Implications of TRIPS Flexibilities for Access to Non-communicable Disease Medicines in Lower and Middle Income Countries

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***Abstract*—Over 60% of deaths in the world are due to non-communicable diseases (NCDs), principally referring to cardiovascular diseases, diabetes, cancer and chronic respiratory disease. Nearly 80% of these NCD deaths occur in low- and middle-income (LMIC) countries, where it is difficult for people to access essential medicine for treatment. The problem of effective access results in part from the exorbitantly high prices that arise from the negative effects of global patent protection. The WTO Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) offers flexibilities, such as compulsory licenses and parallel importing, to remedy those negative effects. Hence, two fundamental questions arise. To what extent do LMIC countries benefit from these safeguards when it comes to providing essential medicines for their populations? What options and political barriers do these countries have when making the case for being able to make NCD essential medicines accessible to their populations, and what lessons can be learned from the successes of increased and affordable access to AIDS/HIV medicines from the early 2000s? Through introspection of emerging case studies, this article explores ways to reduce barriers to essential medicines for NCDs under the WTO TRIPS frameworks and other relevant regulations related to pharmaceutical trade and patents.**

***Index Terms*—Noncommunicable Disease, TRIPS Agreement, Access to Essential Medicines, Lower and Middle Income Countries (LMIC)**

I. Background

According to the World Health Organization, 63 percent of 57 million global deaths in 2008 resulted from NCDs, which principally refer to cardiovascular diseases, diabetes, cancer and chronic respiratory disease. NCDs are estimated to impose a cumulative output loss of US$ 47 trillion till 2030, which is equivalent to 75% of global GDP in 2010 (Bloom, Cafiero, et al. 2011). This loss also represents enough money to eliminate 1.25 dollar-a-day extreme poverty among the 1.29 billion people for more than half a century.

The economic burden of NCDs on developing countries is significant. A report of US Institute of Medicine suggested that the economic impact of cardiovascular diseases (CVD) and related chronic diseases, such as diabetes and chronic obstructive pulmonary disease (COPD) ranged from an annual US$ 3 billion for direct medical costs of obesity-related diabetes, coronary heart disease, hypertension and stroke in China to US$ 72 billion for treatment of and productivity losses due to five chronic conditions in Brazil (Bloom, Cafiero, et al. 2011).

NCDs are also imposing a heavy toll on individuals and national productivity. For most patients suffering from NCDs in developing countries, the exorbitantly high prices of medicines and out-of-pocket healthcare treatment expense trap people in poverty. In addition, because NCDs are having an impact on younger generations, who comprise most of the working class in developing countries, national productivity is at risk. For instance, 25% of people between 18 – 59 years old in Ukraine have at least one NCD, which made could result in 'Losing the next generation to chronic diseases' (The World Bank, the Ukrainian Medical Alliance, 2010).

In terms of the heavy toll seen in LMICs, there has also emerged a trend known as the 'double burden', or 'double jeopardy'. This trend essentially refers to the simultaneous prevalence of NCDs alongside communicable disease prevalence in low-income countries. In 2002 NCDs accounted for 44 percent of the total death burden. Projections show that by 2030 the share of the death burden for NCDs in LMICs will be 54 percent while the share for communicable diseases will be reduced to 32 percent of all deaths (Figure 1) (Department of State and the Department of Health and Human Services , 2007).

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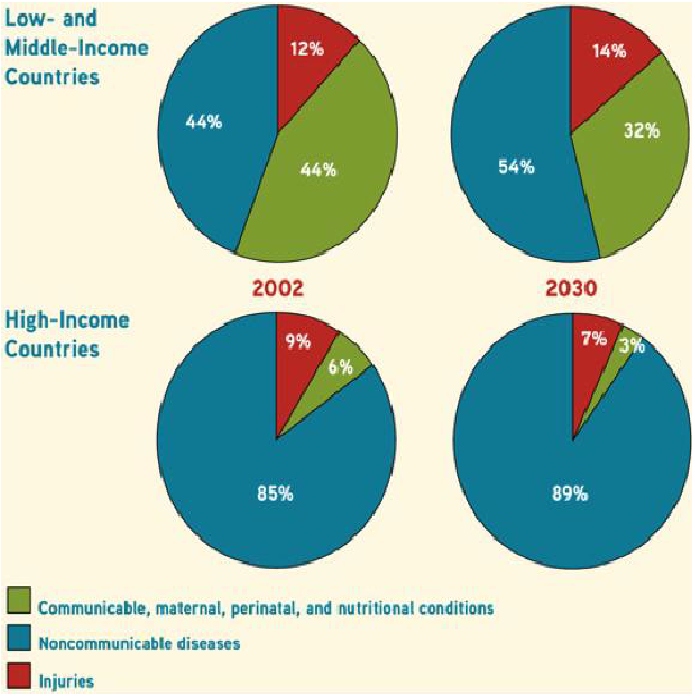

Fig 1: 2002 and 2030 Projections for Share of Communicable and Noncommunicable Diseases

Source: Lopez et al., 2006

Limited access to NCD essential medicines is one of the barriers to treatment as well as controlling progression of certain NCDs. There are many reasons for lack of access to essential medicines, but the high prices of drugs often stem from strong intellectual property protections. Governments in developing countries that attempt to lower the price of medicines have come under pressure from industrialized countries and the multinational pharmaceutical industry. Therefore, this paper is mainly focusing on the treatment problems as they are related to access around essential medicines for treatment in LMICs. Based upon the World Health Organization (WHO) definition of essential medicines, the term refers to '…those [medicines] that satisfy the priority health care needs of the population' and is based on the following criteria: disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness (World Health Organization, 2011).

Due to the low cost and potential benefits of preventing NCDs, national and international communities have already been engaging in advocacy efforts that promote the reduction of the NCDs risk factors, which include tobacco use, physical inactivity, unhealthy diet and the harmful use of alcohol. The reduction of these risk factors falls into the public health category of primary prevention. Still, compared with the primary prevention strategy, NCD treatment receives less attention because of the relatively high cost and health systems capacity to treat. As Secretary-General of the United Nations, Ban Ki-moon, stated during the High-level Meeting of the General Assembly on the Prevention and Control of Noncommunicable Diseases in September 2011, 'treating the NCDs could be affordable, while preventing them could cost next to nothing, and even save money' (United Nation General Assembly GA/11138, 2011).

Thus far, low public sector availability of NCD essential medicines is often due to lack of public resources or under-budgeting, inaccurate demand forecasting, and inefficient procurement and distribution. This is the point where government and patients turn to the private sector in order to access generic medicines, which are often 2-3 times more expensive. These high prices are mostly due to high manufacturer's prices secondary patent protections, taxes and tariffs, and high mark-ups in the supply chain (WHO Essential Medicines Briefing Document, 2011). Besides the barrier posed from patents in the private sector, many low-income countries do not have the local infrastructure and capacity for innovative research and development for pharmaceuticals. In contrast, middle-income countries are able to reproduce generic medicines at cheaper prices with the same active ingredients that are currently established for medications.

The essential medicine needs around the global burden of NCDs, calls for a broader perspective and scope of public health policy frameworks as they relate to international pharmaceutical products and trade. The first major framework is the international legal cornerstone of intellectual property, the TRIPS agreement and the WTO debates around it. The second is current free trade and regional trade agreements that act as extensions and implementation mechanisms, or, in some cases, contradictions of TRIPS.

I. TRIPS AND THE INTELLECTUAL PROPERTY REGIME

The Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) was drafted during the creation of the World Trade Organization (WTO) in 1995. TRIPS set out to establish a common global standard for the protection of intellectual property rights, including patents (Beall & Kuhn, 2012). Indeed, agreement to TRIPS is often described as a package deal whereby developing countries acceded to TRIPS requirements in exchange for other benefits of WTO membership, including increased access to foreign markets.

One cannot talk about TRIPS without also understanding the Doha Declaration on Public Health from 2001. Although the statements that were made on public health under the Doha Declaration do not have the same legal clout as TRIPS, these statements have played a major role in framing the way TRIPS should be interpreted and how the terms discussed in it should be defined (Backhoum, LLM, 2008). In order to reduce the inequality in essential medicine access between the developing and developed countries, the declaration included protective provisions to address public health concerns.

These protective provisions established the following tools: compulsory licenses and parallel imports, both of which are considered as TRIPS flexibilities. The third tool, differential pricing, is looser and is not used as much of a bargaining chip or threat as the other two, but is still a major part of affordable access to essential medicines. Aside from the legal statements and WTO discourse behind these tools, one should also pay attention to the way countries used the tools as forms of negotiation. For this reason, this section provides an overview of these tools through a review of the articles in TRIPS, in

conjunction with disputes around these tools that were argued before the WTO.

First, there are compulsory licenses, which were officially introduced in TRIPS Article 31. This article recognized the right of member states to invoke compulsory licenses for different types of patents, including pharmaceuticals. Compulsory licenses are a provision in which 'governments allow someone else to produce the patented product or process without the consent of the patent owner' (World Trade Organization, 2006). However, the problem mainly lies in which medicines should be listed under the compulsory license and how. At the same time TRIPs also limited compulsory license action by requiring a period of negotiation between the member state and the patent holder. The exception to this negotiation, however, as noted in subparagraph (b), is if there is a 'case of a national emergency or other circumstances of extreme urgency' (Sinhaya, 2012).

In 2001, around the time of the Doha Rounds, Article 31 came into question in regards to public health. In terms of an actual public health 'emergency', the Doha Declaration on TRIPS and Public Health confirms that countries are free to determine the grounds for granting a tool known as compulsory licenses. Hence, the Doha Declaration has not fully defined when compulsory licenses are actually valid to use, which has shown to be controversial as this paper later discusses with the case studies from India and Thailand. Another barrier with Article 31(f) of the TRIPS Agreement is the restriction that compulsory licensing is valid 'predominantly for the supply of the domestic market of the member authorizing such use'. This means that a country making use of a compulsory license must manufacture the product locally for the domestic market. Clearly, such an assumption takes for granted that the country has sufficient local manufacturing capacity, which is not the case for many LMICs (Sinhaya 2012).

As a result of these barriers, the WTO granted TRIPS waivers. The first waiver said that exporting countries' obligations under Article 31(f) are waived. This means that any member country can export generic pharmaceutical products made under compulsory licenses to importing countries that have a need for their populations. The second waiver addressed remuneration to the patent holder, stating that importing countries were not obligated to compensate in order to avoid double payment. Remuneration is only required on the export side. The final waiver was a vague. The waiver stated generally that exporting constraints would be waived for developing and least developed countries. This was done in order to allow for these countries to export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision (World Trade Organization, 2006).

Another aspect of the waiver negotiations that was debated was the scope of diseases covered by TRIPS waivers. This is especially important for the scope of this paper and for the urgency of essential medicine access for NCDs in LMICs. The United States called for limitations of the waivers to HIV/AIDS, malaria, tuberculosis 'and potentially a small group of others infectious diseases'. The European Union, was not as specific, but rather very vague and, "proposed that the solution be confined to 'grave' public health problem". LMICs adopted an unrestricted approach regarding the scope of diseases (Backhoum, LLM 2008).

The second tool in consideration of TRIPS flexibilities is parallel importing, which, in short, allows countries to import a product made legally abroad without the permission of the intellectual property right holder, such as the patent or trademark holder (World Trade Organization, 2006). Understanding the tool at its best requires understanding how it has actually been used. The HIV/AIDS epidemic was at its most critical point during the inclusion of parallel imports in TRIPS. Civil society and international advocacy groups in LMICs were putting pressure on their governments to reform access to HIV medications. The case that set the precedent for questioning the validity of the parallel importing tool under TRIPS was in South Africa in April 2001.

The South African government had previously passed the 'Medicines and Related Substances Control Amendment Act' in 1997. This law made medicines more affordable by allowing parallel imports, enforcing generic substitution, and implementing price controls. The Pharmaceutical Industry Association and 39 of its affiliate pharmaceutical companies sued the Government of South Africa regarding provisions of this act. These parties argued that the law was unconstitutional and violated the TRIPS Agreement (Medicins Sans Frontieres/Doctors Without Borders, 2001).

Public protests in South Africa and neighboring African countries focused on access to antiretroviral treatment. The cost of patented medicines was, at the time, the main obstacle to bringing life-saving treatment to South Africa's 4.7 million people living with HIV/AIDS. In terms of the actual way in which the South African Government defended its legislation as constitutional, it argued two major grounds. First, it argued that it did not abrogate any patent rights. Second, it stated that section 15C complied with TRIPS, arguing that TRIPS did not, after all, prohibit parallel imports. With the South African parallel importing case in consideration, WTO members realized that they needed to come to a consensus on the issues around exports and imports of pharmaceuticals. The legal problem for exporting countries was resolved in August 2003 when WTO members reached an agreement to make it easier for countries to import cheaper generics made under compulsory licensing if they have little capacity to manufacture the medicines themselves (Fisher & Rigamonti 2005).

The third tool for TRIPS discourse is differential pricing, which proponents defend as a more viable and politically feasible option. Although WTO member nations conducted a workshop in 2001, when TRIPS was being debated in general and in the context of the Doha Declaration on Public Health, the research and discussion for differential pricing still continues. In the context of pharmaceutical and other health products, differential pricing is the adaptation of product prices based on the purchasing power of consumers in different geographical or socio-economic segments (Yadav 2010). Still, even with the support of differential pricing in theoretical models, the differential pricing mechanisms across pharmaceutical products are not always equal.

Historically, the pharmaceutical industry had been cautious of extending low prices for a large number of drugs in low-income markets due to the fear of eroding profit margins in

high- and middle-income markets (Yadav 2010). While there are many differential pricing models, one suggestion that Yadav puts forth in his WHO paper is that pharmaceutical firms could use the model of intra-country differential pricing. This means that different socio-economic segments of the population in LMICs seek treatment and obtain medicines from different channels, with wealthier patients seeking treatment in channels different from their poorer counterparts. One example of this 'intra-country' method is Novartis' segmentation strategy by public and private sector for the malarial treatment drug, Coartem (Figure 2) (Yadav 2010).

Fig 2: Novartis' Intra-country Differential Pricing for Coartem

Source: Novartis 2009

A final point that, while not in the scope of this paper, is the current barriers that are now posed by the emergence of discussions on TRIPS Plus. TRIPS Plus is not necessarily a 'formal agreement', and is beyond the scope of the original TRIPS Agreement. It rather is a loose concept that is referring to:

> *…the adoption of multilateral, plurilateral, regional and/or national intellectual property rules and practices which have the effect of reducing the ability of developing countries to protect the public interest aims to increase the level of protection for right holders beyond that which is given in the TRIPS Agreement...* (Musungu & Dutfield 2003).

So far, these rules have been in the context of bilateral free trade agreements (FTAs), of which two major ones are the Thailand and South African Customs Union (SACU) FTAs. When moving forward in the discussion of advocating for affordable access to NCD medications in LMICs, the restrictions of patents imposed by these FTAs are important. They represent new challenges taking place as a result of the end of flexible patent regulations that ended for middle-income countries, which have some pharmaceutical manufacturing capacity.

II. Foundations for Making the Case for NCD Essential Medicine Access to TRIPS Governing Bodies

International health attention, on both social and economic terms, has traditionally focused on communicable diseases, such as tuberculosis, polio, and HIV/AIDs. The first statement in the Doha Declaration on TRIPS Agreement and Public Health, the statement reads as follows:

> *We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics,* (World Trade Organization Declaration on TRIPS and Public Health, 2001).

What remains vague here is how the declaration defines the 'other epidemics' part of the statement. There is particular emphasis over the three most devastating communicable diseases, but there seems to be no consensus as to what constitutes an epidemic. The word is instead left up to interpretation. This presents a unique question now that NCDs have moved to the international forefront. In September 2011, the United Nations hosted a two-day meeting on NCDs. It was only the second UN High Level Meeting (UNHLM) that was based upon a health issue. The first high-level meeting focused on HIV/AIDS in 2001 (Bollyky, 2011).

For NCDs, the mortality statistics certainly speak to the urgency of the situation, but how to actually create measurable targets to reduce their burden was something the UNHLM addressed. Princess Dina Mired, who spoke on behalf of the Union for International Cancer Control at the introduction of the high-level meeting, pointed out that:

> *[While the UN Declaration] noted that chronic diseases were a great equalizer among the rich and poor, the Declaration failed to recognize that the burden of those diseases was an epidemic,* (United Nation General Assembly GA/11138, 2011).

She stressed that NCDs needed to be labeled adequately and appropriately, and not simply as 'a [watered-down] problem of epidemic proportions' (United Nation General Assembly GA/11138, 2011). She also stated that the Political Declaration on NCDs lacked clear and measurable targets. To the credit of the declaration, Paragraph 45 specifies the usage of TRIPS flexibilities to the fullest. Paragraph 52 says that international organizations should provide technical assistance and capacity to developing countries in areas of NCD prevention and control, as well as, promote access to medicines (United Nations General Assembly A/66/L.1, 2011). Still, the lack of targets points to the idea that international organizations have not discussed the burden of NCDs with the same types of tangibility as HIV/AIDS. One

major reason for this gap is a misconception of 'emergency' taking precedence over the term 'epidemic'. Pharmaceutical industries have disseminated this misconception publicly and have used it, for example, to restrict when compulsory licenses can or cannot be used (Abbott, 2011). This has very narrowly limited the scope of pharmaceutical patents as they relate public health issues to just the HIV/AIDS issue.

Hence, this was the major reason why the high-level meeting was needed and targets needed to be set. Interestingly, among those targets, Princess Dina mentioned essential medicines (Abbott, 2011). In regards to the mention of TRIPS in the 2011 NCD UNHLM, Liow Tion Lai, Minister of Health of Malaysia emphasized major issue with TRIPS. He drew upon the United Nations Declaration on HIV/AIDS, which had endorsed the use of 'flexibilities' guaranteed by WTO TRIPS in order to address that trade did not trump the right of patients. Using this precedent, he emphasized that Malaysia, like many countries were challenged to provide access to essential medicines to manage NCDs and, for Malaysia, generic drugs were essential to delivering health care to its people (United Nation General Assembly GA/11138, 2011). In other words, to have TRIPS as a barrier in the case of NCDs would be counteractive for developing countries, which are already lacking in health systems and infrastructural resources.

Fortunately, since the high-level meetings, the World Health Organization (WHO) has been circulating discussion papers between member state stakeholders from a working group. So far, in response to paragraph 8 of the World Health Assembly decision WHA65(8), the WHO Secretariat has the responsibility of developing a revised WHO Discussion Paper on a global NCD monitoring framework that includes indicators and a set of voluntary global targets both for prevention and control of NCDs. WHO regional committees have finished their meetings, and a formal meeting took place between member states in November 2012. The draft report at that meeting has listed 11 'targets' to be addressed by 2025. There are three categories of targets: (1) outcome targets (premature mortality rate reduction), (2) exposure targets (i.e. alcohol use, fat intake, obesity, etc.), and (3) health systems response targets. In the third category, there are two targets, both of which deal with NCD drug treatments and medications.

One target requires that '50% of eligible people receive drug therapy to prevent heart attacks and strokes, and counseling'. The other requires '80% availability of basic technologies and generic essential medicines required to treat major NCDs in both public and private facilities' (World Health Organization NCD Discussion Paper 2012). The indication of these two targets as health systems responses speaks to Lai's point, and therefore, gives preliminary international legitimacy and attention to the need for facilitating affordable access to NCD essential medicines and drug treatments. However, a question remains, at least with regards to TRIPS flexibilities and where patents are a concern. Which NCD-based patent drugs are actually needed to provide effective treatment and to what extent are patents a problem (Abbott, 2011)? This is something these targets need to address, rather than just a vague idea of availability, in order for the essential medicine targets to have some legitimacy in TRIPS and WTO-related discussions.

Given how new the international discourse on NCD essential medicine access is, it is crucial to see what insights LMICs can adopt from the HIV/AIDS case. Besides the international pressure and attention in South Africa, Brazil presented a case of being able to 'fight back' economically. Simultaneously, with the 2001 South African battle over the exorbitant price of HIV/AIDS drugs, as previously explained, Brazil purchased two patented HIV/AIDS drugs, efavirenz and nelfinavir, both of which are sold in the U.S. for more than US$ 4,000 per patient. In short, Brazil made these drugs available at no cost to its own population, and threatened to allow its local pharmaceutical companies to manufacture generic versions of the medicines if the prices were not reduced. After seven months of unsuccessful negotiations, the United States, on 8 January 2011, asked the WTO to form a dispute settlement panel regarding Brazilian patent law. Essentially, the U.S. was not successful in this proceeding when Brazil threatened to use a compulsory license per its own laws, and the U.S. was compelled, to a great degree by international pressure, to withdraw its complaint against Brazil in the WTO on 25 June 2001 (Thomas, 2001).

Therefore, a major part of the general HIV/AIDS pharmaceutical access story was the use of compulsory licenses for antiretroviral (ARV) medications, or in Brazil's case, the threat of using compulsory licenses. Between 2001 and 2010, 24 compulsory licensing episodes in 17 countries were reported, based on a recent database analysis by Beall and Kuhn. Most of the compulsory license episodes involved drugs for HIV/AIDS, with a few for 'other communicable diseases', and five cases involving drugs for NCDs, such as cancer. These five cases were only in Thailand and India, which are further discussed in the case studies section (Figure 3) (Beall & Kuhn 2012). The authors concluded that:

> *…the barriers to compulsory license use in LDCs and low- income countries go well beyond the lack of production capacity, and likely extend to health system incapacity, political pressure against compulsory licenses, and the legislative difficulties of issuing a compulsory license,* (Beall & Kuhn 2012).

The authors may have a point because the case for NCD medications, though still very new, may face new limitations and challenges as delineated above. It will be interesting to see what current and new methods and measures LMICs will or will not employee under TRIPS provisions in order to advocate for NCD essential medicines at an affordable price. This is further explored in the following section of case studies.

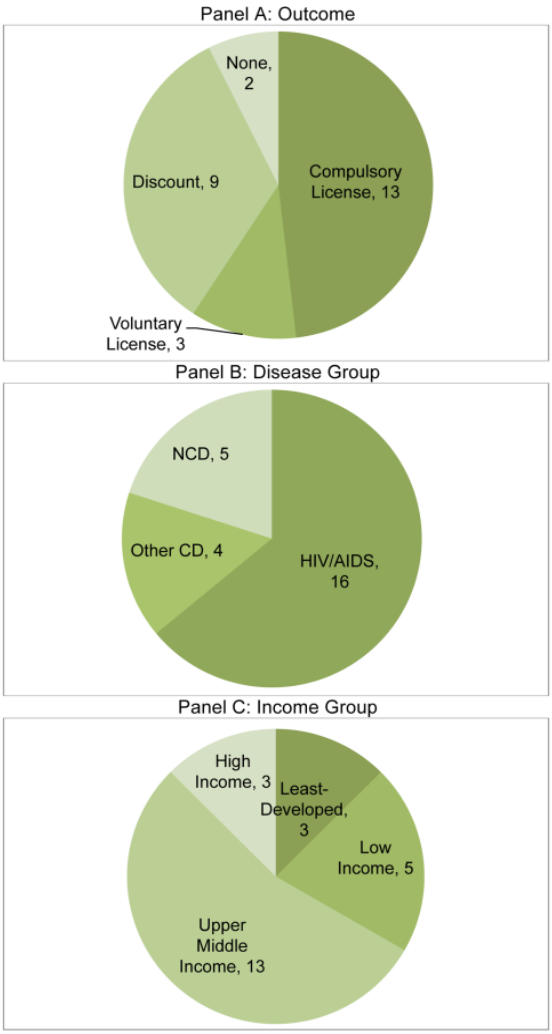

Fig 3: Distribution of Compulsory License Cases by WTO Outcome, Disease Group, and Income

Source: Beall and Kuhn 2012

III. Case Studies

For a better view on LMICs' current use of TRIPS flexibilities and obstacles, this section provides several case studies on specific developing countries to investigate the effectiveness, feasibility and potential risks when using TRIPS flexibilities, mainly compulsory licenses, for better access to NCD treatment. The only two countries that have so far issued compulsory licenses on NCD drugs, Thailand and India, illustrated the effectiveness of using TRIPS flexibilities to drive down high prices of patented NCD drugs. This was true even though both countries received various international responses, including opposition from the pharmaceutical industry and developed countries led by the US.

Although China is an example of a middle-income developing country with a pharmaceutical manufacturing capacity, it has not issued any compulsory license for any drugs. This illustrates the obstacles and concerns middle-income countries have before issuing compulsory licenses. The last case study is about the use of TRIPS flexibilities in Sub-Saharan African region, where most countries are suffering from the disease double burden. Some Sub-Saharan African countries, as the representative low-income countries, have issued compulsory licenses on HIV/AIDs drugs during the past decades. The Sub-Saharan African case studies explore the implication of extending the use of compulsory licenses on NCDs in Sub-Saharan Africa and discuss the challenges low-income countries face in adopting TRIPS flexibilities.

A. Thailand

With the increased economic development and living standards during the past three decades, Thailand has made several achievements in the public health sector. Although HIV/AIDs is still one of the country's major health problems, the prevalence rates of other communicable diseases have declined. For instance, the mortality rate of Malaria decreased from 10.9 per 100,000 persons in 1977 to 0.1 per 100,000 persons in 2009 (Wibulpolprasert, 2010). However, with the environmental factors of changing lifestyle, urbanization and international trade, Asian countries, including Thailand, are seeing an increase in NCD risk factors. According to the WHO, NCDs are estimated to account for 71% of all deaths in Thailand (World Health Organization, 2011). Therefore, a shift in public health has taken place from a strong focus on communicable diseases to NCDs.

In order to address the urgent NCD problems in Thailand, the Thai government emphasized the prevention and control of NCD risk factors, as well as the need to pay attention to effective treatment of NCDs. One of the measures for NCD treatment is to issue a compulsory license to local pharmaceutical manufacturers to drive down the high price of NCD medicines. So far, the Thai government has issued seven compulsory licenses, of which two were antiretroviral, one was for heart disease and four were for cancer treatment (Wibulpolprasert, 2010). The issuance of compulsory licenses has driven down the prices for those medicines dramatically, making them more affordable and available to more patients in Thailand.

The Thai government has formed its own patent laws in accordance with Article 31 of the TRIPS Agreement to authorize compulsory licenses and government use of patents on any patented drugs under two circumstances. According to Section 51 of the Patent Act of Thailand, any ministry, sub-ministry, or department of the Thai government can issue a compulsory license. The second circumstance under which a compulsory license can be issued is by the Prime Minister with the Cabinet's approval during a state of war or emergency, in accordance with Section 52 (Wibulpolprasert, 2010).

In 2007, Thailand issued a compulsory license on Plavix for the treatment of cardiovascular diseases. It was considered significant not only because cardiovascular disease is one of the top causes of deaths, but also because it was the first compulsory license issued to a NCD medicine in Thailand. The compulsory license on Plavix reduced the price from US$ 2.75 per tablet to US$ 0.03 per tablet (Wasserman, Priest. 2012). Since 2008, four other drugs for cancer treatment have been granted compulsory licenses. The five compulsory

licenses on NCDs drugs have created a new controversy since the case of HIV/AIDS. Pharmaceutical industries opposed to the issuance of compulsory licenses argued that compulsory licenses denied the patent right to the innovator and discouraged pharmaceutical companies from further R&D. In 2007, The United States Trade Representative placed Thailand on its 'Special 301' Report Priority Watch List, criticizing Thailand's deficiency in IPR protection and the lack of transparency and due process during the issuance of compulsory licenses (Wetzler, Mankad, Burrowbridge, 2009).

Patent Act in Thailand

Section 51: A person shall enjoy an equal right to receive standard public health service, and the indigent shall have the right to receive free medical treatment from State's infirmary. The public health service by the State shall be provided thoroughly and efficiently. The State shall promptly prevent and eradicate harmful contagious diseases for the public without charge.

Section 52: A person shall enjoy an equal right to receive standard public health service, and the indigent shall have the right to receive free medical treatment from public health centers of the State, as provided by law. The public health service by the State shall be provided thoroughly and efficiently and, for this purpose, participation by local government organizations and the private sector shall also be promoted insofar as it is possible. The State shall prevent and eradicate harmful contagious diseases for the public without charge, as provided by law.

Source: Thailand Health Profile Report 2008-2010 (Wibulpolprasert, 2010)

B. India

India is the third largest pharmaceutical producer by volume in the world, but like other middle-income countries, it is also suffering from NCDs. In 2004, 4.8 million of the estimated 8.1 million Indian deaths were due to NCDs. In 2004, out of pocket health care expenses amounted to 3.3 percent of India's GDP, among which the share of NCDs increased from 31.6 percent in 1995 to 47.3 percent in 2004. If NCDs were completely eliminated, the estimated GDP in a year such as 2004 would have been 4-10 percent higher (Mahal, Karan, Engelgau 2010).

One of barriers in the battle against NCDs in India is the difficult access to expensive patented drugs for patients. India is the fourth largest generic drug producer and globally ranks thirteenth in generic drug consumption. India's generic drug industry provides 95% of its domestic medical needs (TATA Strategic Management Group, 2008). The price of generic drugs is usually a small fraction of the price of patented branded drugs. Still, with NCDs accounting for the major cause of death in India, people need more affordable and reliable NCD drugs.

India has a long history of including compulsory license in its legal system since 1970. Under Section 84 of the Patent Act 1970, any person can apply for compulsory license three years from the expiration date of a patent approval. The Government of India allows this given the following circumstances: the patented invention does not satisfy the reasonable requirement of the public; the patented invention is not available to the public at a reasonable price. After joining the WTO and the TRIPs Agreement in 1995, India amended its Patent Act 1970 three times in 1999, 2002, and 2005, respectively, to meet the standard of intellectual property rights protection. For instance, the amendment expanded the introduction of product patents in the areas of chemicals, pharmaceuticals, agricultural chemicals, and food, which was not allowed under Patent Act 1970 (Kurian, 2011).

In response to TRIPs flexibilities that give LMICs an extended period of time to fully comply with TRIPS requirement, India further allowed the granting of compulsory licenses on patented pharmaceutical exports to countries lacking manufacturing capacity under the 92A of Patent Act 2005. Doing this would help countries lacking such capacity address public health problems, assuming the country allows the importation from India.

In March 2012, India issued its first NCD compulsory license to its domestic generic drug producer, Natco, which ended the monopoly of German pharmaceutical company Bayer-AG in anti-cancer medicine. Natco suggested selling the drug 'sorafenib tosylate' at US$ 162 per patient per month, which lead to a 97 percent price cut compared to Nexavar, produced by Bayer-AG of US$ 5162.51 (Kurian, 2011). The Indian government grants the compulsory license till 2020. Natco is not entitled to export the drug or to outsource its production. In addition, Natco must pay royalties to Bayer on a quarterly basis at the rate of 6 percent of the net sales of the medicine.

International NGOs, such as Médecins Sans Frontières', welcomed the use of compulsory licenses, arguing that it offered hope to patients. It also showed that compulsory licenses could serve as a means of providing life-saving drugs under patent at a low price, while patent holder receive their royalties. This success has positive implications for drug access not only for Indian patients, but also for patients suffering from NCDs around the world. Nonetheless, developed countries led by the United States heavily criticized India for issuing a compulsory license on an anti-cancer generic drug, sorafenib tosylate (Silverman, 2012; ICTSD, 2012).

In January 2013, the Department of Pharmaceuticals under the Government of India decided to issue compulsory licenses for three more patented cancer drugs. These are trastuzumab for breast cancer, ixebepilone for chemotherapy, and dasatinib for leukemia. Trastuzumab is marketed under the pharmaceutical company Roche as Herceptin, while ixabepilone and dasatinib are marketed under Bristol-Myers Squibs as Ixempra and Sprycel, respectively. Trastuzumab, ixabepilone and dasatinib currently cost approximately US$ 810, US$ 1135-1300, and US$ 245, respectively, for a month's regimen (Indian Express, 2013). There are no

projections yet regarding how much the price would be reduced. However, this development shows a significant shift towards the Government of India's efforts to address its growing cancer burden, which reflects a paradigm shift in the question of what constitutes a public health emergency.

However, the Natco compulsory license) does not allow the exporting sorafenib tosylate. This may also be most likely the case for the licenses for the three most recent cancer drugs. India, as the largest provider of cheap medicines is able to export its generic drugs to other countries, especially low-income countries, based on the Indian domestic Patent Act 2005 and TRIPS flexibilities (Bajaj, Pollack, 2012).

The implication of exporting affordable generic drugs from middle-income countries to low-income countries is twofold. For middle-income countries, exporting generic drugs can expand their pharmaceutical markets, both domestically and abroad. For low-income countries, importing generic drugs can solve the problem of lacking pharmaceutical manufacturing capacity, while providing patients with affordable access to NCD drugs. Although no generic drugs for NCDs have been exported from middle-income countries to low-income countries so far, there are several examples for HIV/AIDS generic drugs already. For instance, in 2005, Ghana issued a government use compulsory license for importing Indian generic HIV/AIDS medicines (Ghana Ministry of Health, 2005). This example shows the feasibility of using compulsory license in NCD drugs.

C. China

NCDs account for over 80 percent of 10.3 million annual deaths (Wang, Kong, Wu, Bai, and Burton. 2005). Based on a World Bank estimate, the economic benefit of reducing Cardiovascular Disease mortality by 1 percent per year over a 30-year period could generate an economic value of 68 percent of China's GDP in 2010, more than US$ 10.7 trillion (Wang, Marquez, Langenbrunner, 2011). However, China is largely dependent on the imported patented drugs that are barely affordable for patients, due to the lack of research and development in the domestic pharmaceutical industry (Huang, 2012).

However, as a middle-income country that is also seriously affected by NCD problems, China has taken a different approach from Thailand and India. Rather than utilizing TRIPS flexibilities for NCD treatment, China has taken advantage of bilateral price negotiations with pharmaceutical companies to reduce the price for NCD patented drugs. CFR Senior Fellow Yanzhong Huang argued that in the fear of losing foreign direct investment (FDI), China does not have strong incentives in using compulsory licenses (Huang, 2012). According to World Development Indicators & Global Development Finance 2010, the net flow of FDIs in China was more than eight times of that in India and twenty times of that in Thailand, respectively (The World Bank, 2012). Attracting FDI, so far, holds more benefit for China than the costs of issuing compulsory licenses, as well as the risk of strong opposition from multinational companies and developed countries.

Another reason why China has not issued any compulsory license for NCD treatment is to affirm its image of being committed to intellectual property right protections and standards, since joining the WTO in 2001. China immediately launched domestic procedures to enforce TRIPS, and became one of the earliest members to accept the Protocol amending the TRIPS agreement after it joined the WTO (Huang, 2012). Moreover, in December 2011, China's National Development & Reform Commission (NDRC) published the amended Industry Catalogue for Foreign Investments, which removed foreign investments in the pharmaceutical distribution business from the Restricted Category. It also encouraged foreign pharmaceutical companies to localize the manufacturing of more novel vaccines in China (Sidley Austin LLP. 2012). The amendment subjected foreign pharmaceutical companies to less regulation. China also made further commitments to the protection of intellectual property rights during the 18th National Congress of the Communist Party of China in November 2011 (Hu. 2012).

In March 2012, China amended its intellectual property laws in order to allow the government to issue compulsory licenses for local generics makers to produce and export patented drugs (Taylor, 2012). The inclusion of compulsory licenses in China's legal system may lay the groundwork for China to further issue compulsory licenses for NCD drugs in the future, if the benefit of issuing compulsory license to address public health concerns outweighs the risks of losing foreign direct investment.

D. Sub-Saharan Africa

Sub-Saharan African countries are experiencing the double burden of communicable diseases and NCDs. HIV/AIDs still remains the leading cause of deaths in Sub-Saharan Africa (Mathers, Boerma, Fat. 2009). In 2005, the United Nations Programme on HIV/AIDS estimated that about 40 million people are currently infected with HIV, of whom about 25.8 million, or 64 percent of the total, are in Sub-Saharan Africa (UNAIDS, WHO, 2005). However, the epidemiological transition from predominantly communicable diseases to NCDs is already well underway in Sub-Saharan Africa. In 2004, 25% of all deaths in Sub-Saharan Africa were caused by NCDs. It is estimated that by 2030, NCDs will cause 46% of all the deaths (WHO, 2012).

Although there has been little application of TRIPS flexibilities on NCDs in Sub-Saharan Africa, several examples of its use on communicable diseases can provide insights and learning for further extrapolation to NCDs. The major way to use TRIPs flexibilities for Sub-Saharan Africa is to grant compulsory licenses within the national legal framework to manufacture locally or import generic drugs from other countries, due to the limited production capacity. For example, Mozambique and Zambia, respectively, issued compulsory licenses to local producers to manufacture antiretrovirals in 2004, with royalties paid to the original patent holders (Zambia Ministry of Commerce, Trade and Industry, 2004; The Government of Mozambique, 2004). The Ministries of Health of Guinea and Eritrea, respectively, issued compulsory

licenses for importation on patents on drugs to treat HIV-AIDS in 2005 (Eritrea Ministry of Health, 2005).

NCDs first became prevalent in developed countries and are now spreading to the developing world at a faster pace. Thus, pharmaceutical companies in developed countries have had the opportunity to develop their NCD drugs and make them available to their target populations. However, LMICs have not had the same opportunity, since their focus has traditionally remained on communicable diseases. Therefore, pharmaceutical companies in developed countries can exorbitantly price NCD drugs (Mattke, Haims, et al. 2011). For example, the prices of insulin for treating diabetes are higher in Africa than in the Eastern Mediterranean and South East Asia. Even within the same region, the price of insulin by a producer ranged from US$ 9 in Zimbabwe to over US$ 44 in Congo (Abegunde). This makes it crucial for middle-income countries to make full use of TRIPS flexibilities because they can strengthen their domestic capacities to produce generic drugs and to be able to provide them at an affordable price to different income-based population segments in low-income countries.

Groups that support strong pharmaceutical patent protection argue that patents are not the obstacles for access to essential NCD medicines in Sub-Saharan Africa. The World Intellectual Property Organization (WIPO) asserts that the real issue for access to NCD treatment is the inadequate financing of overall health systems and the severe lack of health care infrastructures, since most drug companies have not obtained patents widely in Africa (IIPI. 2000). There is little doubt that the lack of access to essential medicines in Sub-Saharan Africa does not rest solely with patent protection, but also with non-patent problems such as poverty, the lack of supportive infrastructure, and poor governance (Zainol, Amin, et al. 2011). However, with the NCD situation getting worse in this region, patented drugs will not only detract from current patient treatment, but also create a monopoly in the region's market. Such an event will be detrimental to their national capacity for addressing public health issues in the long run.

IV. Policy and Advocacy Recommendations

Based upon a combination of theoretical and practical factors related to TRIPS and the international discourse on the global NCD burden, the following are three major recommendations which address current barriers that make it difficult to make the case for using TRIPs framework for LMICs to be able to have access to essential NCD medications.

1.) *Extend the time frame for least developed countries (LDCs) to be able to use TRIPS flexibilities to 2025 rather than 2016. Also, allow this extended deadline for middle-income countries.*

Currently, the 2016 deadline is only for LDCs, but because of the groundwork and level of advocacy growing for NCD prevention and control, this deadline is not feasible. Another issue that arises is that since there is not clear consensus as to what NCD drugs are affected by patent regulations just yet. This means middle-income countries need more time with pharmaceutical industry capacities to be able to also develop these drugs. To simply say that the HIV/AIDS case was a victory and then ignore the alarming rate of NCD mortality and lack of treatment in LMICs would be contradictory to the goals of TRIPS and the Doha Declaration on Public Health.

The rationale for the 2025 deadline is that it would streamline the goals of TRIPS, the Doha Declaration on Public Health, and the processes discussed at the NCD UN High Level Meeting of 2011. One of these processes is creating a goal of achieving universal targets for NCD reduction on the mortality, exposure, and health systems levels by 2025. Although these targets have not been finalized, they will be a tangible way of gauging the urgency and the time needed to be able to ensure access to NCD essential medicines, which is a part of the health systems targets.

2.) *Explore differential pricing alternatives to compulsory licenses as a bargaining chip for middle-income countries.*

Differential pricing, as discussed earlier, allows for prices to be charged to different countries based on income and poverty levels. As previously discussed, the major concern for pharmaceutical companies is that profit margins in high and middle-income markets and high distribution channel markups in low-income countries could dilute the benefits of differential pricing to poor patients. However, this is slowly changing because with economic and demographic growth in low- and middle-income markets the potential market size of many LMICs is greater. This trend is so significant that ignoring it would not be feasible in the long run given the amount of international pressure put on companies to be more socially responsible, and more importantly the growth of emerging markets for generic pharmaceutical manufacturing.

What this means is essentially a compromise and win-win situation both for social good and the business goals of pharmaceutical companies (Yadav, 2010). While it is not in the scope of this paper to discuss all models, pharmaceutical companies would have to, in the end, be innovative in creating the right strategies and fairly assessing risks based upon the markets they are trying to reach. This was illustrated in the earlier example of Novartis' method of intra-country pricing for the drug Coartem (see section II). Of course, in low-income countries, differential pricing alone cannot be successful. There would need to be, in this case, some public-private collaboration in which some government subsidies keep the drugs at a low cost in order for differential pricing to work at its best (Yadav, 2010).

3.) *Make efficient use of bilateral and multilateral trade agreements in a way that is coherent with TRIPS flexibilities for better medication access.*

With this recommendation low-income countries which lack NCD drug production capacity, even in generic form, can collaborate with middle-income countries to achieve the much needed drugs that are typically very cost prohibitive. This

would mean, to some degree LMICs need to be wary of the free trade agreements that fall under TRIPS Plus, which would hinder, as discussed earlier, not only access to NCD essential medicines, but also the growth of foreign direct investments. Instead, developing countries should utilize Preferential Trade Agreements (PTA) for deeper integration. Although the participation of developing countries, including LDCs, have increased significantly, the scope of PTAs needs to be further extended to address public policy concerns, such as public health (WTO, 2011). Developing countries can make use of PTAs with developed countries to include preferential trade on NCD essential medicines. This could reduce prices and eliminate tariffs on advanced technologies in order to strengthen domestic manufacturing capacity for NCD treatment. LDCs should also utilize the South-South agreement to import cheaper NCD drugs from middle-income countries such as India, China and Brazil.

However, policy makers in developing countries should be aware that some PTAs, especially with the US and European countries, include agreements on a more strict intellectual property rights protection regime, which can go beyond the TRIPS minimum standards. For instance, the US Trade Promotion Authority Act of 2002 stipulates that provisions of any trade agreement should be 'a standard of protection similar to that found in US law', including the full implementation of the TRIPS obligations (Trade Act of 2002). Developing countries need to balance the benefits and potential risks under PTAs, realizing the complexities of these agreements. In the case of the agreements with the US, countries should be careful about the stringent monitoring processes by the United States Trade Representative (USTR) through the 301 annual reviews (Roffe, Spennemann. 2012).

In the end, the opening up of further discussion in addressing NCD problems can be enhanced by keeping up with specific targets for reducing NCD mortality rates and drugs, as prescribed by the World Health Organization. Allowing imports and exports of generic drugs for affordable NCD treatment in poor nations could also be useful. Opening up further discussion on import and export of generic drugs does not necessarily mean that the definition of 'public health emergency' should be made specific, as that could hurt the cause and process of increasing access to NCD medications.

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REFERENCES

[1] Abbott, F. (2011, 23 September). Essential Meds, Patents & NCDs: Abbott Explains. (E. Silverman, Interviewer) PharmALot. Retrieved December 9, 2012 from http://www.pharmalot.com/2011/09/essential-meds-patents-ncds-abbott-explains/

[2] Abegunde, D. Essential Medicines for Non-Communicable Diseases. *World Health Organization*. Retrieved from http://www.who.int/medicines/areas/policy/access_noncommunicable/EssentialMedicinesforNCDs.pdf

[3] Backhoum, LLM, M. (2008). *TRIPS, Patent Rights, and Right to Health: "Price" or "Prize" For Better Access to Medicine*. (Max Planck Institute for Intellectual Property) Retrieved December 2, 2012, from infojustice.org: http://infojustice.org/download/acta-a2m/scholarly/TRIPS,%20PATENT%20RIGHTS%20AND%20RIGHT%20TO%20HEALTH.pdf

[4] Bajaj, V., Pollack A. (2012, March 6). India's Supreme Court to Hear Dispute on Drug Patents. *The New York Times*. Retrieved from http://www.nytimes.com/2012/03/07/business/global/indias-supreme-court-to-hear-long-simmering-dispute-on-drug-patents.html?pagewanted=all

[5] Beall, R., & Kuhn, R. (2012). Trends in Compulsory Licensing. *PLoS Med, 9*(1). Retrieved November 12, 2012 from http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001154

[6] Bloom, D.E., Cafiero, E.T., et al. (2011). The Global Economic Burden of Noncommunicable Diseases. *Geneva: World Economic Forum*. Retrieved from http://www3.weforum.org/docs/WEF_Harvard_HE_GlobalEconomicBurdenNonCommunicableDiseases_2011.pdf

[7] Bollyky, T. (2011, September 22). *The Path Forward on NCDs*. Retrieved November 22, 2012, from Council on Foreign Relations: http://www.cfr.org/health-and-disease/path-forward-ncds/p26006

[8] Department of State and the Department of Health and Human Services . (2007, March). *Why Population Aging Matters: A Global Perspective*. National Institute on Aging, National Institutes of Health, Washington, D.C.

[9] Eritrea Ministry of Health. (2005). Issuance of Compulsory License. Retrieved from http://www.cptech.org/ip/health/cl/Eritrea.png

[10] Fisher, W., & Rigamonti, C. (2005). *The South Africa AIDS Controversy*. Cambridge: Harvard Law School.

[11] Ghana Ministry of Health. (2005). Notification of Emergency and Issuance of Government Use License. Retrieved from http://www.cptech.org/ip/health/cl/Ghana.png

[12] Ghosh, A. (2013, January 12). Govt moves to make three key cancer drugs cheaper. *The Indian Express*. Retrieved from http://www.indianexpress.com/news/govt-moves-to-make-three-key-cancer-drugs-cheaper/1058247/

[13] Ho, C. M. (2007). A New World for Addressing Patent Rights and Public Health. *Chicago-Kent Law Review*.

[14] Hu YY. (2012, November 12). Patent applications, R&D spending up sharply. *China Daily USA*. Retrieved from http://usa.chinadaily.com.cn/2012-11/12/content_15915320.htm

[15] Huang, YZ. (2012). The Compulsory Licensing of Pharmaceuticals: Will China Follow in India's Footsteps? *Council on Foreign Relations: Asia Unbound*. Retrieved from http://blogs.cfr.org/asia/2012/10/01/the-compulsory-licensing-of-pharmaceuticals-will-china-follow-in-indias-footsteps/

[16] ICTSD International Centre for Trade and Sustainable Development. (2012). India Grants First Compulsory License to Generic Drug Producer. *Intellectual Property Programme. 16(10)*. Retrieved from http://ictsd.org/i/news/bridgesweekly/128236/

[17] IIPI International Intellectual Property Institute. (2010). Patent Protection and Access To HIV/AIDS Pharmaceuticals In Sub-Saharan Africa. *The World Intellectual Property Organization*. Retreived from http://www.wipo.int/about-ip/en/studies/pdf/iipi_hiv.pdf

[18] Kurian, PH. (2011). Compulsory License Application No.1 of 2011. *Controller General of Patents, Designs and Trade Marks*. Retrieved fromwww.ipindia.nic.in/iponew/compulsory_license_12032012.pdf

[19] Lopez AD, Mathers CD, Ezzati M, Jamison DT, Murray CJL, eds. Global Burden of Disease and Risk Factors. Washington , DC : The World Bank Group, 2006

[20] Mahal, A., Karan, A., Engelgau M. (2010). The Economic Implications of Non-Communicable Disease for India. *The World Bank*.

[21] Mathers, CD., Boerma, T., Fat, DM. (2009). Global and Regional Causes of Death. *British Medical Bulletin 2009. 92:* 7-32. Retrieved from http://bmb.oxfordjournals.org/content/92/1/7.full.pdf+html

[22] Mattke, S., Haims, MC., et al. (2011). Improving Access to Medicines for Non-Communicable Diseases in the Developing World. *Rand Corporation*. Retrieved from http://www.rand.org/content/dam/rand/pubs/occasional_papers/2011/RAND_OP349.pdf

[23] Medicins Sans Frontieres/Doctors Without Borders. (2001). *International Activity Report-South Africa: Big Pharma Backs Down*. Retrieved November 30, 2012, from http://www.doctorswithoutborders.org/publications/ar/report.cfm?id=1204

[24] Musungu, S., & Dutfield, G. (2003). *Multilateral agreements and a TRIPS Plus World: The World Intellectual Property Organisation*

(WIPO). Retrieved December 2, 2012, from Quaker United Nations Office: http://www.geneva.quno.info/pdf/WIPO%28A4%29final0304.pdf

[25] Roffe, P., Spennemann, C. (2012). Intellectual Property Rights in Preferential Trade Agreements. *Initiative for Policy Dialogue*. Retrieved from http://policydialogue.org/files/events/Roffe_Spennemann_Preferential_Trade_Agreements_and_IPRs_Paper.pdf

[26] Sidley Austin LLP. (2012, January 3). China Further Revises Rules for Foreign Investment in Pharmaceutical Industry. *Sidley Austin LLP. Global Life Sciences: China Update.* Retrieved from http://www.sidley.com/China-Further-Revises-Rules-for-Foreign-Investment-in-Pharmaceutical-Industry-01-03-2012/

[27] Silverman. (2012, July 2nd). USPTO: Indian Compulsory License Was Wrong. Posted to http://www.pharmalot.com/2012/07/uspto-indian-compulsory-license-was-wrong/

[28] Sinhaya, B. (2012). *Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya*. Retrieved November 22, 2012, from Managing the Challenges of WTO Participation - 45 Case Studies: http://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm

[29] TATA Strategic Management Group. (2008). Overview of Indian Pharmaceutical Industry. *Osaka International Business Promotion Center*. Retrieved from http://www.ibpcosaka.or.jp/network/e_abg/e_india_abg_pharmacy_report200803.pdf

[30] Taylor, L. (2012, June 13). China amends patent laws to enable compulsory licensing. *Pharma Times.* Retrieved from http://www.pharmatimes.com/article/12-06-13/China_amends_patent_laws_to_enable_compulsory_licensing.aspx

[31] The Government of Mozambique. (2004). The Compulsory License No. 01/MIC/04.Retrieve from http://www.cptech.org/ip/health/c/mozambique/moz-cl-en.pdf

[32] The World Bank, the Ukrainian Medical Alliance. (2010). What Underlies Ukraine's Mortality Crisis? *The World Bank*. Retrieved from http://siteresources.worldbank.org/UKRAINEINUKRAINIANEXTN/Resources/PrichinysmertnostivukrainiENG.E.pdf

[33] Thomas, J. R. (2001, July 27). *HIV/AIDS Drugs, Patents and the TRIPS Agreement: Issues and Option.* Retrieved December 6, 2012, from Congressional Research Service: http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL31066.pdf

[34] Trade Act of 2002. Section 2102 of the Trade Promotion Authority. Retrieved from http://www.gpo.gov/fdsys/pkg/PLAW-107publ210/html/PLAW-107publ210.htm

[35] UNAIDS, WHO. (2005). AIDS Epidemic Update.

[36] United Nations General Assembly GA/11138. (2011, November 30). *Noncommunicable Diseases Deemed Development Challenge of Epidemic Proportions in Political Declaration Adopted During Landmark General Assembly Summit*. Retrieved November 30, 2012, from http://www.un.org/News/Press/docs/2011/ga11138.doc.htm

[37] United Nations General Assembly A/66/L.1. (2011, September 16). *Political declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases.* Retrieved December 5, 2012, from United Nations: http://www.un.org/ga/search/view_doc.asp?symbol=A/66/L.1

[38] Wang, L., Kong L., Wu F., Bai Y., and Burton R. (2005). Preventing Chronic Diseases. *Lancet. 366*: 1821–24

[39] Wang, S., Marquez P., Langenbrunner, J. (2011). Toward a Healthy and Harmonious Life in China: Stemming the Rising Tide of Non-Communicable Diseases. *The World Bank.* Retrieved from http://www.worldbank.org/content/dam/Worldbank/document/NCD_report_en.pdf

[40] Wasserman, M., Priest, V. (2012). Compulsory Licenses For Non-Communicable Diseases: Implications For Pharmaceutical Pricing In Low-Income Countries. *Double Helix Consulting.* Retrieved from http://www.doublehelixconsulting.com/media/31969/compulsory_licensing_a4.pdf

[41] Wetzler, J., Mankad, M., Burrowbridge A. (2009) Timeline for US-Thailand Compulsory License Dispute. Version 3. *Program on Information Justice and Intellectual Property*. Retrieved from http://infojustice.org/wp-content/uploads/2012/11/pijip-thailand-timeline.pdf

[42] Wibulpolprasert, S. (2010). Thailand Health Profile 2008-2010, Printing Press, *The War Veteran Organization of Thailand.* Retrieved from http://www.moph.go.th/ops/thp/index.php?option=com_content&task=view&id=176&Itemid=2

[43] World Health Organization. (2012). Global Burden of Disease. Projections of mortality and burden of disease, 2002–2030. Retrieved from http://www.who.int/topics/global_burden_of_disease/en/

[44] World Health Organization. (2012, October 31). *A draft comprehensive global monitoring, framework, including indicators, and a set of voluntary global targets for the prevention and control of noncommunicable diseases.* Retrieved December 5, 2012, from WHO: http://apps.who.int/gb/ncds/pdf/A_NCD_INF1-en.pdf

[45] World Health Organization. (2011). NCD Country Profiles 2011 Thailand. *World Health Organization.* Retrieved from http://www.who.int/nmh/countries/tha_en.pdf

[46] World Health Organization. (2011, April). *Briefing Document: Essential Medicines for Non-Communicable Diseases (NCDs).* Retrieved December 9, 2012, from WHO: http://www.who.int/medicines/areas/policy/access_noncommunicable/NCDbriefingdocument.pdf

[47] World Health Organization. (2011, March). *WHO Model List of Essential Medicines, 17th Version*. Retrieved December 2, 2012, from http://whqlibdoc.who.int/hq/2011/a95053_eng.pdf

[48] World Trade Organization. (2011). The WTO and Preferential Trade Agreements: From Co-existence To Coherence. WTO Trade Report 2011, World Trade Organization.

[49] Zainol, ZA., Amin, L., et al. (2011). Pharmaceutical Patents and Access to Essential Medicines in Sub-Saharan Africa. *African Journal of Biotechnology Vol. 10(x)*, pp. 12376-12388. Retrieved from http://www.academicjournals.org/ajb/PDF/pdf2011/30SepConf/Zainol%20et%20al.pdf

[50] Zambia Ministry of Commerce, Trade and Industry. (2004). Compulsory License No. CL 01/2004. *Republic of Zambia, Ministry of Commerce, Trade and Industry.* Retrieved from http://www.cptech.org/ip/health/c/zambia/zcl.html

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