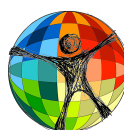


Medicine and Marginalization: How Intellectual Property Laws Provide a “Generic” Solution to a Grave Human Rights Problem



INTERNATIONAL HUMAN RIGHTS INTERNSHIP WORKING PAPER SERIES



About the Working Paper Series

The Center for Human Rights and Legal Pluralism (CHRLP) Working Paper Series enables the dissemination of papers by students who have participated in the CHRLP's International Human Rights Internship Program. Through the program, students complete placements with NGOs and tribunals where they gain practical work experience in human rights investigation, monitoring, and reporting and participate in a seminar that critically engages with human rights discourses in which they write a research paper through a peer review and support process.

In accordance with McGill University's Charter of Students' Rights, students in this course have the right to submit in English or in French any written work that is to be graded. Therefore, papers in this series may be published in either language.

The papers in this series are distributed free of charge and are available in PDF format on the CHRLP website. Papers may be downloaded for personal use only. The opinions expressed in these papers remain solely those of the author(s). They should not be attributed to the CHRLP or McGill University. The papers in this series are intended to elicit feedback and to encourage debate on important public policy challenges. Copyright belongs to the author(s).

Table of Contents

About the Working Paper Series.....	2
Table of Contents	3
Acronyms	4
Introduction	5
Part 1. Intellectual Property Laws and Inequality.....	8
I. Access to Medicines as a Human Rights Issue.....	8
II. Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)	9
III. The Doha Declaration	12
IV. Putting the Pieces Together: Trade, Patents, and Access to Medicine as a Human Rights Issue	13
Part 3. Policy Analysis	16
I. The Reality of Compulsory Licensing: An Analysis of the TRIPS Agreement and Doha Declaration.....	16
II. Pharmaceutical Industries and Access to Medicines: The Case of Uganda	20
III. Uganda's Industrial Property Bill	23
IV. Sexual Rights and Intellectual Property Rights – The Not-So Tenuous Cross-Over	27
Part 4. New Frontiers: Envisioning Access-Oriented Intellectual Property Strategies by Recasting the Debate on Intellectual Property Rights.....	30
I. Policy Recommendations	30
II. System-Based Recommendations.....	31
Conclusion	36
Bibliography	37
Legislation	37
Secondary Material: Monographs.....	37
Secondary Material: Articles	38

Acronyms

ART = Antiretroviral Therapy

EALA = East African Legislative Assembly

HRT = Hormone Replacement Therapy

IP = Intellectual Property

IPR = Intellectual Property Rights

WTO = World Trade Organization

WHO = World Health Organization

LDC = Least Developed Country

LGBT = Lesbian, Gay, Bisexual, Transgendered

QALY = Quality Adjusted Life Year

R&D = Research and Development

TRIPS = Trade Related Aspects of Intellectual Property Rights

Introduction

On the afternoon of January 26, 2011, David Kato was bludgeoned to death in his home in Kampala, Uganda. His crime? Being a gay man.

Prior to his murder, David Kato was a prominent gay rights activist in Uganda who actively fought for the rights of the LGBT community (Lesbian, Gay, Bisexual, and Transgendered). The unfortunate reality is that persons of the LGBT community face discrimination from many angles. While this phenomenon is not confined to Uganda, the African region, generally, demonstrates certain distinct issues as it relates to discrimination against LGBT persons.

While data on LGBT experiences in sub-Saharan Africa, much less Uganda, are scarce, general trends indicate that members of this group are more likely to be physically and verbally abused, encounter discrimination both in and outside the workplace, and experience mental health issues including depression, anxiety, and suicidal ideation.¹ Beyond the social milieu which marginalizes this community, the health of LGBT persons is also severely compromised as certain members of the community (particularly men who have sex with men or “MSM”) are more likely to be infected with HIV and other sexually transmitted infections (STIs) while simultaneously less able to access health care services.² The political and legislative context can further compound this situation as evidenced by the increase in the number of countries seeking to criminalize homosexuality.³ For instance, in Uganda, it is illegal under Ugandan Penal Code Act to commit an “unnatural offence”⁴

Criminalization of one’s sexual orientation can further inhibit health seeking behaviours which can reciprocally make it more difficult for service providers to deliver

¹ Wolfgang Hladick et al., “HIV Infection Among Men Who Have Sex With Men in Kampala, Uganda – A Respondent Driven Sampling Survey” (2012) PLoSOne 1 at 1-2; Phoebe Kajubi et al., “Gay and Bisexual Men in Kampala, Uganda” (2008) 12:3 AIDS Behaviour at 492.

² Paul Semugoma, Chris Beyrer, Sefan Baral, “Assessing the Effects of Anti-Homosexuality Legislation in Uganda on HIV Prevention, Treatment, and Care Services” (2012) 9:3 Social Aspects of HIV/AIDS 173 at 174-175.

³ Semugoma, *supra* note 2 at 174.

⁴ *Ugandan Penal Code Act*, 1950 Ch 120 s 145.

essential services, such as information about how to prevent the transmission of HIV and other STIs, as well as medicines, to those that need them.⁵ In a country where there is already a dearth of medical resources, this can have disastrous effects.

Given the backdrop in which David Kato worked to advance the rights of the LGBT community, his sexuality wasn't his only "crime". Arguably, being born in Uganda, a country where international rules on intellectual property dictate which goods and services will reach the population (such as essential medicines like antiretroviral therapy (ART) for HIV/AIDS) is a significant impediment to the full realization of one's rights. Already marginalized groups, such as LGBT persons, but additionally, persons with disabilities, people of lower socioeconomic status, refugees, and so on, can be driven further underground by such international laws and agreements. Thus, the attention to the social and political milieu and particulars of the domestic issues in Uganda is but one part of a complex puzzle. Another important part is the international regime within which lower-resource countries are situated.

The specific piece of the puzzle that this paper seeks to disentangle is the access to medicines issue in developing countries as it relates to intellectual property laws. The plight of LGBT groups illustrated at the beginning of this paper is meant to elucidate and humanize one specific manifestation of exclusion from gaining full access to public health resources. While there are a host of other complex issues surrounding the LGBT population in Uganda (interested readers should refer to some additional key resources provided if they would like to grasp a more thorough understanding of the issues surrounding the LGBT population in Uganda)⁶, this paper contends that the way in which agreements on international intellectual property rights (IPRs) are structured do not alone offer a solution to the problem of access to medicines (or lack thereof) in least developed countries (LDCs) such as Uganda. This is partially because "the essence of intellectual property rights is the right to exclude."⁷ We

⁵ Semugoma, *supra* note 2 at 175-176.

⁶ Sylvia Tamale "Out of the Closet: Unveiling Sexuality Discourses in Uganda" in Catherine M. Cole, Takyiwa Manuh & Stephan F Miescher, eds, *Africa After Gender* (Indiana: Indiana University Press, 2007) 17; Michael Hollander, "Gay Rights in Uganda: Seeking to Overturn Uganda's Anti-Sodomy Laws" (2009) 50:1 Va J Int'l L 219; Vasu Reddy, "Homophobia, Human Rights and Gay and Lesbian Equality in Africa" (2012) 16:50 Africa, Agenda 83; Jamila Ddamulira Mujuzi, "The Absolute Prohibition of Same-Sex Marriages in Uganda" (2009) 23:3 Int J Law Policy Family 277.

⁷ Abbe E L Brown, *Intellectual Property, Human Rights and Competition* (Northampton: Edward Elgar Publishing Limited, 2012) at 1.

can, however, turn to principles of human rights to serve as a potential source of synergy in updating the efficacy of IP laws.

This paper explores the limits of IPRs in the context of access to medicines in three parts. Each element of this paper ultimately seeks to present a case for why IPRs in the context of the access to medicines debate is a human rights issue and how the agreement on TRIPS has come up as a significant challenge to the realization of these rights, especially in the context of LDC countries such as Uganda. The first part explains and contextualizes the current debate and issues surrounding IPRs, human rights, and access to medicines. Part two then delves into an international and domestic policy analysis of key international agreements, namely, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and the Doha declaration, identifying the most problematic provisions and how they affect availability of medicines in developing countries. Additionally, the Ugandan Industrial Property Bill is analyzed in light of the TRIPS agreement and a discussion of the Ugandan LGBT community is re-examined. Finally, part three of the paper offers policy and system based recommendations in light of the preceding analysis by critically drawing upon proposals that are gaining traction as a response to the ethical issues raised by the TRIPS agreement.

Part 1. Intellectual Property Laws and Inequality

I. Access to Medicines as a Human Rights Issue

IPRs are an area of law that have not traditionally been examined in tandem with human rights law. However, a cursory overview of the data illustrates how intertwined the issues are. In a 2003 report, the WHO estimated that 30% of the world's population lacked access to essential medicines in 1999. Additionally, the UN reports that essential medicines were available for only 34.9% of public health services in 27 developing countries.⁸

On a fundamental level, the issue of access to medicines is linked to the right to health and therefore, conventional conceptions of human rights. This idea is enshrined in various manifestations in a number of international human rights tools using traditional human rights language. For instance, Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) stipulates the right to the highest attainable standard of health.⁹ Similarly, Article 25 of the Universal Declaration of Human Rights (UDHR) states,

*...everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing, and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.*¹⁰

The recognition of the right to health is found in numerous other international human rights instruments including the Constitution of the World Health Organization (WHO), the Convention on the Elimination of All Forms of Racial Discrimination (CERD), the Convention

⁸ Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Portland: Hart Publishing, 2011) at 1.

⁹ *International Covenant on Economic, Social and Cultural Rights*, 19 December 1966, 993 UNTS art 12 ILM 368.

¹⁰ GA Res. 217(III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc A/810 (1948) 71 [UDHR]

on the Elimination of All Forms of Discrimination Against Women (CEDAW), and the Convention on the Rights of the Child (CRC).¹¹

The commitment to the right to health on an international level is evidently crystallized through the sheer number of human rights instruments that have codified the right. This wide recognition of the right to health indicates a common understanding and primacy placed on health in the international community. While there are compelling debates surrounding what the “the right to health” means in more concrete terms, a common articulation of the right is that “it contains both curative and preventative aspects in order to ensure the enjoyment of this human right”.¹²

In view of the right to health as a human right, the issue of access to medicines aptly situates itself in human rights discourse. How the access to medicines debate manifests itself as a human rights *problem* is through the limits to accessing socially valuable goods, which often arises as a result of stringent IP protection.¹³ What further complicates the debate is when human rights are pitted against competing rights, such as IPRs. Rights begin to clash, and more often than not, intellectual property rights have tended to prevail. A powerful cog that has dictated how IPRs manifest themselves on the international stage and has given legitimacy to the protection of IPRs over access to medicines is the Agreement on TRIPS.

II. Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

TRIPS agreements have been posited to stem from a position of staunch protection of property rights; a position that is not particularly novel. Rewinding back to the era of John Locke, his seminal work in the *Second Treatise* conceptualizes property as a natural right and

¹¹ WHO – article 1, CERD article 5, CEDAW article 11(f) and 12, CRC article 24(1)

¹² Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Leiden: Martinus Nijhoff Publishers, 2012) at 35.

¹³ Katharina Gamharter, *Access to Affordable Medicines* (New York: SpringerWien New York, 2004) at 4-13.

a reward of labour; an idea that lends itself towards the preservation of IPRs in this day and age.¹⁴ Similarly, John Rawls' proposal of ranking rights has been argued to support IP.¹⁵

The historical legacy that has placed a premium on property rights, therefore, provides a lens through which we can understand how TRIPS agreements came to fruition. Essentially, IP laws seek to protect the rights of inventors by giving them exclusive control over intangible "creations of the mind". Ardent protectors of Intellectual Property Rights tend to echo the same idea articulated by Locke and Rawls but packaged in a new form, the essence of which is that IPRs are a natural right and nobody should be able to copy one's inventions.¹⁶

This line of thinking brings us to the Agreement on TRIPS. In 1995, the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) entered into force for the Members of the World Trade Organization (WTO).¹⁷ This Agreement outlines the minimum standards for intellectual property rights protection for WTO Members. The Agreement on TRIPS was created with the intent to globally increase incentives to invest in the research and development of new ideas and technology.¹⁸ Furthermore, the TRIPS agreement compels all member countries to protect IPRs in all fields with respect to both the processes and the products. Non-compliance is subject to the WTO's dispute settlement mechanism, which may lead to trade sanctions.¹⁹

The TRIPS Agreement provides a degree of flexibility with respect to how certain countries may formulate their national IP laws and industrial or public policies in order to uphold their TRIPS obligations. These "TRIPS flexibilities" are the explicit and implicit provisions of the TRIPS Agreement that "allow developing countries and least developing countries (LDCs) to adopt measures necessary to protect things surrounding public health and to promote public interest in sectors of vital importance to their socio-economic and

¹⁴ John Locke, *Two Treatises of Government* (London: Black Swan, 1690) book II.

¹⁵ Yamane, *supra* note 8.

¹⁶ Gamharter, *supra* note 13 at 7.

¹⁷ World Trade Organization, *TRIPS Work in the WTO*, online: WTO <http://www.wto.org/english/tratop_e/trips_e/trips_e.htm>

¹⁸ Yamane, *supra* note 8, at 1.

¹⁹ *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, 15 April 1994, 33 I.L.M. 1143, online: The Trading Floor <<http://trading.wmww.com/gatt>> at 1197, Annex IC: *Agreement on Trade-Related Aspects of Intellectual Property Rights [TRIPS Agreement]*.

technological development.”²⁰ I would contend that the flexibilities provided by TRIPS that are of particular interest as they relate to access to medicines in developing countries are:

- (1) Transition Periods²¹: LDCs are not obliged to implement the provisions of the TRIPS agreement on pharmaceutical products (and therefore are not required to enforce IPRs) until January 1, 2016. LDCs may be granted extensions of this transition period if they have not built a viable technological base by the deadline.
- (2) Compulsory Licensing²²: The government can authorize a third party to produce a patented invention without the consent of the patent holder. Often, the third party will charge less than the patent holder. However, this flexibility requires that the holder of the compulsory license produce strictly for the domestic market.
- (3) Parallel Importation²³: Parallel importation gives governments the right to import drugs, without the authorization of the patent holder, from countries where the cost is cheaper. This situation arises when a patent holder sells its drugs at substantially different prices in different countries and where this product has been marketed by the patent holder or in another legitimate manner.
- (4) The Bolar Provision²⁴: The Bolar provision allows competitors to prepare to produce a patented medicine before a patent expires.

These flexibilities will be explored in greater detail in the policy analysis section.

However, it is worth noting for now how these TRIPS flexibilities attempt to address the unique needs of low resource settings in providing goods for their population and how the philosophical underpinnings of IPRs can potentially inhibit that attempt at equalization.

²⁰ Centre for Health Human rights and Development, *Intellectual Property and Human Rights: A Pocketbook for Journalists* (Kampala: KIOS, 2012) at 13 [CEHURD Pocketbook].

²¹ TRIPS Agreement, *supra* note 19, art. 66.1.

²² *Ibid* at art. 31(f).

²³ *Ibid* at art. 6.

²⁴ *Ibid* at art. 30.

III. The Doha Declaration

At the fourth WTO Ministerial Conference, which took place from November 9 to 11 2001 in Doha, Qatar, The Declaration on the TRIPS Agreement and Public Health was adopted. The Doha Declaration was adopted as a response to bewilderment among some governments with respect to how they could interpret the flexibilities contained with the TRIPS Agreement. Thus, the Doha Declaration was drafted as an attempt at encouraging governments to utilize TRIPS flexibilities and also acknowledging the unique sphere in which patents, pharmaceuticals, and public health situate themselves on the trade agenda. The culmination of these ideas is perhaps best illustrated with the statement in the Doha Declaration that says, "TRIPS Agreement does not and should not prevent members from taking measures to protect public health."²⁵

The WTO ministers emphasized that states should use the flexibilities included in the TRIPS Agreement, particularly compulsory licensing so that countries unable to produce pharmaceuticals domestically can import patented drugs made under compulsory licensing.²⁶ The Doha Declaration was a particularly important step for the advancement of the health agenda in the area of trade. The Ministers recognized "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"²⁷ and stressed "the need for the WTO TRIPS Agreement to be part of the wider national and international action to address these problems"²⁸ The Declaration went even further, and laudably, acknowledged the problem of access to medicines by "expressing the concern that patents have an impact on prices, while recognizing that IP protection is important for the development of new medicines."²⁹

²⁵ Yamane, *supra* note 8 at 305.

²⁶ Andrew Law, *Patents and Public Health* (Munich: Munich Intellectual Property Law Center, 2008) at 21.

²⁷ WTO, *Doha WTO Ministerial Declaration*, WTO Doc. WT/MIN(01)/DEC/1 (2001), 41 I.L.M. 746, para 1 [*Doha Declaration*].

²⁸ *Ibid* at para 2.

²⁹ Yamane, *supra* note 8 at 306.

IV. Putting the Pieces Together: Trade, Patents, and Access to Medicine as a Human Rights Issue

Given the unique puzzle formed by the interlocking pieces of trade agreements, intellectual property laws, and human rights, the access to medicines issue presents itself as one that largely hinges on two key ideas: monopoly and protection. This is perhaps best exemplified by Article 28 of the TRIPS agreement that sets out the minimum rights that each WTO member must grant to a patentee. These rights include the right to exclude third parties from carrying out the following actions in relation to a patented invention: making, using, offering for sale, selling or importing.³⁰ Furthermore, the TRIPS Agreement confers monopoly rights to a patent holder for a minimum of twenty years. These monopolistic rights bestowed upon patent holders enable them to charge prices well above the marginal cost of production.³¹ Even beyond patents, stringent IPR protection, generally, can halt access to new knowledge, limit production, keep prices high, and restrict access to new products in developing and least developed countries.

The puzzle becomes more complex with the introduction of generic drug manufacturers. Generic drugs are those that contain the same active ingredient and chemical make-up of their brand-name counterparts but are usually not associated with the particular company that makes the brand-name version of the drugs. Generic drugs can appear on the market once monopoly rights of the patent-holder expire (as previously mentioned; often after 20 years, but it can be longer). Generic drugs tend to be much cheaper simply because their manufacturers do not have to incur the expenses of actually developing and marketing a new drug. When a pharmaceutical company brings a new drug onto the market, a substantial amount of money is expended on its research, development, marketing and

³⁰ TRIPS Agreement, *supra* note 19, art. 28.

³¹ Marumo Nkomo, *The WTO Medicines Decision in Light of its Utilization: Resolution or Resignation?* (Berlin: Lambert Publishing, 2010) at 12.

promotion. Thus, the patent gives the company that developed the drug an exclusive right to sell the drug as long as the patent is in effect.³²

Since generic drugs are essentially copies of brand name drugs, their producers can produce the drugs without having to incur the startup costs associating with the development of the drug.³³ Thus, they can sell them for much cheaper, sometimes almost 50% less than the cost of brand-name drugs; an asset that is particularly appealing for developing countries.³⁴ However, since exclusive rights are conferred to patentees, generic producers of medicines are excluded from the market for benefit of pharmaceutical companies who are often the originators and holders of patents on essential medicines. In fact, the vast majority of patents are held by US, Japan and various European countries.³⁵

Generic medications, therefore, are a key piece of the puzzle in access to medicines issues, especially in developing countries. For instance, over 90% of HIV/AIDS medicines in Uganda are produced by generic manufacturers.³⁶ TRIPS agreements, despite their flexibilities, grant extensive patent rights to pharmaceutical companies which subsequently prevent developing countries from producing or buying generic drugs. The problem is particularly exacerbated when examining the contradictory duality between newly patented drugs that are often essential but at the same time unaffordable for poor people in countries that are disproportionately affected by certain diseases such as HIV/AIDS, TB, and Malaria. For example, the cost of an ARV drug therapy in developed nations can easily exceed \$30 a day when three billion people live on less than two dollars a day.³⁷

An example of the detrimental effects that this sort of a monopoly can have in the context of access to medicines can be found in the case of South Africa. In 1998, South Africa implemented the *Medicines Amendment Act no. 90 of 1997*.³⁸ This Act attempted to

³² Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (New Delhi: Oxford University Press, 2005) at 15.

³³ Xiong, *supra* note 12 at 81.

³⁴ *Ibid* at 129.

³⁵ Nkomo, *supra* note 31 at 14.

³⁶ *CEHURD Pocketbook*, *supra* note 20 at 2.

³⁷ Carsten Fink, "Intellectual Property and Public Health: The WTO's August 2003 Decision in Perspective" (2003) World Bank Note 191 at 191.

³⁸ *Medicines Amendment Act no. 90 of 1997*

use legislation that made compulsory licensing a genuine policy tool in an effort to reconcile public health needs with TRIPS obligations. The result was that 41 of the biggest pharmaceutical companies brought a case against the South African government saying the law was a violation of article 31 of the TRIPS Agreement.³⁹ Ultimately yielding to public pressure, the pharmaceutical companies dropped the lawsuit. However, the case provides an example of the palpable resistance by “big pharma” against TRIPS flexibilities or measures taken by countries to expand access to essential medicines at the cost of undermining patents.

While the WTO has been lauded for circumventing the stringencies of IPR regulation through the TRIPS agreement flexibilities, there are still a number of problematic provisions that inhibit it from its full realization. The next part of this paper will undertake a policy analysis highlighting the most problematic provisions associated with the TRIPS Agreement and Doha Declaration and how they manifest themselves on a domestic level in Uganda.

³⁹ Doctors without Borders, *South Africa: Big Pharma Backs Down*, online: Doctor's Without Borders <<https://www.doctorswithoutborders.org/publications/ar/report.cfm?id=1204>>

Part 3. Policy Analysis

The proceeding section will provide an analysis of the relevant provisions of the TRIPS Agreement and Doha Declaration, which will then be used as a lens through which to examine the situation legal landscape in Uganda. In particular, the problematic aspects of Articles 30 and 31 of the TRIPS Agreement which relate to compulsory licensing schemes will be explored in light of mandates put forth by the Doha Declaration.

I. The Reality of Compulsory Licensing: An Analysis of the TRIPS Agreement and Doha Declaration

Article 31 of the TRIPS Agreement – “Other Use Without Authorization of the Right Holder” - is perhaps the most interesting aspect of the Agreement as it elicits a number of legal, policy, ethical, and human rights issues when applied in the access to medicines debate. Essentially, Article 31 stipulates requirements around the issuance of compulsory licenses (which, as stated in section 2(II) of this paper, refers to the authorization of a third party to produce a patented invention without the consent of the patent holder). It is interesting to note that the language of the TRIPS Agreement does not explicitly refer to “compulsory licenses” but, rather, uses the following phrasing to describe the concept: “Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government.”⁴⁰

Article 31 was among the most intensely negotiated provisions of the TRIPS agreement perhaps due to the disputed role of compulsory licenses in making available patented inventions at more competitive prices.⁴¹ On an academic level, there is a significant body of literature that strongly argues that compulsory license have a negative impact on the

⁴⁰ TRIPS Agreement, *supra* note 19, art. 31.

⁴¹ Law, *supra* note 26 at 124.

research and development of pharmaceutical companies.⁴² Conversely, other advocates promote the position that compulsory licenses should be considered an indispensable component of patent laws, especially in developing countries.⁴³

While WTO Members can determine the grounds on which compulsory licenses are issued, there are, however, several restrictions on compulsory licences.⁴⁴ First, these licences cannot be exclusive. This means that compulsory licences must be granted on the same terms for all parties who seek one. Second, production under the compulsory licenses can only be for domestic markets. Third, “adequate remuneration” must be paid to the patent-holder, taking into account the ‘economic value’ of the patent.⁴⁵ Furthermore, before a compulsory license can even be obtained, the party must first attempt to acquire a voluntary licence from the patent holder on “reasonable commercial terms”.⁴⁶ An exception to the voluntary license acquisition requirement is provided in the case of a national emergency.

Perhaps the most serious concern that arises from Article 31 is the second restriction mentioned above; production only for domestic markets. Quite simply, the developing countries that could most benefit from compulsory licensing are also the ones who lack the technological capacity for domestic production of drugs. This renders the compulsory licensing scheme largely inadequate at addressing the access to medicines issue. This is further compounded by an idea posited by O’Carroll, whereby “these medicines could not be obtained from another country under a compulsory licence because the stipulations in Article 31 would prevent another country from issuing a compulsory licence for the manufacture of medicines for export.”⁴⁷

The Doha Declaration takes into account the needs of developing countries that lack manufacturing capacity and attempts to accommodate that deficiency. This idea is encompassed in paragraph 6 of the Doha Declaration, which reads,

⁴² *Ibid.*

⁴³ Gamharter, *supra* note 13 at 97.

⁴⁴ *Ibid.*

⁴⁵ *TRIPS* Agreement, *supra* note 19, art. 31(j).

⁴⁶ Sorcha O’Carroll, “Importing Indian Generic Drugs Following TRIPS: Case Studies from Zambia and Kenya,” Online: <www.law.utoronto.ca/documents/ihrp/HIV_Ocarroll.doc>

⁴⁷ *Ibid* at 4.

*We recognise that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council...*⁴⁸

The corollary of the Article 31 and Paragraph 6 problem, therefore, extends beyond what has traditionally been viewed as the problem with respect to compulsory licensing, that is, encouraging countries to utilize the provision. The lack of domestic pharmaceutical manufacturing capacity is at the root of the problem, yet the solution to this particular issue is circumvented by the Declarations and Agreements (or at least relegated to the rhetoric of “finding an expeditious solution to the problem”.) While the Doha Declaration acknowledges this conundrum in Paragraph 6, the philosophical problems of compulsory licensing under the TRIPS agreement persist. Thus, the question arises; what good are compulsory licences for the domestic production of domestic medicines if there are no pharmaceutical companies to create them?

The Doha Declaration also sought to remedy the other problematic requirement of compulsory licenses; the requirement of a state to first seek a voluntary license. Paragraph 5(3) of the Doha Declaration recognises the rights of member states to grant compulsory licences, and to determine the grounds on which they grant such licences.⁴⁹ Paragraph 5(3) states,

[e]ach member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to

⁴⁸ *Doha Declaration*, supra note 27 at para 6.

⁴⁹ *Ibid* at para 5(1).

*HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.*⁵⁰

This revision of Article 31 of TRIPS gives member states room for flexibility to determine when they are experiencing an emergency without having to declare a full-fledged state of emergency in order to tap into the compulsory licensing provisions.⁵¹ It would be interesting to see countries tap into this provision by strategically framing their public health problems through the lens of an emergency in order to gain access to the benefits afforded by Article 31. For instance, would a high prevalence of anxiety disorders in a state qualify as a “national emergency” given the amorphous nature of mental health illnesses compared to diseases with a more obviously manifested pathology like HIV/AIDS? Similarly, would the WTO be open to construing high morbidity rates from chronic diseases such as diabetes as a national emergency? The open-ended nature of this provision alludes to a potentially useful avenue through which states can frame their public health issues in order to gain access to the benefits of compulsory licensing.

In sum, the compulsory licensing scheme reflects the general spirit of TRIPS, particularly the balance of rights and obligations, the promotion and protection of technology and knowledge, the relationship between users and producers of technological knowledge and the social and economic impact of these issues against the backdrop of public health. Despite the aforementioned problematic areas of TRIPS, it is noteworthy to mention that the TRIPS agreement brought IPRs to become part of the WTO. Arguably, it achieved 3 major landmarks in international IP protection. First, it set minimum standards for the protection of 7 categories of IPRs including patents. Second, it requires WTO Members to provide effective procedures and remedies for the enforcement of IPRs through the normal civil judicial process including criminal procedures in certain circumstances. Third,

⁵⁰ *Ibid* at 5(3).

⁵¹ Jerome H. Reichman, “Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under TRIPS and an Overview of the Practice in Canada and the United States of America” (Case Study for UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, 2002) Online: <http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf>.

TRIPS made relevant IPRs subject to the WTO's Dispute Settlement Understanding. This was of great importance to the pharmaceutical industry, which had become disillusioned with the World Intellectual Property Organization (WIPO) as a forum from which their governments could guarantee effective international protection of IPRs.⁵²

II. Pharmaceutical Industries and Access to Medicines: The Case of Uganda

Given the framework and contested contours of the compulsory licensing scheme, as it is set out in the TRIPS agreement and modified in the Doha Declaration, it is worth analyzing how the agreement manifests itself "on the ground" in developing countries and LDCs. Uganda presents a particularly interesting example of a least developed country significantly impacted by the TRIPS agreements, especially in light of its social, economic and public health landscape. A cursory overview of population data reveals the substantial constraints within which the TRIPS and Doha agreements operate.

Millions of people in Africa continue to die of preventable and treatable diseases such as malaria, tuberculosis and HIV/AIDS.⁵³ In Uganda, between 70,000 and 110,000 people die from malaria yearly and the HIV prevalence rate is situated at 7.3%.⁵⁴ This is juxtaposed against the rampant poverty in the country. According to national household survey data, 38% of the Ugandan population lives below the poverty line and this figure is even higher in rural communities.⁵⁵ The cumulative effect of a large public health burden and a sizeable poor population (two groups that tend to overlap) precipitates a problem whereby the people who have the greatest need for medicines for preventable diseases are often the same ones least able to afford them. Even though the cost of antiretroviral therapy (ART) has

⁵² Abbe, *supra* note 7 at 25.

⁵³ USAID 'Fighting Malaria in Africa: US to sponsor low-cost mosquito net program in Uganda' (2006), Online: <<http://www.usaid.gov/press/releases2006/pr06425.html>>

⁵⁴ *Ibid.*

⁵⁵ Ben Twinomugisha, "Implications of the TRIPS Agreement for the Protection of the Right of Access to Medicines in Uganda" (2013) 2 Malawi Law Journal 253 at 255.

decreased in recent years, the price of treatment is still unaffordable for most Ugandans.⁵⁶ In fact, by 2005, slightly over 50% of the people in need of ART were able to access them.⁵⁷

The seemingly bleak portrait of Uganda is, unfortunately, not one that is particularly unique and echoes within other least developed countries in the East African region such as Malawi and Rwanda. The capacity of Uganda and other similar LDCs to make medicines more accessible to its population is partly constrained by the international trade regime.

As alluded to in section 3(l) of this paper, at the heart of the access to medicines issue is the underdeveloped technological base that is simply incapable of domestically manufacturing the drugs required by the population. This challenge equally applies in Uganda. For instance, in 2007, out of the 210 patents that were registered in the African Regional Intellectual Property Organization (ARIPO), 6 patents were filed from Uganda and of those, only 1 was registered, according to the Uganda Registration Services Board (URSB)⁵⁸.

Table 1. Industrial Property Rights Statistics for Uganda 2003-2007 (URSB)

		2003	2004	2005	2006	2007
Trademarks	(reg)	811	947	1078	1123	629
Patents	National (app)	5	12	3	11	6
	PCT (reg)	0	1	0	0	1
	ARIPO (reg)	312	409	473	451	210
Utility Models	(reg)	0	3	0	2	0

(reg) = registered, (app) = applications Figures - for 2007 are up to July 26, 2007

So, what does the technological infrastructure in Uganda look like? The country has only six active pharmaceutical manufacturing companies with significantly limited capacities.⁵⁹ It was only very recently that one pharmaceutical company, Quality Chemicals Ltd., in cooperation with Indian generics pharmaceutical company, Cipla, commenced domestic production of generic drugs for high burden diseases.⁶⁰ In 2007, Quality Chemicals

⁵⁶ USAID, *supra* note 53.

⁵⁷ *Ibid.*

⁵⁸ Reproduced by Mart Leesti & Tom Pengelly, *Technical and Financial Co-Operation Needs for Implementation of the WTO TRIPS Agreement in Uganda* (Needs Assessment Report, Ministry of Tourism, Trade and Industry, 2007: International Center for Trade and Sustainable Development).

⁵⁹ Twinomugisha, *supra* note 53 at 274.

⁶⁰ *Ibid* at 275.

Limited set up a pharmaceutical plant in Kampala, Uganda to produce ARTs for the domestic market and eventually for export to the East African region and beyond. In February 2009, the plant started producing the antimalarial drug, Lumartem.⁶¹ This success exists against the backdrop of the fact that over 90% of the drugs consumed in Uganda are still imported, of which 80% are generics.⁶²

The development of Uganda's own local manufacturing of drugs will inevitably be a long process that will require supplemental assistance to meet the public health demands of the country. While the success of Quality Chemicals is laudable, it is rare. Potential manufacturers are generally reluctant to invest in pharmaceutical production in countries like Uganda due to the absence of a viable domestic market, lagging development, and poor infrastructure.⁶³

These issues are further compounded by the fact that Uganda does not yet have a comprehensive, integrated national IP policy and legal framework. Some laws have been passed, such as the Copyright and Neighbouring Act 2006 and the Trademarks Act, 2010, and very recently, the Industrial Property Bill, while others are still being debated, including the Plant Variety Protection Bill, Trade Secrets Bill, Geographical Indications Bill, Competition Bill and the Counterfeit Bill.⁶⁴

Uganda's Industrial Property Act was passed in August 2013 and is TRIPS-plus, that is, it unnecessarily goes over and above the minimum required standards in protecting IPRs. Interestingly, Uganda's Industrial Property Act contains extensive IP protections and is coupled with the failure to utilize the flexibilities that the TRIPS Agreement offers LDCs. In light of the aforementioned issues, particular provisions from this Bill will be de-constructed in the next section through the lens of TRIPS, Doha, and the access to medicines debate. However, it is important to note that the Industrial Property Act was passed a few weeks before the completion of the research and authoring of this paper. The provisions that will

⁶¹ UNAIDS, *Implementation of TRIPS and Access to Medicines for HIV after January 2016: Strategies and Options for Least Developed Countries* (2011) at 6.

⁶² *Ibid* at 6.

⁶³ Twinomugisha, *supra* note 53 at 255.

⁶⁴ Memorandum from Health Civil Society Organizations to Ugandan Parliamentarians [nd] *Effect of Industrial Property Bill of 2009 on Access to Medicines by Ugandans* [unpublished] [*Memo from CSOs*].

be detailed below are based on an analysis of the Bill, not the Act, as it is not currently publicly available.

III. Uganda's Industrial Property Bill

The TRIPS-plus nature of the Industrial Property Bill (hereafter, "the Bill") has triggered wide spread criticism and scrutiny by civil society, academics, and policy makers. The Bill contains provisions on compulsory licensing, parallel importation, and transition periods which were identified in section 3(i) of this paper as TRIPS flexibilities with a significant source of utility for least developed countries in maximizing their ability to uphold TRIPS provisions and provide essential medicines to their populations. The manifestation of how Ugandan lawmakers envisioned these obligations into domestic laws will be analyzed in turn.

Compulsory licensing as it is currently regulated under the Bill presents perhaps the greatest obstacle to the full realization of IPRs and access to medicines in Uganda. The Bill requires an application to the court in order to grant a compulsory license, thus setting up a system that would require an unnecessarily lengthy court process and a corresponding delay in issuing a license.⁶⁵ The procedure of obtaining a remedy from the court is often expensive, labour-intensive, overly technical, and excessively bureaucratic with respect to application requirements.⁶⁶ To compound the situation, Article 60 1(1) of the Bill enables courts to fix the terms of compulsory licenses.⁶⁷ Article 63(2a) goes on to enable the court to dictate "remuneration which is equitable with due regard to all the circumstances of the case, including the economic and social value of the license."⁶⁸ The upshot of courts dictating the actual terms of compulsory licensing has the potential to be disastrous, most likely because of the subsequent lack of predictability that would follow suit in determining remuneration on an *ad hoc*, litigated basis.

⁶⁵ *Uganda Industrial Property Bill of 2009*, No. 5, art. 61(1). [*Industrial Property Bill*].

⁶⁶ Twinomugisha, *supra* note 53 at 270.

⁶⁷ *Industrial Property Bill*, *supra* note 65, art. 61(1), 61(2).

⁶⁸ *Industrial Property Bill*, *supra* note 65, art. 63(2a).

In response to challenges presented by the Bill's stringent requirements for compulsory licensing, Uganda's civil society has taken an active role in advocating for reform of the Bill's problematic provisions through the creation of model provisions, lobbying the government, and advocacy work. As part of my consultative work with the Centre for Health Human Rights and Development (CEHURD), a not-for profit advocacy and strategic litigation organization in Kampala, lobbying efforts from the joint efforts of both civil society and coalitions of non-governmental organizations have demonstrated modest returns on pushing for reform on the Bill.

With respect to compulsory licensing, CEHURD, along with the Coalition for Health Promotion and Social Development (HEPS) has posited, first, that compulsory licensing should be managed not through the courts, but rather, through an administrative process. This would simplify and expedite the process, and therefore, those "who can produce particular products enter the market to either increase supplies or offer lower supplies as quickly as possible."⁶⁹ In fact, taking compulsory licensing out of the courts appears to be standard practice in many other countries.⁷⁰ For the case of Uganda, CEHURD suggests that the compulsory licensing system for pharmaceuticals would operate optimally if the Ministry of Justice in consultation with the Ministry of Health administered it.

On the issue of remuneration in compulsory licensing, policy advocates have posited that pre-determined remunerations should be created under the auspices of a schedule or annex.⁷¹ In fact, Ben Twinomugisha, a prominent Ugandan scholar in the area of IPRs remarks that "establishing the remuneration should not be overly complicated or bureaucratic as this would undermine the primary goal of compulsory licensing-enhancing availability and access to medicines."⁷²

A provision for parallel importation is also provided for in the Bill. Given Uganda's current landscape for pharmaceutical innovation (or lack thereof), it is likely that parallel

⁶⁹ Twinomugisha, *supra* note 53 at 274.

⁷⁰ Law, *supra* note 26 at 186.

⁷¹ *Memo from CSOs* *supra* note 64 at 2.

⁷² Twinomugisha, *supra* note 53 at 171.

importation may serve the short-term interests of efficiently disseminating affordable medicines more widely than compulsory licensing schemes. Despite the utility of parallel importation, the Bill provides for a restricted form of the TRIPS provision. As noted in section 3(i), the TRIPS Agreement does not prohibit parallel imports nor does it require authorization from the patent holder. Article 43(2) of the Bill, however, unnecessarily goes above and beyond the TRIPS flexibility and requires that the express consent of the patent owner be obtained before parallel importation can be implemented.⁷³ In order to respond to this particular gap in the bill so that Uganda can fully capitalize on the benefits of parallel importation, the recommendation would be to simply allow the widest possible scope to parallel importation such that consent (a requirement not even dictated by TRIPS) would no longer serve as an unnecessary obstacle to importation.

Finally, while the Bill provides for LDC transition periods and the implementation of TRIPS provisions for pharmaceutical products in 2016,⁷⁴ it does not provide a mechanism for Uganda to directly seek an extension for this period from the TRIPS council under Article 43(2). What this effectively translates into is that patents on pharmaceutical products will not have to be implemented in Uganda until January 1, 2016. Upon the arrival of this date, Uganda must start enforcing its patents. This would mean that all generic manufacturing and importation of these drugs would need to cease by 2016. Keep in mind that generic manufacturers produce over 90% of the ARTs in Uganda and similarly high proportions of essential medicines in the country. In light of this, a particularly bleak picture emerges given the time constraint required to both develop the viable technological base needed to start producing brand-name medicines *and* begin importing expensive patented medicines. In order to combat the issue arising from the Bill's desire to opt out of further enacting TRIPS Extension periods, CEHURD has proposed the following provision on transition periods displace the current version in the Bill:

⁷³ *Industrial Property Bill*, supra note 65, art. 43(2).

⁷⁴ See section 3(II) for an explanation

*The bill should expressly provide under section 8 (3) that pharmaceutical products are excluded from patent protection until 1st January 2016 or such other date as may be extended in the future. The bill should under section 28 (13) and (14) indicate that applications for pharmaceutical products should only be filled after 1st January 2016 or such other date as may be extended in the future.*⁷⁵

If Uganda chooses to opt out of the TRIPS transition period flexibility, the chilling effect in the post 2016 era will affect access to medicines directly, as many Ugandans are already unable to afford medicines at existing prices. Less directly, it will also hinder the facilitation of independent research to produce drugs locally as the current capacities set up in Uganda, such as the Cipla partnership, heavily rely on capacity building to strengthen generic medicine production which takes time, investment, and mentorship.⁷⁶

Despite being passed into law, there is widespread reluctance towards accepting the Industrial Property Act in its current form by a myriad of actors. As a representative of the civil society movement on the issue, I worked closely with the Ugandan delegates to the TRIPS Council to lobby for flexibilities for Uganda and other LDCs on the WTO forum. There has also been a great deal of movement on other provisions of the Bill. The East African Legislative Assembly (EALA), in particular, has been formative in mobilizing a response against the problematic WTO provisions. In May 2013, EALA expedited the passing of a resolution urging the WTO to extend the TRIPS flexibilities for all LDC countries. This particular intergovernmental organization will likely be tapped into as a regional resource for pressuring the appropriate Ugandan Ministries on the pitfalls of the current Bill and its TRIPS-plus provisions.

⁷⁵ CEHURD, “Model Provisions to Promote Access to Affordable Medicines in the Industrial Property Bill 2009” [Unpublished].

⁷⁶ UNAIDS, *supra* note 61 at 6.

Whether the criticisms of Uganda's Industrial Property Bill detailed above will be taken into account by legislators remains to be seen. A great deal of work has been done to garner and cultivate the interest of key actors, even during my short time in Uganda. The effects of a poor law will not manifest immediately. Rather, a slow corrosion over a period of time will intensify an already dire situation. The result may ultimately be one where Uganda will have relinquished its responsibility under the right to health to ensure the access to essential medicines to the poor and vulnerable groups.

IV. Sexual Rights and Intellectual Property Rights – The Not-So Tenuous Cross-Over

I just want to live a normal life, but I can't. I haven't been accepted by anyone since the day I stepped foot on this earth. Even if I could fully live as a woman, which I can't, my society would cripple me. I think...maybe...I could get over the scars society has inflicted on me, but if I can't live as a woman, I don't know how I'll be able to find meaning in my life and the things I do.

- Alexis, Transgendered woman⁷⁷

The opening of this paper began with a cursory presentation of the LGBT community. To some, the presentation of this particular group in relation to the access to medicines debate, IPRs, and trade may initially appear to have a tenuous connection. However, upon hearing the first hand accounts of members of this community through my work in a focus group with the LGBT community in Kampala, Uganda, the interrelated nature of these issues becomes apparent.

The access to medicines debate has been largely framed through the narrative of the exigency of supposedly daunting lethal diseases, such as HIV/AIDS, malaria, and tuberculosis; diseases the global west has grown to sympathize for and pledge

⁷⁷ Name has been changed to respect anonymity

commitments. However, the access to medicines debate actually transcends these issues. The quote above illustrates the plight of Alexis, a transgendered woman from Uganda. For her, gender re-assignment surgery is a dream that she has wished for since she first realized there were medical options to correct the mismatch in her gender identity and sex. Part of the transitioning process for many transgendered men and women includes hormone replace therapy (HRT), whereby sex hormones are administered for the purpose of precipitating secondary sexual characteristics. In the case of Alexis, Estrogen is part of her HRT regimen.

For others in the LGBT community in Uganda, the ability to access to health care services is also severely impaired by attitudes surrounding the group. Paradoxically, it is this particular group that is also more likely to require attention to specific health issues, such as mental health issues (studies show that LGBT people suffer from depression, anxiety and suicide at higher rates than the general population), higher rates of substance use and abuse, and high rates of STIs (including, HIV, syphilis, gonorrhea, chlamydia, and trichomoniasis, to name a few).⁷⁸ LGBT persons are a diverse group in their experiences of health and well-being, but unfortunately, find common ground in the increased health risks arising from social marginalization and the stress of coping with prejudice and discrimination.

Seeking out medical resources to obtain HRT, gender re-assignment surgery, and general support for a transgendered woman in Uganda is tough as it is. The social and political milieu, which already disadvantages the LGBT community from living fully, is entangled with the paucity of resources that inhibits medicines perceived as less pressing in the LDC context (such as estrogen for transgendered persons) from widely entering the market. In fact, in a study by the WHO, researchers found that only 55% of medicines classified as “essential” were available in Uganda.⁷⁹ While data is unavailable on the issue, one can surmise that for Ugandans seeking treatment outside of the essential medicines categories, the situation is likely much bleaker. The access to medicines debate, therefore, is

⁷⁸ Hladik, *supra* note 1 at 495.

⁷⁹ World Health Organization & Uganda Ministry of Health, “Access to and Use of Medicines by Households in Uganda” (2008) Ministry of Health, online: <<http://apps.who.int/medicinedocs/index/assoc/s16374e/s16374e.pdf>>

not confined to the images of the poor, rural LDC populous. Its implications extend further and wider.

The story of Alexis and the Ugandan LGBT community is just one example of a group that stands to be significantly impacted by the Ugandan Industrial Property Bill's overzealous application of TRIPS provisions. The LGBT community exemplifies a very specific facet of the access to medicines debate; it demonstrates the wider impact of how policies can limit access to medicines beyond the narrowly defined groups traditionally thought to be the sole victims of such policies. If basic medicines can't be provided, then medicines for the less prevalent but equally devastating issues will have even less chance of reaching the populous, especially in light of Uganda's struggle to manufacture its own medicines, generic or otherwise.

Perhaps the plight of Alexis and the LGBT community, broadly, can shed light on the far-reaching nature of the access to medicines debate in Uganda and LDCs, generally. The groups that these IPR policies will end up hurting the most are often the ones who are already significantly disadvantaged. Whether it is the transgendered woman seeking to reconstruct her gender identity in Kampala or a rural farmer suffering from TB in Northern Uganda, the full realization of one's health has effectively become a competing interest against the protection of IPRs on the international forum.

Part 4. New Frontiers: Envisioning Access-Oriented Intellectual Property Strategies by Recasting the Debate on Intellectual Property Rights

This final section seeks to re-envision international IP laws through a series of policy-based and system-based recommendations. The policy based recommendations will speak to specific aspects of the TRIPS Agreement and suggest modifications to existing provisions or the introduction of new provisions that would enable these international agreements to operate in a more equitable manner. The system-based recommendations seek to present more holistic arguments seeking system-wide reform by using human rights arguments as a backdrop through which traditional notions of IPR protection can be challenged. Cumulatively, the recommendations seek to address the challenges posed to developing countries and LDCs by the problem of access to medicines.

I. Policy Recommendations

Both the parallel importing and compulsory licensing provisions espoused by TRIPS have been highlighted in this paper as serving a great source of potential for alleviating the access to medicines burden in LDCs. However, certain structural constraints have inhibited the dual provisions from realizing their full potential. While states sign on to the TRIPS agreement, it is peculiar that implementing compulsory licensing into domestic legislation is not mandatory. Rather, it is written as an option. The result, as one author notes, is that “only five jurisdictions that have the pharmaceutical capacity to be exporting countries under compulsory licensing have actually made progress on implementing these measures into their domestic legislation.”⁸⁰

⁸⁰ Junaid Subhan, “Scrutinized: The TRIPS Agreement and Public Health” (2006) McGill J Med 152 at 158.

Arguably, mechanisms such as compulsory licensing have very little public health utility if the only nations that adopt these provisions are the ones with capacity constraints.⁸¹ Paradoxically, LDCs can only benefit from compulsory licensing “if more developed nations enact it into their own legislation.”⁸² While parallel importation is similarly worded as an option rather than an obligation, it is not contingent on the cooperation of other states to operate. In light of the analysis on compulsory licensing, the central policy recommendation presented in this paper is that compulsory licensing should be made an obligation rather than an option.

On its own, this policy maneuver (making compulsory licensing an obligation) will not address the myriad of other issues stemming from lack of technological infrastructure, limited R&D support, barriers to financing, and ideologies surrounding protectionism. It, will, however, facilitate greater access to generic medications and the potential for LDCs to muster up the resources to manufacture them on their own, as seen in the Cipla/Uganda partnership.

It would be naïve to overlook the resistance that such a proposal would likely come up against by hegemonic states. Rather, this particular policy proposal would need to be coupled with a significant shift in how IPRs are envisioned, which is the focus of the next section of this paper.

II. System-Based Recommendations

The narrative surrounding IPRs has set up a discourse that has and will continue to result in ideological clashes between seemingly irreconcilable theories of protection, trade, and human rights. While the human rights position frames issues of patent protection as subordinate to issues of access to medicines and the right to health, the IPR position has similarly hierarchized social justice goals to a position inferior to protecting the fruits of research and development

⁸¹ *Ibid* at 158.

⁸² *Ibid* at 158.

Examining these pieces independently and against one another in a militant fashion has largely proven ineffective and resulted in unnecessary ideological clashes. Where IPRs, human rights, and trade may find common ground, however, is in the domain of innovation and the mechanisms we use to incentivize innovation. The advent of prize schemes is one such method by which has sought to recast the IPR system by revising the object of incentives. Essentially, prize schemes operate by awarding pharmaceutical companies on the basis of being the first to develop a drug that “meets the requirements with respect to medical profile as determined by an independent committee of experts.”⁸³

A key feature of prize schemes is that it intends to sever the link between the price of a drug and the incentive to innovate. Thus, the intent is to stimulate R&D for less “popular” diseases that affect low-income countries.⁸⁴ The caveat to prize schemes, and the point at which most criticism is directed, is that in exchange for the remuneration, the innovators renounce all IPRs surrounding the invention, in this case, the medicine. The medicine is then placed in the public domain and available for generic manufacturing. In theory, this process will bring the price of the innovation down to close to cost of production, which in turn will minimize the access problem and the economic inefficiency. One such example of a prize scheme is the Health Impact Fund (HIF), pioneered by Yale philosopher, Thomas Pogge and economist, Aidan Hollis.⁸⁵ Through the HIF, innovators can insist on their patent rights or they can opt into this particular prize scheme whereby they are rewarded in proportion to the global health impact of the medicine (measured using the quality adjusted life year or QALY) and must sell their product at the lowest feasible cost of production and distribution.

Despite its promise, the Health Impact Fund has received a significant amount of criticism regarding the feasibility of the venture. Pogge and Hollis estimate that the program will require \$6 billion per year to fund a sufficient incentive for drug companies to register

⁸³ Jorn Sonderholm, “Intellectual Property Rights and the TRIPS Agreement: An Overview of Ethical Problems and Some Proposed Solutions.” (2010) World Bank Development and Dialogue on Values and Ethics Working Paper 1 at 10.

⁸⁴ *Ibid* at 12.

⁸⁵ Aidan Hollis & Thomas Pogge, *The Health Impact Fund: Making Medicines Available for All* (New Haven: Incentives for Global Health, 2008) at 11; Amitava Banerjee, Aidan Hollis & Thomas Pogge, “The Health Impact Fund: Incentives for Improving Access to Medicines” (2010) 375 *The Lancet* 166 at 168.

products that target the neglected diseases. This price tag has been criticized as being too high a cost and could be otherwise funneled towards other aid activities.⁸⁶ Another often cited criticism of the program is that it is designed to allow the inventor to maintain a monopoly over the medicine as there is no obligation to allow open licensing. Though the inventor has waived their ability to earn profits on the monopoly of the drug, they still retain other benefits of the patent monopolies such as preventing generic pharmaceutical companies from manufacturing the drugs and therefore, may “stifle market competition to produce the drugs at as low a cost as possible.”⁸⁷ Furthermore, in practice, the HIF largely concentrates on equipping large pharmaceutical industries, thus failing to support small and medium scale companies.

In spite of these logistical criticisms of the HIF, it is still worth noting the ideological shift that the HIF is attempting to cultivate. It is attempting to challenge the current IPR system by introducing strong currents of human rights principles to the incentive process by working within the system to elicit change. With regards to the access to medicines issues, creating a practical, realistic, and compelling alternative to the patent system is key. Gradual buy-in to the alternative choice may cast the alternative choice as one, over time, that becomes viable. This response is far more compelling than ivory tower engagement on radically changing the culture around patent protection. In fact, creating a viable alternative system may be one way to move away from Lockean notions of property and individualism when we start to view certain commodities, such as medicines, as shared goods that should benefit states and individuals irrespective of their despite their financial capacities.

Perhaps an addendum to the HIF program would be a more thorough appreciation of small and medium sized local pharmaceutical companies in low resource settings. Providing this niche with resources would have the effect of stimulating R&D in developing countries and also maximizing the reach of investments. As the chart below illustrates, larger pharmaceutical industries are actually responsible for only a fraction of the patents for many

⁸⁶ Brita Pekarsky, “Should Financial Incentives be Used to Differentially Reward ‘Me-Too’ and Innovative Drugs” (2010) 28:1 *Pharmacoeconomics* 1 at 14.

⁸⁷ Sakiko Fukuda-Parr & Proochista Ariana *Health Impact Fund – Raising Issues Of Distribution, IP Rights And Alliances* (26 September 2011), online: IP Watch <<http://www.ip-watch.org/2011/09/26/health-impact-fund—raising-issues-of-distribution-ip-rights-and-alliances/>>

neglected diseases that are often found in developing countries.⁸⁸ For these diseases, “unexpected” researchers tend to be more active, but face the difficulty of a dearth of funding. Tapping into this group could prove to be both profitable and efficacious is securing willing producers of generic medications, if harnessed properly.

Disease	Total PCT (Patent Cooperation Treaty) Patents Filed	Big Pharma 10 ⁸⁹
HIV/AIDS	3263	573
Tuberculosis	419	33
Malaria	533	108
Leishmania	146	6
Onchocerciasis	3	0
Chagas Disease	50	1
Leprosy	155	2
Schistomiasis	31	4
Lympahtic Filariasis	2	0
African Tripanosomiasis	38	1
Dengue	83	9

Ultimately, all solutions need buy-in, not only from pharmaceutical companies, but also from states, governments, and intergovernmental organizations. As Yamane posits, “it is time to recast the debate to view IPR protection as an element within a larger effort to encourage knowledge creation and technological innovation through integrated national policies and international cooperation.”⁹⁰ The recasting of this debate may entail more

⁸⁸ Yamane, *supra* note 8 at 515.

⁸⁹ Big Pharma 10 were: Pfizer, GSK, Merck, Astrazeneca, Aventis, Bristol-Myers Squibb, Novartis, Eli Lilly, Hoffmann-La Roche, Abbott

⁹⁰ Yamane, *supra* note 8 at 520.

critical scrutiny of our existing policies in light of a wholly re-envisioned intellectual property rights system.

Conclusion

Renowned academic, Noam Chomsky once exclaimed in a speech, "There is nothing liberal about [the TRIPS agreement]. It is a highly protected system, designed to ensure that private tyrannies, which is what corporations are, monopolize the technology and the knowledge of the future."⁹¹

While I can sympathize with the impulse behind this scathing sentiment, having seen first hand the devastating effects of being denied access to essential medicines such as ARTs or even non-essential medicines, such as HRT, I believe the dialogue around the issue needs to be more constructive. A constructive dialogue is not one that will attempt to dismantle the existing TRIPS structure altogether, but rather, one that will find utility in it as an agent for change.

The TRIPS flexibilities offer a lot of potential vis-à-vis compulsory licensing, transition periods, and parallel importation to assist LDCs in not only procuring medicines, but also, developing the R&D infrastructure to make those industries self-sustaining. To achieve the latter, however, certain reforms need to be introduced with how the IPR system is currently envisioned. This can be realized with a little push from human rights principles that place a greater premium on ideas such as the right to health. While the Health Impact Fund is one such initiative that has sought to propagate a paradigm shift in the IPR framework, more work is needed. As this paper has discussed, tapping into local initiatives and making certain protocols in the TRIPS Agreement obligations instead of options offers one such first step. Above all, however, innovative thinking that provides a compelling reason for innovators to step away from their staunch stance of protectionism may be where the ultimate solution lies. As the international community awaits with baited breath to see how the Ugandan Industrial Property Act will ultimately play out, we can only hope that in the interim, Chomsky's dystonic prophecy does not manifest itself in Uganda or beyond.

⁹¹ Interview of Noam Chomsky [nd] at Asian College of Journalism, Chennai. <http://www.greenmac.com/World_Events/aninterac.html>.

Bibliography

Legislation

Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, 15 April 1994, 33 I.L.M. 1143, online: The Trading Floor <<http://trading.wmw.com/gatt>> at 1197, Annex IC: *Agreement on Trade-Related Aspects of Intellectual Property Rights [TRIPS Agreement]*.

GA Res. 217(III), UN GAOR, 3d Sess., Supp. No. 13, UN Doc A/810 (1948) 71 [UDHR]

International Covenant on Economic, Social and Cultural Rights, 19 December 1966, 993 UNTS art 12 ILM 368.

Uganda Industrial Property Bill of 2009, No. 5.

Ugandan Penal Code Act, 1950 Ch 120 s 145.

WTO, *Doha WTO Ministerial Declaration*, WTO Doc. WT/MIN(01)/DEC/1 (2001), 41 I.L.M. 746, para 1 [*Doha Declaration*].

Secondary Material: Monographs

Abbe E L Brown, *Intellectual Property, Human Rights and Competition* (Northampton: Edward Elgar Publishing Limited, 2012).

Aidan Hollis & Thomas Pogge, *The Health Impact Fund: Making Medicines Available for All* (New Haven: Incentives for Global Health, 2008).

Andrew Law, *Patents and Public Health* (Munich: Munich Intellectual Property Law Center, 2008).

Carsten Fink, "Intellectual Property and Public Health: The WTO's August 2003 Decision in Perspective" (2003) World Bank Note 191.

Catherine M. Cole, Takiwaa Manuh & Stephan F Miescher, eds, *Africa After Gender* (Indiana: Indiana University Press, 2007).

Hiroko Yamane, *Interpreting TRIPS: Globalization of Intellectual Property Rights and Access to Medicines* (Portland: Hart Publishing, 2011).

John Locke, *Two Treatises of Government* (London: Black Swan, 1690) book II.

Katharina Gamharter, *Access to Affordable Medicines* (New York: SpringerWien New York, 2004).

Marumo Nkomo, *The WTO Medicines Decision in Light of its Utilization: Resolution or Resignation?* (Berlin: Lambert Publishing, 2010).

Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement* (Leiden: Martinus Nijhoff Publishers, 2012).

Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (New Delhi: Oxford University Press, 2005).

Secondary Material: Articles

Amitava Banerjee, Aidan Hollis & Thomas Pogge, "The Health Impact Fund: Incentives for Improving Access to Medicines" (2010) 375 *The Lancet* 166.

Ben Twinomugisha, "Implications of the TRIPS Agreement for the Protection of the Right of Access to Medicines in Uganda" (2013) 2 *Malawi Law Journal* 253.

Brita Pekarsky, "Should Financial Incentives be Used to Differentially Reward 'Me-Too' and Innovative Drugs" (2010) 28:1 *Pharmacoeconomics* 1.

Doctors without Borders, *South Africa: Big Pharma Backs Down*, online: Doctor's Without Borders <<https://www.doctorswithoutborders.org/publications/ar/report.cfm?id=1204>>

Jamila Ddamulira Mujuzi, "The Absolute Prohibition of Same-Sex Marriages in Uganda" (2009) 23:3 *Int J Law Policy Family* 277.

Jerome H. Reichman, "Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework Under TRIPS and an Overview of the Practice in Canada and the United States of America" (Case Study for UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, 2002) Online: <http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf>.

Junaid Subhan, "Scrutinized: The TRIPS Agreement and Public Health" (2006) *McGill J Med* 152.

Jorn Sonderholm, "Intellectual Property Rights and the TRIPS Agreement: An Overview of Ethical Problems and Some Proposed Solutions." (2010) World Bank Development and Dialogue on Values and Ethics Working Paper 1.

Michael Hollander, "Gay Rights in Uganda: Seeking to Overturn Uganda's Anti-Sodomy Laws" (2009) 50:1 Va J Int'L 219.

Paul Semugoma, Chris Beyrer, Sefan Baral, "Assessing the Effects of Anti-Homosexuality Legislation in Uganda on HIV Prevention, Treatment, and Care Services" (2012) 9:3 Social Aspects of HIV/AIDS 173.

Phoebe Kajubi et al., "Gay and Bisexual Men in Kampala, Uganda" (2008) 12:3 AIDS Behaviour.

Sakiko Fukuda-Parr & Proochista Ariana *Health Impact Fund – Raising Issues Of Distribution, IP Rights And Alliances* (26 September 2011), online: IP Watch <<http://www.ip-watch.org/2011/09/26/health-impact-fund—raising-issues-of-distribution-ip-rights-and-alliances/>>

Sorcha O'Carroll, "Importing Indian Generic Drugs Following TRIPS: Case Studies from Zambia and Kenya," Online: <www.law.utoronto.ca/documents/ihrp/HIV_Ocarroll.doc>

Vasu Reddy, "Homophobia, Human Rights and Gay and Lesbian Equality in Africa" (2012) 16:50 Africa, Agenda 83.

Wolfgang Hladick et al., "HIV Infection Among Men Who Have Sex With Men in Kampala, Uganda – A Respondent Driven Sampling Survey" (2012) PloSOne 1.

Secondary Materials: Other

Centre for Health Human Rights and Development, *Intellectual Property and Human Rights: A Pocketbook for Journalists* (Kampala: KIOS, 2012) at 13 [CEHURD Pocketbook].

Centre for Health Human rights and Development, "Model Provisions to Promote Access to Affordable Medicines in the Industrial Property Bill 2009" [Unpublished].

Memorandum from Health Civil Society Organizations to Ugandan Parliamentarians [nd] *Effect of Industrial Property Bill of 2009 on Access to Medicines by Ugandans* [unpublished] [Memo from CSOs].

Reproduced by Mart Leesti & Tom Pengelly, *Technical and Financial Co-Operation Needs for Implementation of the WTO TRIPS Agreement in Uganda* (Needs Assessment Report, Ministry of Tourism, Trade and Industry, 2007: International Center for Trade and Sustainable Development).

UNAIDS, *Implementation of TRIPS and Access to Medicines for HIV after January 2016: Strategies and Options for Least Developed Countries* (2011) at 6.

USAID 'Fighting Malaria in Africa: US to sponsor low-cost mosquito net program in Uganda' (2006), Online: <<http://www.usaid.gov/press/releases2006/pr06425.html>>

World Health Organization & Uganda Ministry of Health, "Access to and Use of Medicines by Households in Uganda" (2008) Ministry of Health, online: <<http://apps.who.int/medicinedocs/index/assoc/s16374e/s16374e.pdf>>

World Trade Organization, *TRIPS Work in the WTO*, online: WTO <http://www.wto.org/english/tratop_e/trips_e/trips_e.html>