPS Agreement art. 8.
[125] Itaru Nitta, *Patents and Essential Medicines: An Application of the Green Intellectual Property Project*, at 2, http://www.who.int/intellectualproperty/submissions/ITARUNITTA.pdf (last visited Sept. 25, 2011).
[126] *Id*.

drug has come on the market despite nearly 3 million deaths from the diseases each year.[127] The major disincentives for MPCs to develop anti-tuberculosis drugs include: the high costs of drug development; the risk of patent violations; strong pricing pressure from the WHO; the availability of the current cost-effective treatment that may force down the price of any new drug.[128] All of these disincentives are relevant to financial return. Simply put, without financial return, no company would be willing to invest in a scientifically challenging, lengthy and costly drug discovery process. Since tuberculosis affects primarily DLCs and LDCs, most patients cannot afford to purchase the drugs even at a low price; the WHO will pressure MPCs to lower the price or give it out for free; no patent protection or disrespect for patents will lead to generic competition that eventually drives MPCs out of the market.[129]

On the other hand, an enormous amount of patents have been granted for the discovery of essential medicines in the area of public health, which not only benefits the pharmaceutical companies commercially and the medical society scientifically, but also the IP system itself. Through granting patent rights to inventors of new drugs that can save millions of lives, the IP system attained a higher and nobler objective and is more justified. Of course, patent rights can be easily abused by individual patent holders and are frequently condemned when this happens. Therefore, a carefully designed pharmaceutical patent system is needed to balance the demand of public health for non-diminished patent-incentivised new drug R&D on one side of the coin and the need of pharmaceutical companies having IPR protection on the other side of the coin. To create such a balanced system, we must have an objective assessment of the impact of patents on medicine access, and find practical solutions for solving both the problem of medicine access and the conflicts between IP and public health.

B. Impact of Patents on Medicine Access: Objective Assessment

From the discussions in the preceding sections, we can see that public health problems involving HIV/AIDS, Malaria, Tuberculosis and other epidemic diseases have become increasingly grave, but access to essential medicines to prevent and treat these diseases still presents a serious challenge. IPRs are monopoly rights that can have a negative impact on medicine access and public health if they are not properly limited and balanced, which are manifested by case studies in developing countries

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[127] Diana Chang Blanc & Paul Nunn, *Incentives and Disincentives for New Anti-tuberculosis Drug Development: Situational Analysis*, at 5 (2000), http://apps.who.int/tdr/publications/tdr-research-publications/incentives-disincentives-anti-tuberculosis/pdf/incentives-disincentives-anti-tuberculosis.pdf (last visited Sept. 25, 2011).

[128] *Id*. at 11-23.

[129] *Id*.

such as Thailand, Brazil, South Africa and China in which MPCs' patents on essential medicines for the purpose of preventing local generic competition have, to some extents, created an impediment to medicine access. The drug patents can even be abused by MPCs to make their term of exclusivity lengthier or "everygreen" using various patent strategies.

On the other hand, blaming patents as the sole or main source of inaccessibility of essential medicines is equally unconvincing and unconstructive. Patents may be one of many factors attributable to inaccessibility, but certainly not the only or major one. The results of empirical studies carried out by Attaran in individual countries show that drug patents are not a factor at all in some of LDCs because MPCs forgo patent protection in these countries due to the fact that annual drug spending is US$2 or less per person there and the market is not profitable.[130] "Poverty" has been cited as the most fundamental cause of the inaccessibility in those countries as people there cannot even afford the cheapest generics.[131] Lack of price control and lack of incentives to produce essential medicines due to low profitability are also factors causing the medicine access problem as shown by the examples of India and China. The overall status of drug patenting in developing countries also implies a lesser role patents play in inaccessibility because, among 319 items on the WHO Essential Medicines List (EML), only 17 have basic patents since April 1, 1982. And for the 65 developing countries studied, only 1.4% of the time patents and patent applications exist for essential medicines, therefore "patents cannot cause essential medicines to be inaccessible in 'many' developing countries because they do not exist 98.6% of the time," although the researcher also cautioned that this norm also has exceptions in particular countries (e.g., South Africa) and for particular drugs (e.g., antiretroviral drugs) in which case the impact of one patent on one drug or more patents in one country "can be highly significant for public health."[132]

Even for the few patents in some DLCs blocking generic competition, balancing schemes such as delayed patent protection for pharmaceutical products in DLCs and LDCs, the Bolar-exception, compulsory licensing, differential pricing in LDCs, and "Paragraph 6 system" were created within the international and national IP system to improve medicine access. Whether these schemes can efficiently solve the medicine access problem in DLCs is doubted as discussed earlier, but the positive outcomes in India (10-year delay in product patent protection), Thailand and Brazil (using compulsory licensing to lower drug prices), and Uganda/Canada (using "Paragraph 6 system" to export ARV drug to LDCs) have proven that the IP

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[130] Amir Attaran, *How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?*, 23(3) HEALTH AFFAIRS 155, 159 (2004).
[131] *Id.* at 163.
[132] *Id.*

system has a self-adjusting ability according to the demand of public interest, and such an ability can be enhanced and further developed along with the growth of MPCs' sense of social responsibility and the willingness to cooperate with NGOs and INOs to increases medicine access on the one hand, and the increase in awareness and capacity of DLCs in using the balancing schemes to negotiate drug prices and prompt their generic competitiveness on the other hand.

C. The Way Forward: Practical Steps in Improving Medicine Access

Evidence shows that institutional arrangements within the IP system at the international level such as the "Paragraph 6 system" have their limitations in improving medicine access. There has to be a wider effort including poverty reduction, education, price control, or better national health policies. Due to space constraints, this article tries only to find some practical steps adopted or being considered by MPCs or other organizations to improve medicine access, which may be helpful in finding more systematic solutions to the problem.

Despite the widely cited case of 39 pharmaceutical companies challenging South Africa's medicine legislation and a few other incidences putting MPCs under a negative light, more and more MPCs have taken or have started to take steps to voluntarily limit or surrender their patent monopoly for the benefit of public health. One practice adopted by MPCs is "fair pricing clause in pharmaceutical licensing agreement." For example, in February 1998, the NIH invented antiretroviral drug didanosine and granted a licence to Bristol-Myers Squibb (BMS) to produce the drug for an initial period of 10 years with option of a 5-year extension. The licenses included a fair-pricing clause, stating that a fair pricing is available if there is "a reasonable relationship between [the] licensee's pricing of [a] licensed product and the health and safety needs of the public and . . . this relationship [is] supported by evidence."[133] The clause was reportedly not properly enforced, nevertheless it is an alternative that could help reduce the high price created by patents and promote public access to medicines.

Some MPCs choose to forgo or not to enforce patents for essential medicines. In April 2004, Roche announced that it would not file or enforce its patents for ARV drugs in LDCs, and it adopted a "not-for-profit" approach to selling its protease inhibitors in LDCs.[134] The "not-for-profit" approach allows Roche to recover its costs for making a drug, but does not make a profit on it. Roche said that such moves "underscore its belief that

[133] Ford et al., *supra* note 58, at 561 (within the "Panel 1").

[134] Henry J. Kaiser Family Foundation, Roche Will Not Enforce Patents on Antiretroviral Drugs in "Least-developed" Countries (Apr. 1, 2004), http://www.thebody.com/content/art11253.html (last visited Sept. 25, 2011).

long-term success requires business to operate in ways that are not only economically, but also socially and environmentally sustainable."[135] GSK, like Roche, also adopted a "not-for-profit" approach. By 2007, all its ARVs are available at not-for-profit prices to the public sector and NGOs in total 64 LDCs, and all private sectors in sub-Saharan Africa that provide care and treatment to their uninsured employees can purchase GSK's ARVs at not-for-profit prices.[136] In 2006, GSK further reduced its not-for-profit price of Abacavir and added two new ARVs, Kivexa and Telzir, to its not-for-profit list.[137]

Granting a voluntary license to generic manufacturers is a favored approach adopted by many MPCs because it benefits both MPCs and generic companies. On July 12, 2011, Gilead Sciences, Inc. announced a plan to expand its global access program for treatment of HIV/AIDS including new licensing terms with four India-based drug manufacturers (Hetero Drugs Ltd., Matrix Laboratories Ltd., Ranbaxy Laboratories Ltd. and Strides Arcolab Ltd.) for three drugs (elvitegravir, cobicistat, "Quad") which are currently in late-stage clinical development.[138] Gilead's original license agreement grants Indian manufacturers non-exclusive rights to produce active pharmaceutical ingredient and finished products and to sell generic versions of Gilead's HIV medicines Viread and Truvada in 95 developing countries, and the expanded license agreement allows Indian partners to produce and sell the three new drugs if they are approved.[139]

Gilead has also entered a licensing agreement with the Medicines Patent Pool Foundation (MPPF) to license its three new HIV/AIDS drugs. The MPPF was established with the support of UNITAID in July 2010, and "aims to improve access to affordable and appropriate HIV medicines in developing countries through voluntary licensing of critical intellectual property."[140] The MPPF is responsible for "negotiating with patent holders to share their IP with the Pool, and then licensing it to other producers to facilitate the production of affordable generic medicines well-adapted for use in resource-poor settings."[141] In addition to Gilead, the U.S. National Health Institute (NIH) has also signed a license agreement with MPPF showing the government's support for this new initiative. According to MPPF, "the pool is a win-win-win model, whereby patent holders are compensated for sharing their patents, generic manufacturers gain access to

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[135] *Id.*
[136] Matt Worrall, *Global Health and the Pharmaceutical Industry*, at 11, The Association of the British Pharmaceutical Industry (July 2007), http://www.abpi.org.uk/our-work/library/industry/Documents/global_health.pdf (last visited Sept. 25, 2011).
[137] *Id.*
[138] Gilead Press Release, *supra* note 32.
[139] *Id.*
[140] Medicines Patent Pool, http://www.medicinespatentpool.org/ (last visited Sept. 25, 2011).
[141] *Id.*

markets, and patients benefit more swiftly from appropriate and adapted medicines at more affordable prices." Whether this model can really produce the result envisioned by the foundation still remains to be seen, but this is at least another practical solution to the medicine access problem.

In 2007 and 2008, a new model was being adopted to make non-patented anti-malaria drugs available in Africa and South America. A non-governmental group, Drugs for Neglected Diseases initiative (DNDi), formed a partnership with the French pharmaceutical company Sanofi-Aventis and Brazilian company Farmanguinhos/Fiocruz, to create non-patented anti-malaria drugs such as ASMQ with financial support from the EU, MSF, and various national governments such as The Netherlands, Spain, and the U.K. Farmanguinhos/Fiocruz then formed a technology transfer agreement with India's generic company Cipla to transfer information on development and production of ASMQ to Cipla.[142]

Lately, a group of scientists, researchers and organizations in India established Open Source Drug Discovery (OSDD) with a vision "to provide affordable healthcare to the developing world by providing a global platform where the best minds can collaborate and collectively endeavor to solve the complex problems associated with discovering novel therapies for neglected tropical diseases like Malaria, Tuberculosis, Leshmaniasis, etc."[143] Some Indian scientists joined the initiative and chose not to patent the tuberculosis genome that they mapped out.[144]

These are some of practical steps that have been taken by MPCs, NGOs and national governments to solve medicine access problem. MPCs' steps demonstrate their willingness and efforts in taking public health into consideration when formulating IP strategies. However, as some commentators pointed out, MPCs' steps are voluntary in nature and can be stopped and withdrawn any time.[145] Some believe that access to essential medicines is a component of the right to the highest attainable standard of health, and suggest imposing legal obligations on MPCs to make essential medicines accessible in poor countries.[146] But how to impose, particularly

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[142] Catherine Saez, *Innovative Partnership to Create Another Patent-free Malaria Drug* (Apr. 17, 2008), http://www.ip-watch.org/weblog/2008/04/17/innovative-partnership-to-create-another-patent-free-malaria-drug/ (last visited Sept. 25, 2011).

[143] Open Source Drug Discovery, What is OSDD, http://www.osdd.net/about-us (last visited Sept. 25, 2011).

[144] Techdirt, Indian Scientists Refuse to Patent Tuberculosis Genome, Encourage Anyone to Make the Drugs, http://www.techdirt.com/articles/20100412/0118378969.shtml (last visited Sept. 24, 2011).

[145] Per the comments by Professor Chang-fa Lo in the conference and the written comments by an anonymous article reviewer.

[146] Rajat Khosla & Paul Hunt, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines: The Sexual and Reproductive Health Context*, at 2, *available at* http://www.essex.ac.uk/human_rights_centre/research/rth/docs/Final_pharma_for_website.pdf (last visited Sept. 25, 2011).

how to enforce, these legal obligations at the international level is always a challenging issue, not to mention that it has been extremely controversial as to whether it is appropriate to impose human rights obligations that belong to the public domain on private entities. Among all the measures and steps described above, DNDi's partnership with pharmaceutical companies to create non-patented drugs for diseases affecting mostly DLCs and LDCs with financial support from international organizations, NGOs and national governments may be the best option to solve medicine access problem because the financial assistance from various organizations can remedy the loss of MPCs from being able to patent the drug, and non-patenting can lower drug price, thereby increasing medicine access. After all, requiring private commercial companies to give up their rights and interests to fulfill a public function is too much to ask as they are not publicly funded and have to recover costs and make profits in order to maintain competitiveness. Increasing medicine access and solving public health problems in DLCs and LDCs requires more participation, particularly from international organizations, NGOs and national governments, and collaboration between these entities with the pharmaceutical companies to find practical ways that can create a win-win situation for all stakeholders.

VI. CONCLUSION

IP and public health are two sides of the same coin, inseparable and mutually dependent, striving for the same goal of promoting the health and happiness of humanity. Without IPRs, many medicines essential for human health and lives may have never been discovered and developed; in the same vein, the IP system and medical sciences may have never been able to advance without taking part in R&D and commercialization of the medicines essential to public health. Therefore, it is important to perceive and construct the relationship between the two sides in a positive, forward looking and pragmatic way, rather than mutual condemnation and destruction. To do so scholars and practitioners in both fields should collaborate to have an in-depth understanding of the issues, objectives, schemes and practices in the two fields, and an objective assessment of the impact each has exerted, efforts to reconcile, and positive outcomes achieved.

The investigation in this article demonstrates that the IP system has a self-adjusting ability to accommodate public interest needs by introducing various exceptions (e.g., experimental use, Bolar-exception, compulsory licensing, etc.), flexibilities (e.g., special transition arrangement for LDCs and developing countries) and practical solutions (e.g., "Paragraph 6 system"). Furthermore, IPRs play different roles in different countries. They may only play a very minor or no role at all in the medicine access

problem in some LDCs as no drug patent are allowed or filed there. In DLCs, on the other hand, the examples of Brazil, Thailand, India and China testify that IPRs may be responsible for high drug prices, but they are not the sole factor, and that they can be negotiated or completely forgone in countries that have good drug price policy and mature voluntary/compulsory licensing systems. The studies in this article also show that IPRs in the pharmaceutical field can be extended and expanded legitimately or illegitimately (e.g., patent term restoration, data exclusivity, new use, authorized generics and reverse settlement, evergreening, etc.). Hence, in addition to the limitations and flexibilities set within the IP law framework, it is also imperative for pharmaceutical companies to fulfill their corporate social responsibility and take public health into account in formulating their IP strategies. They should find practical ways to work with generic companies to help increase accessibility to essential medicines in countries suffering a public health pandemic, while maintaining their own incentives and resources in discovery and developing essential medicines. The steps taken by MPCs such as forgoing patents, not-for-profit schemes, fair-price clauses and medicine patents pools are positive steps towards this direction. However, it is too much to expect that a private pharmaceutical company invests in a costly and lengthy drug discovery process and then donates the drug as a public good. Financial assistance from international organizations, NGOs and national governments to provide incentives and remedies for MPCs to engage in R&D of essential drugs, and various forms of licensing arrangements between MPCs and generic drug companies are all very important to facilitate medicine access and to solve public health problems.

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