Global Trade Limitations to HIV Medication Access in Developing Countries

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International trade and patent laws pose monetary and logistical challenges to all countries affected by the HIV/AIDS epidemic in their abilities to access the most current and effective treatments. The development of international patent law applicable to medications has undergone significant changes since the 1990's under The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) established by the World Trade Organization (WTO). Case studies of China, India and Brazil's implementation of pharmaceutical patent protection reveal the limitations of TRIPS and its subsequently recognized flexibilities. Although the goal of these flexibilities is to allow for greater access to medications, they fall short in reaching the universally accepted goal of a right to health.

Despite decreasing incidence, in 2012, 35.3 million people were living with HIV worldwide, and 2.3 million are newly infected each year (UNAIDS, 2013). In order to alleviate the HIV/AIDS epidemic, the World Health Organization (WHO) has expanded coverage of HIV treatment. Still, in 2012, only 9.7 million out of over 30 million people in low- and middle-income countries received antiretroviral therapy (UNAIDS, 2013). Meanwhile, in wealthier industrialized countries, even more advanced forms of antiretroviral medications are sold that are less toxic, are more effective, and require simpler regimens.

Challenges to expanding HIV treatment in low-income and developing countries include the inabilities of these countries to import inexpensive pharmaceuticals or manufacture antiretroviral medications domestically because of restrictions placed by the World Trade Organization (WTO). Global patent protections on pharmaceuticals increase costs and constrain developing countries' attempts to access the most advanced forms of antiretroviral medications. The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) requires countries within the WTO to adopt International Intellectual Property Rules (IPRs) which provide strict national protections for competing pharmaceutical companies internationally. Specifically, TRIPS obliges all WTO member

countries to grant at least 20 years of patent protection for new medications, resulting in costly market prices for new medications (Alikhan & Mashelkar, 2004). As corporations in developed countries hold the majority of pharmaceutical patents, some advocates maintain that IPRs generally reflect the economic interests of those developed countries.

To improve access to HIV medications in least developed countries, in 2001, the WTO developed the concept of TRIPS flexibilities. Initiating TRIPS flexibilities to obtain lower cost medications has proven difficult at a practical level. The challenges and importance of TRIPS policy, its established flexibilities and successes serve to underline inequity in healthcare as a human rights issue. With a focus on the conflict between patent rights and the right to health, this paper focuses on Brazil, India, and China as examples of how TRIPS flexibilities help provide adequate access to HIV medications. Then, this paper will advocate that TRIPS flexibilities should be unconditionally expanded to all developing countries experiencing an HIV/AIDS epidemic, not only to those at the lowest degree of development. Social workers, particularly those involved in the formulation and evaluation of macro-level policy, are bound under the National Association of Social Workers (NASW) Code of Ethics to advocate for just and equal treatment of all people, which includes access to healthcare and treatment. This article serves to inform social workers of the complexities involved in accessing HIV/AIDS treatment in order to improve their ability to advocate for universal access.

TRIPS Framework

The research and development (R&D) of a new HIV medication requires the investment of billions of dollars and intense intellectual labor over many years (Smelyanskaya, 2013). In order for pharmaceutical manufacturers to recover R&D costs and provide protection for their products, companies patent their new medications. Patent registration grants the manufacturer a certain period of time to exclusively sell their medication on the open market. Entities seeking to produce or sell formulations must obtain permission from the patent holder. As a result, pharmaceutical manufacturers may set high prices for their products to maximize profits due to the *de facto* legalized monopoly that the patent registration effetively creates.

Established in 1994 during the Uruguay Round of the General Agreement on Tariffs and Trade, TRIPS requires countries within the

WTO to establish domestic minimum protection standards for intellectual property products. In addition to IPRs inherited from predecessor agreements, TRIPS introduced patent protection of pharmaceuticals into the international trading system. WTO members must internalize the IPRs of TRIPS into their domestic laws to gain national jurisdiction against international intellectual property rights infringements. Developing countries not part of the WTO can potentially sell, manufacture, or make use of patented HIV pharmaceuticals without permission of patent holders. However, "special and differential treatment" as a WTO member, exemplified in technology transfer and investments from wealthy countries and preferential trading rules, attracts developing countries to join the WTO. For example, while WTO members trade amongst one another with relatively low tariffs on goods, non-WTO countries who trade with WTO members incur higher tariffs, potentially hindering domestic economic growth.

Historically, developing countries strived to become members of the WTO and established or modified domestic patent laws to adopt TRIPS IPRs in preparation. Once admitted, if the patent of a new HIV medication is filed and international valuations remain constant, prices would likely be unattainable for most national health programs in developing countries (Intellectual Property Watch, 2013). Under this framework, industrialized countries that export medications achieve legal grounds to initiate trade actions against piracy in developing countries. These restrictions, while offering intellectual protections, place remarkable burden on emerging international economies.

While international patent laws may be necessary to drive innovation, royalties drastically drive up the price of new HIV medications and put low-income patients' lives at risk. Generally speaking, the average cost of HIV treatment is $14,000 - $20,000 a year (Vann, 2009), which is more than ten years' income for people living in low-income countries (UNDESA, 2013). For instance, Uganda has one of the highest HIV/AIDS adult prevalence rates around the world (Central Intelligence Agency, 2014), but its gross national income per capita was only $479 a year in 2011 (World Bank, 2014). As such, Ugandans living with HIV are often unable to access the most effective HIV treatments.

The History of Flexibilities

With the implementation of TRIPS pharmaceutical IPRs in the

1990's, the conflict between the right to health and intellectual property intensified. In 2010, companies within industrialized countries held more than 80% of the pharmaceutical patents (Julian-Arnold & Gianna, 1993), while over 80% of people living with HIV were in developing countries (AVERT, 2011).

Increasingly, the clash between healthcare and economic development began to receive attention internationally, and on August 17, 2000, the United Nations High Commissioner for Human Rights approved a resolution on intellectual property and human rights. The resolution claimed that TRIPS did not "adequately reflect the fundamental nature and indivisibility of all human rights, including…the right to health…[t]he apparent conflicts between the intellectual property rights regime embodied in the TRIPs Agreement…and international human rights law" (United Nations High Commissioner for Human Rights, 2000). On June 27, 2001, a UN report further discussed the relationship between TRIPS and human rights, encouraging governments to take legal and administrative measures to protect human rights under the TRIPS framework (United Nations Committee on Economic, Social and Cultural Rights, 2001).

The TRIPS Agreement was reinterpreted during the WTO Doha Round (WTO, 2001) in order to explicitly deliver an international consensus that the private interest of patent rights should not go against public interest and human rights during a public health crisis. The Doha Declaration clarified the scope of TRIPS and detailed the application of its flexibilities. One of the most crucial flexibilities is compulsory licensing, which can be applied under a "national emergency or other circumstance of extreme urgency" such as "public health crises, including those relating to HIV/AIDS" (WTO, 2001*).* It allows a national government to issue licenses to domestic pharmaceutical manufacturers to produce generic versions of patent medications without the permission of patent holders.

In 2003, a permanent amendment was inserted in TRIPS allowing WTO members of least developed countries (LDCs) to import inexpensive generics made under compulsory licensing provisions (WTO, 2003). Therefore, even LDCs lacking production capacity could continue to access inexpensive medications. Kenya, an LDC, currently has 1.6 million people living with HIV out of a population of about 40 million (UNAIDS, 2014), but in 2003 only 5% of the people who needed antiretroviral treatment received it (WHO/UNAIDS/UNICEF, 2007). Following

the TRIPS amendment, the government of Kenya passed a bill to legalize the purchase of generics from other countries (AVERT, 2013). The impact was significant – in 2010, 540,000 people living in Kenya could access antiretroviral drugs (NACC and NASCOP, 2012), more than 30% of the total population living with HIV.

Implementation of Flexibilities

While LDCs enjoy unconditional application of flexibilities and are granted a transition period to defer the implementation of TRIPS on pharmaceuticals until January 2016, the transition period for other developing countries ended in January 2005. Since then, many developing countries have been urged under TRIPS guidelines to issue or protect patents for new HIV medications. China, India and Brazil are three active WTO member countries with high HIV prevalence rates. Owing to their rapidly growing national economies, the international community expects these countries to take steps to combat their HIV epidemics while adhering to TRIPS IPRs. The divergence of these countries' domestic social practices reveals how TRIPS flexibilities fail to adequately provide access to medication for people living with HIV in many developing countries.

China

In 2000, China modified its Patent Law to comply with TRIPS in preparation for joining the WTO. The Patent Law was last amended in 2008 when China fully internalized TRIPS flexibilities and exhaustively listed the grounds for initiating compulsory licensing. According to the Law, China can grant compulsory licenses to domestic pharmaceutical manufacturers or import lower cost HIV generic medications from other countries to combat the HIV crisis. In spite of a well-developed legal basis, China has not yet issued any compulsory licenses for HIV medications in practice because the country has been categorized as having low HIV prevalence (Ministry of Health of the People's Republic of China, 2012) and thereby does not qualify for compulsory licensing according to international standards. However, China's HIV epidemic is quite severe. China ranks 13th in the world in number of people living with HIV with more than half of this population living in poorer provinces (Index Mundi, 2014).

In order to provide treatment to its 780,000 people living with HIV (UNGASS, 2012), China began to provide free HIV medications to low-income communities in 2003 (Yardley, 2003). However, as TRIPS obliges all WTO member countries to grant at least 20 years of patent protection for new medications (Alikhan & Mashelkar, 2004), the Chinese government provided patients with an older generation of antiretroviral therapies. One study found that half of the patients who received these older forms of therapy did not benefit from the treatment after five years, most often due to regimen ineffectiveness or medication side effects (Zhang et al., 2009). Although the Chinese government started to provide newer medications in 2009, as of 2011 only 18,703 adults and 216 children had received them (UNGASS, 2012).

India

India has the 85th greatest HIV incidence rate yet ranks third in the world in terms of prevalence, with 2.4 million people living with HIV (Central Intelligence Agency, 2014). Having established its own generic drug industry, India exports inexpensive HIV medications to other developing countries while also selling them domestically. In 1995, when India the joined WTO and internalized TRIPS IPRs into its domestic patent laws, the Indian government chose to continue to allow generic medication production by domestic companies. While HIV medications cost $14,000-$20,000 per year in industrialized countries, Cipla, an Indian drug manufacturer, offers the medications for as low as $80 per year (Harris, 2008). As Indian patent laws support robust generic medication manufacturing to the detriment of patent protections, an abundance of pharmaceutical patent disputes initiated by foreign pharmaceutical manufacturers have arisen in Indian courts. As a result, the United States placed India on its trade blacklist (Carter & Siddiqui, 2013). Internationally, TRIPS IPRs have challenged India's efforts to promote universal access to HIV medications. Utilizing international legalities and trade agreements, the governments of pharmaceutical exporting countries have filed complaints against India within the WTO dispute settlement body. However, for a government providing universal healthcare and free HIV medication for 2.4 million people since 2004 (NACO, 2013), India should retain its proactive position of applying TRIPS flexibilities and challenging the tolerance of international patent holders.

Brazil

As a result of rapid economic growth, the international community has expected Brazil to fight HIV independently while adhering to TRIPS IPRs. Brazil provides free HIV medications for its 530,000 to 660,000 people living with HIV (UNAIDS, 2012). The Brazilian government has found it increasingly difficult to manage its budget for free HIV medications since 1997, when they became a WTO member and internalized TRIPS into intellectual property laws. To overcome challenges, in 2007, Brazil issued its first compulsory license to bypass Merck's patent on Efavirenz, a modern antiretroviral drug. This action would offer treatment to 75,000 people living with HIV and was celebrated by human rights activists, but regarded as a step backward by the U.S.-Brazil Business Council (Janeiro, 2007). The U.S.-Brazil Business Council did not support compulsory licensing for Brazil because the country is neither an LDC nor under conditions of "extreme urgency" with regard to the HIV epidemic. As there are no quantifiable definitions of "extreme urgency" or "public health crisis," Brazil used "extreme urgency" to justify its actions. Former President Luiz Inacio Lula da Silva responded to censure from international trade partners by defending the action under the name of public health, saying, "between our trade and our health, we have chosen to look after our health" (Janeiro, 2008).

Conclusion

Intellectual property rights and licensing laws stem from the ownership of ideas for profit–an appropriate concept in a generally capitalistic world. International organizations that monitor trade and offer individuals, companies, and countries protections for their intellectual and physical properties are essential in ensuring this system. Pharmaceutical patent law offers a method to protect intellectual and market interests. TRIPS flexibilities bridge international law and medical need, however, unregulated infringement would undermine incentives for new R&D projects.

Facing a public health crisis, many poor and developing economies are unable to offer their citizens available treatments and alleviate human suffering. These countries lack resources, making them vulnerable to trade systems driven purely by profit. The technicalities of policies and securing profits, however, have superseded universal access to treatment for HIV–one of the most devastating public health crises in

modern times.

Brazil's use of TRIPS flexibilities contrasts with China's inaction and, what some consider, India's patent infringements. The diversity of responses these countries have chosen demonstrates how technicalities and profit margins inhibit countries from ensuring the wellbeing of their citizens. Each exemplifies challenges faced by developing countries to apply TRIPS flexibilities under accepted WTO guidelines. The strict, yet poorly defined, TRIPS flexibilities make it difficult for many developing countries to initiate compulsory license mechanisms to address public health crises. The improbability of pharmaceutical companies foregoing their profitable patent rights on new HIV medications creates significant delays in access to inexpensive generics. Historically in WTO pharmaceutical disputes, wealthier countries, which have a disproportionate number of companies with pharmaceutical patents, resist TRIPS flexibilities to appease companies and foster economic growth. Strict TRIPS IPRs have become weapons to hinder access to HIV medicines in developing countries.

If we choose to live in a world where human rights are valued above profit, the WTO should work to encourage its member countries to protect human rights by expanding the application of TRIPS flexibilities for HIV medications unconditionally.

References

Alikhan, S., & Mashelkar, R. A. (2004). *Intellectual Property and Competitive Strategies in the 21st Century*. The Netherlands: Kluwer Law International.

Attaran, A. & Gillespie-White, L. (2001, October, 17). Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment In Africa? *The Journal of the American Medical Association,* 286(15), 1886-1892.

AVERT. (2011). *Regional Statistics for HIV and AIDS, end of 2011*. Retrieved from: http://www.avert.org/worldwide-hiv-aids-statistics.html

AVERT. (2013). *Treatment Access.* Retrieved from: http://www.avert.org/treatment-access.htm

AVERT. (2014*). Global Epidemic: Asia – HIV&AIDS in China.* Retrieved from: http://www.avert.org/hiv-aids-china.htm#footnote86_

gfxc8fa
Carter, Z., & Siddiqui, S. (2013, May 1). India's U.S. Drug Rulings Earn Trade Blacklist Spot from Obama Administration. *Huff Post – Politics.* Retrieved from: http://www.huffingtonpost.com/2013/05/01/india-us-drugs-trade_n_3196458.html
Central Intelligence Agency. (2014). *The World Factbook: Country comparison HIV/AIDS Adult Prevalence Rate (Based on 2009 Estimates).* Retrieved from: https://www.cia.gov/library/publications/the-world-factbook/rankorder/2155rank.html
Harris, G. (2008, October 31). The Safety GAP. *New York Times.* Retrieved from: http://www.nytimes.com/2008/11/02/magazine/02fda-t.html?pagewanted=all
Index Mundi. (2014). *Country Comparison: HIV/AIDS: people living with HIV/AIDS top 100.* Retrieved from: http://www.indexmundi.com/g/r.aspx?v=35&t=100
Intellectual Property Watch. (2013). *Fact Sheet: Extending the TRIPS waiver for least developed countries.* Retrieved from: http://www.ip-watch.org/weblog/wp-content/uploads/2013/02/LDC-extension-Fact-Sheet.pdf
Janeiro, R. D. (2008, July, 30). Brazil's success in AIDS fight depends on cheap drugs. *AFP.* Retrieved from: http://www.google.com/hostednews/afp/article/ALeqM5ieT0IHsJgOHEPjVBfKCZg75I\OCRQ
Janeiro, R. (2007, May 4). Brazil to break Merck AIDS drug patent. Government wants lower price on anti-retroviral medication. *NBCNEWS.* Retrieved from: http://www.nbcnews.com/id/18490388/ns/health-aids/t/brazil-break-merck-aids-drug-patent
Julian-Arnold, & Gianna. (1993). International Compulsory Licensing: the rationales and the Reality. *Idea: The Journal of Law and Technology,* 33(4), 349-400.
Ministry of Health of the People's Republic of China. (2012). *2012 China AIDS Response Progress Report.* China: Ministry of Health
Naco. (2013). *Annual Report 2012-13.* India: Ministry of Health and Family Welfare.
National Bureau of Statistics of China. (2012). *National Data:*

Population [Data file]. Retrieved from: http://data.stats.gov.cn/workspace/index?m=hgnd

NACC, & NASCOP. (2012). *The Kenya AIDS Epidemic Update 2011.* Nairoby, Kenya: Office of the President National AIDS Control Council.

SAPA-AFP. (2001, May 28). AIDS activists in Kenya launch campaign for cheap drugs bill. *South African Press Association.* Retrieved from: http://www.hst.org.za/news/aids-activists-kenya-launch-campaign-cheap-drugs-bill

Smelyanskaya, M. (2013). Funding Scientific Innovation: Global Investments in HIV Treatment Research and Development in 2010 and 2011. *Treatment Action Group.*

UNAIDS. (2010, June, 10). *UNAIDS welcomes the efforts of UNITAID towards the creation of a patent pool entity.* Retrieved from: http://www.unaids.org/en/Resources/ PressCentre/Featurestories/2010/June/20100610UNITAIDPP/

UNAIDS. (2012). *HIV and AIDS Estimates: Brazil.* Retrieved from: http://www.unaids.org/en/regionscountries/countries/brazil/.

UNAIDS. (2013). Global Report. *UNAIDS report on the global AIDS epidemic 2013.*

UNAIDS. (2014). *County Webpage of Kenya, 2012 Data.* Retrieved from: http://www.unaids.org/en/regionscountries/countries/kenya/

UNDESA. (2013, Augest). *The criteria for identifying least developed countries.* Retrieved from: http://www.un.org/en/development/desa/policy/cdp/ldc/ldc_definitions.shtml

UNGASS. (2012). *China AIDS Response Progress Report.* Retrieved from: http://www.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports/2012countries/

United Nations Committee on Economic, Social and Cultural Rights. (2001, June 27, 42nd session). *The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights*. Retrieved from: *http://www.unhchr.ch/Huridocda/Huridoca.nsf/0/5905*

16104e92e87bc1256aa8004a8191/$FILE/G0114345.pdf

United Nations High Commissioner for Human Rights. (2000, August 17, 25th Meeting). *Intellectual Property Rights and Human Rights. 2000/7.* Retrieved from: http://www.unhchr.ch/Huridocda/Huridoca.nsf/TestFrame/c462b62cf8a07b13c12569700046704e?Opendocument

Vann, M. (2009, May 13). Can you afford your HIV treatment? *Everyday Health*. Retrieved from: http://www.everydayhealth.com/hiv-aids/can-you-afford-hiv-treatment.aspx

WTO. (2001). *Doha Agenda.* Retrieved from: http://www.wto.org/english/tratop_e/dda_e/dda_e.htm

WTO. (2001, November 20). Declaration on the TRIPS agreement and Public Health. *Doha WTO Ministerial 2011: TRIPS.* Retrieved from: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.html

WTO. (2002, June 28). Council approves LDC decision with additional waiver. *The WTO 2002 Press Releases*, Press/301. Retrieved from: http://www.wto.org/english/news_e/pres02_e/pr301_e.htm

WTO. (2003, August 30). Decision removes final patent obstacle to cheap drug imports. *The WTO 2003 Press Release,* Press/350/Rev.1. Retrieved from: http://www.wto.org/english/news_e/pres03_e/pr350_e.htm

WHO/UNAIDS/UNICEF. (2007). *Towards universal access: Scaling up priority HIV/AIDS interventions in the health sector.* Retrieved from: http://www.who.int/hiv/pub/2010progressreport/report/en/

World Bank. (2014). *Country Data: Uganda.* Retrieved from: http://data.worldbank.org/country/Uganda

Yardley, J. (2003, November 8). China begins giving free HIV/AIDS drugs to the poor. *New York Times*. Retrieved from: http://www.nytimes.com/2003/11/08/world/china-begins-giving-free-hiv-aids-drugs-to-the-poor.html

Zakumumpa, H. (2012, May 4). Kenya: Court Ruling on Generic Drugs Sets Precedent for the Region. *All Africa*. Retrieved from: http://allafrica.com/stories/201205050203.html

Zhang, F., Duo, Z., Ma, Y., Zhao, Y., Liu, Z., Bulterys, M., &

Chen, RY. (2009). Five-year outcomes of the China National Free Antiretroviral Treatment Program. *Ann Intern Med.*, 18:151(4), 241-251.