



DISCUSSION PAPER ON

Intellectual Property and Access to Medications

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I. Introduction

Eight Millennium Development Goals (MDGs) were identified to galvanize efforts to improve the lives of “the world’s poorest.”² The aim was to achieve these goals by 2015. 2015 is fast approaching and much work remains. This Report, focusing on the area of intellectual property at the intersection of the MDGs, seeks to identify concrete and feasible reforms to the structure of international intellectual property institutions, practices and rules. It seeks to provide guidance for shaping the post-MDG agenda.

The term “intellectual property” refers to a vast and complicated system of legal protections for “inventions, expressions and products the generation of which typically involves the creative use of the mental faculties.”³ There are four main categories of intellectual property protection: patent, copyright, trademark, and trade secret. Each covers a (more or less) distinct area of creative activity. Arguably all kinds of intellectual property are relevant to the UN’s MDGs. Given space constraints, however, this report will focus on patents.

² *Background*, UN MILLENNIUM DEVELOPMENT GOALS, <http://www.un.org/millenniumgoals/bkgd.shtml> (last visited March 30, 2014).

³ Seana Valentine Shiffirin, *Intellectual Property*, in *A COMPANION TO CONTEMPORARY POLITICAL PHILOSOPHY* 653, 653 (eds. Robert Goodin, Philip Pettit & Thomas Pogge, Blackwell, 2007) [*hereinafter Shiffirin*].

The scope of this Report must be further constrained. The intersection of patents with the MDGs still includes a vast territory. Patents, for instance, are relevant to issues involving hunger through the connection between seed patents and food security (MDG 1),⁴ climate change and environmental sustainability (MDG 7),⁵ and various health issues (MDGs 4, 5, 6, 7, 8).

The focus of this Report will be on the intersection of patents and health, but, again its scope must be further narrowed. Patents have implications both for innovation in health interventions as well as access to health interventions. We will focus on the latter. This choice is not to be construed as suggesting that one focus is more important than another. Rather, this decision is motivated by two considerations.

First, it is rather egregious that in the year 2014 many still die from a lack of access to medications. As of 2012, for example, 9.7 million people in low and middle-income countries received HIV treatment.⁶ This “total represents 65% of the global target of 15 million people set for 2015....”⁷ While this marks a big improvement over the previous year, a full 35% still lack treatment. More than 5 *million* people will eventually die, not because treatments do not exist, but because they are inaccessible. Barriers to access are multifaceted, but a major feature of these problems is affordability. For many, life-saving medications are simply unaffordable. Patent generated monopolies are intimately related to the price of life-saving medications.

Second, investigating the current patent regime at the intersection of access to medications, especially with a focus on the Agreement on Trade-Related Aspects of Intellectual Property

⁴ See e.g. Olivier De Schutter, *The Right of Everyone to Enjoy the Benefits of Scientific Progress and the Right to Food: From Conflict to Complementarity*, 33 HUMAN RIGHTS QUARTERLY 304 (2011).

⁵ See e.g. Thomas Pogge, *Keynote Address: Poverty, Climate Change, and Overpopulation*, 38 GA. J. INT'L & COMP. L. 525 (2010) (discussing the possibility of an ecological impact fund).

⁶ *Global Update on HIV Treatment 2013: Results, Impact and Opportunities*, WHO 13 (June 2013), available at http://apps.who.int/iris/bitstream/10665/85326/1/9789241505734_eng.pdf.

⁷ *Id.*

(TRIPS),⁸ complements previous ASAP work. As many of you may know, ASAP President Thomas Pogge has written extensively on the issue of patents and incentives for innovation. It is well documented that current domestic and international patent regimes do not sufficiently incentivize research and development for diseases predominantly impacting those in developing countries. A number of proposals have been made to address this lack of R&D.⁹ One such prominent proposal with ramifications for both access and innovation, offered by Aiden Hollis and Thomas Pogge, is the Health Impact Fund (HIF). The HIF proposes to increase access to medications through innovations in patent licensing arrangements. As this Report focuses largely on access issues through the lens of TRIPS flexibilities, these efforts are complementary.

This Report proceeds in six parts. Part II describes the current international patent regime. Part III links together the relationships between TRIPS, the MDGs, and access to medications. Part IV canvasses proposals in the literature to increase access to medicines. Part V describes barriers to access imposed on developing countries through free trade agreements and TRIPS-plus provisions. Part VI offers recommendations for institutional reform.

II. The International Intellectual Property Regime

A. What are patents?

Patents can protect many different kinds of inventions from medicines to business methods. The precise features of and legal authority for patent protections varies by jurisdiction. In the

⁸ Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15 1994, 33 I.L.M. 81(1994) [*hereinafter* TRIPS Agreement].

⁹ Gerard F. Anderson, *Spurring New Research for Neglected Diseases*, 28 HEALTH AFFAIRS 1750 (2009), available at <http://content.healthaffairs.org/content/28/6/1750.full>.

United States, the possibility of patent protections is authorized by the Constitution.¹⁰ U.S. patents protect inventions that satisfy five requirements. The invention must be: (1) of patentable subject matter, (2) useful, (3) novel, (4) non-obvious, and (5) disclosed in a manner such that a person skilled in the arts could reproduce and use the invention.¹¹ Thus, not all “inventions” are patentable—only those that meet these requirements.

To receive a patent in the United States one must submit an application for review by the Patent and Trademark Office. If a patent is granted, the patent holder is endowed with powerful exclusive rights to the “making, using, selling, offering for sale, or importing the claimed invention....”¹² These exclusive rights last for a specific period of time. Currently an individual patent is enforceable for a term of 20 years minus the time it spent being reviewed during the application, or “prosecution” process.¹³ During a patent’s life, the patent holder has near unilateral control over her invention. As one author puts it, “patent law permits the holder to refuse to license use no matter what payment is offered, for no reason in particular.”¹⁴ She can suppress infringing uses of her invention, for example, even if this results in great cost, as in the case of pharmaceuticals, to the lives of others.¹⁵

B. Paris Convention for the Protection of Industrial Property

Prior to the mid 1990s, two international agreements served as the primary international instruments for governing intellectual property rights.¹⁶ The first was the Paris Convention for the Protection of Industrial Property administered by the World Intellectual Property Organization

¹⁰ U.S. Const. art. I, § 8, cl. 8.

¹¹ 35 U.S.C. §§101, 102, 103, 112.

¹² ROBERT P. MERGES, PETER S. MENELL & MARK A. LEMLEY, *INTELLECTUAL PROPERTY IN THE NEW TECHNOLOGICAL AGE* 132 (5TH ED. 2010).

¹³ *Id.*

¹⁴ *Shiffrin* at 655.

¹⁵ *Id.*

¹⁶ CHARAN DEVEREAUX, ROBERT Z. LAWRENCE & MICHAEL D. WATKINS, *CASE STUDIES IN US TRADE NEGOTIATION VOL. 1: MAKING THE RULES* 46 (2006) [*hereinafter Devereaux*].

(WIPO). The second, dealing with copyright protection, was the Berne Convention for the Protection of Literary and Artistic Work, also administered by WIPO. Headquartered in Geneva and established in 1967, “WIPO is the global forum for intellectual property services, policy, information and cooperation.”¹⁷ It is an agency of the United Nations and currently has 187 member states.¹⁸

The Paris Convention originated in 1883 and was most recently revised in 1967.¹⁹ “Open to all states, it applies to industrial property in the widest sense, including patents, marks, industrial designs, utility models, trade names, geographical indications and the repression of unfair competition.”²⁰ The provisions of this Convention fall into four main categories.²¹ They establish (1) a basic right to national treatment, (2) a basic right of priority, (3) a set of common rules, and (4) an administrative framework.²² For our purposes, the details of these provisions are not pressing. The important point to keep track of is that the Paris Convention left “the scope and the substance of patent rights” to be controlled domestically.²³ Thus, there was great variability in what was excluded from patentability. A 1988 Report by WIPO, for instance, noted that of the 98 nations party to the Paris Convention at that time 49—or fully 50% of these countries—excluded pharmaceutical products from patent protection.²⁴ Further of importance, the Convention lacked enforcement and dispute resolution mechanisms.²⁵

¹⁷ *Inside WIPO*, WIPO, <http://www.wipo.int/about-wipo/en/index.html> (last visited March 30, 2014).

¹⁸ *Id.*

¹⁹ *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade*, WHO, WIPO, WTO 54 (2013), available at http://www.wto.org/english/res_e/publications_e/who-wipo-wto_2013_e.htm [hereinafter *WHO, WIPO, WTO Report*].

²⁰ *Id.*

²¹ *International Treaties and Conventions on Intellectual Property*, WIPO INTELLECTUAL PROPERTY HANDBOOK: POLICY, LAW AND USE 240, 242 (2004), available at <http://www.wipo.int/export/sites/www/about-ip/en/iprm/pdf/ch5.pdf#paris>.

²² *Id.* See also Standing Committee on the Law of Patents, *Report on the International Patent System*, para. 136-138, SCP/12/3 Rev.2 (Feb. 3, 2009), available at http://www.wipo.int/edocs/mdocs/scp/en/scp_12/scp_12_3_rev_2.pdf.

²³ Rochelle C. Dreyfuss, *TRIPS and essential medicines: must one size fit all? Making the WTO responsive to the global health crisis*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES 35, 35 (Thomas Pogge, Matthew Rimmer & Kim Rubenstein eds., 2010) [hereinafter *Dreyfuss*].

²⁴ International Bureau of the World Intellectual Property Organization, *Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms For the Protection of Intellectual Property*, MTN.GNG/NG11/W/24/ Annex I and II

C. The Creation of TRIPS: Intellectual Property and Trade

This patent protection regime changed dramatically in 1994 when protection of intellectual property became “conceptualized as a trade issue”.²⁶ This regime change was precipitated by decades of agitation from various industrial groups in the United States. The agrochemical, pharmaceutical, creative arts, and computer sectors, among others, were unhappy with the protection afforded their IP abroad.²⁷ Estimating huge financial losses and foregone profits due to insufficient IP protection, these groups wanted to do something.²⁸

Efforts for strengthening patent protection first focused on WIPO and revising the Paris Convention.²⁹ This channel proved ineffectual. The United States did not have a recognized leadership role within this organization, and its agenda met with resistance.³⁰ WIPO was considered too sensitive to issues of concern to developing countries, which made it an inhospitable environment for advocates of increased patent protection.³¹ Furthermore, industry groups wanted robust enforcement mechanisms—something that would be difficult to come by through the WIPO system.

(May 5, 1988), available at http://www.wto.org/gatt_docs/English/SULPDF/92040090.pdf. See also WHO, WIPO, WTO Report at 56; Devereaux at 47.

²⁵ Devereaux at 46.

²⁶ Dreyfuss at 35.

²⁷ Devereaux at 48-52.

²⁸ C. O’Neal Taylor, *The Limits of Economic Power: Section 301 and the World Trade Organization Dispute Settlement System*, 30 VAND. J. TRANSNAT’L L. 209, 231 (1997) (noting that the 1987 International Trade Commission report estimated “\$43 to \$61 billion in worldwide losses to U.S. industries from piracy or counterfeiting of IPRs.”) [*hereinafter Taylor*].

²⁹ Devereaux at 47.

³⁰ *Id.*

³¹ *Id.* See also Laurence R. Helfer, *Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT’L L. 1, 20 (2004) (“Two factors motivated the United States and the EC, in response to pressures from their respective intellectual property industries, to shift intellectual property lawmaking from WIPO to GATT. The first related to dissatisfaction with treaty negotiations hosted by WIPO. The second focused on institutional features of the GATT that facilitated adoption of more stringent intellectual property protection standards that these states favored.”) [*hereinafter Helfer*]; LAURENCE R. HELFER & GRAEME W. AUSTIN, HUMAN RIGHTS AND INTELLECTUAL PROPERTY: MAPPING THE GLOBAL INTERFACE 37 (2011).

Other routes were explored. Industry leaders and U.S. officials pushed to link intellectual property with trade issues.³² Attention was turned to getting intellectual property protection on the Uruguay Round of the GATT multilateral trade talks. GATT—the General Agreement on Tariffs and Trade—was a multilateral trade liberalization system. A host of reasons led member states to attempt to extend and revise this system through the Uruguay Round of negotiations.³³ From these negotiations the World Trade Organization was created, as was TRIPS—the most important international intellectual property trade agreement that exists today.

This forum shift and reconceptualization of intellectual property protection as a trade issue is significant for at least two reasons. First, this connection meant that negotiations on intellectual property protections would not take place in isolation. IP protection is of primary value within the context of trade negotiations when IP is an important export.³⁴ The primary exporters of IP are and were developed countries. Thus, if trade negotiations on IP were confined to this single domain, opportunities and sanctions in kind would not be that motivating to developing countries.³⁵

What the forum shift to the WTO did, was render IP protections negotiated as part of a package with other trade issues for which trade opportunities or sanctions would really matter to developing countries. This immensely raised the stakes. As one text puts it, “A number of observers believe that some nations were willing to trade support of TRIPS for improved access to

³² *Helper* at 19 (“The incorporation of intellectual property rights into the WTO, manifested in the move from WIPO to GATT to TRIPS, was nominally carried out by trade officials from the United States and the EC. But, as I explain in greater detail below, it was a strategy adopted at the urging of American and European intellectual property industries, who were dissatisfied with status quo approaches to intellectual property lawmaking and foresaw considerable advantages from shifting negotiations into the trade regime.”)

³³ *The GATT years: from Havana to Marrakesh*, WTO, http://www.wto.org/english/thewto_e/whatis_e/tif_e/fact4_e.htm (last visited May 22, 2014).

³⁴ MADHAVI SUNDER, FROM GOODS TO A GOOD LIFE: INTELLECTUAL PROPERTY AND GLOBAL JUSTICE 181 (2012) [*hereinafter* *Sunder*].

³⁵ *Devereaux* at 63. See also *Helper* at 22.

industrial markets in agriculture, textiles, and light manufacturing products.... ‘GATT agreements [like TRIPS] would probably never make it if they weren’t carried in a wider negotiation.’”³⁶

The second point of significance with respect to the forum shift has already been mentioned. By locating TRIPS within the WTO system, patent (and other IP) infringements are subject to authoritative adjudicatory bodies and robust enforcement mechanisms. Not only must all members of the WTO sign on to TRIPS, but violators face trade sanctions for non-compliance.³⁷

Forum shifting issues aside, TRIPS dramatically changed the substantive landscape of protection for intellectual property. While individual nations are still primarily responsible for articulating and protecting intellectual property rights,³⁸ TRIPS provides a floor of protection below which no WTO member state may go.³⁹ With respect to patents, Article 27.1 provides that “patents shall be available for *any* inventions, whether products or processes, in *all* fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”⁴⁰ This language leaves space for individualized interpretation of the specific criteria of patentability. This “flexibility” will be discussed momentarily. At this juncture, two momentous changes, spurred by Article 27.1, in patent protection at the intersection of public health must be observed.

First, prior to TRIPS, many WTO member jurisdictions, particularly developing countries, did not offer protections for IP, or did not do so very robustly.⁴¹ As noted above, among WIPO

³⁶ *Devereaux* at 63.

³⁷ *Dreyfus* at 36. *See also Helfer* at 22.

³⁸ *WHO, WIPO, WTO Report* at 56.

³⁹ Hitoshi Nasu, *Public law challenges to the regulation of pharmaceutical patents in the US bilateral free trade agreements*, in *INCENTIVES FOR GLOBAL PUBLIC HEALTH PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES* 77, 78 (Thomas Pogge, Matthew Rimmer & Kim Rubenstein eds., 2010) (TRIPS “extended the minimum standards of intellectual property rights protection for any inventions, whether products or processes, in all fields of technology without discrimination, provided they are new, involve an inventive step and are capable of industrial application.”) [*hereinafter Nasu*].

⁴⁰ *TRIPS Agreement* art. 27.1 (emphasis added).

⁴¹ Anand Grover, Brian Citro, Mihir Mankad, & Fiona Lander, *Pharmaceutical Companies and Global Lack of Access to Medicines: Strengthening Accountability Under the Right to Health*, 40 *J.L. MED. & ETHICS* 234, 236 (2012) (“Prior to TRIPS, most countries, particularly in the developing world, did not have TRIPS-compliant intellectual property laws.”).

members, only 50% recognized patent protection for pharmaceutical products. As a further historical note, many developing country jurisdictions excluded medicines from patent protection on principle.⁴² Against this background, Article 27.1 mandates that patents must be available for any invention in all fields of technology, albeit with a few carve-outs. TRIPS, however, clearly brings pharmaceuticals as a class within the purview of patent protection eligibility.

Second, the mandate of protection for intellectual property processes *and* products was a significant change. Under a solely process patent regime, a patent on a particular process excludes others, for a term of years, from using and replicating that particular process for making a given medicine. No one, however, is excluded from producing the medicine (product) itself. If a scientist can generate the medicine using a different process, no patent infringement takes place. This activity is legal and, indeed, that new process would be a candidate for a patent of its own. Once product patents are recognized, however, different ways of making the same product become moot from an IP perspective. The patent holder on that medicine can exclude all others, no matter whether a competitor created the medicine by a different process.⁴³

India pre-TRIPS is an example of a pharmaceutical process patent only regime. A major player in generic pharmaceuticals, India was able to build up this industry because The Indian Patent Act of 1970 only recognized patents in pharmaceutical processes and not products.⁴⁴ This regime

⁴² Sangeeta Shashikant, *The Doha Declaration on TRIPS and Public Health: An Impetus for Access to Medicines*, in ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY 141, 142 (Gaëlle Krikorian & Amy Kapczynski eds., 2010) (“Whereas previously, many developing countries excluded crucial sectors such as medicines and chemicals from patentability, this is no longer an option.”) [*hereinafter Shashikant*]. We must note in a related vein that TRIPS Article 27 does carve out some exclusions to patentable subject matter including “diagnostic, therapeutic and surgical methods.” *TRIPS Agreement* art 27.3 (a).

⁴³ Another way to think about this is in terms of a difference in monopolistic strength. Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, *Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development*, ¶ 18, H.R.C., A/HRC/11/12 (Mar. 31, 2009) (by Anand Grover) (“While product patents confer absolute monopolies, process patents lead to relative monopolies.”), *available at* http://www2.ohchr.org/english/bodies/hrcouncil/docs/11session/A.HRC.11.12_en.pdf [*hereinafter Grover*].

⁴⁴ *Sunder* at 181. (“So long as a company could develop an alternate way of producing a drug, it was legal.” This framework in conjunction with other favorable policies, “allowed Indian pharmaceutical companies to reverse-engineer

and the consequent flourishing of generic manufacturing in fact led India to be referred to as “the pharmacy of the world....”⁴⁵ Post-TRIPS, India as with all other WTO member nations must recognize pharmaceutical product patents. It began recognizing pharmaceutical product patents in 2005.⁴⁶

TRIPS has significant implications for public health around the world. This international agreement intersects with at least two important dimensions of public health. First, as a system for globally increasing patent protection, TRIPS is implicated in an incentive scheme for pharmaceutical innovation that largely excludes addressing disease burdens affecting poor countries. Second, it has important ramifications for access to medications, especially on behalf of poorer populations in developing countries. Each of these issues is of great importance to many of the MDGs. For the reasons provided in Part I, this Report will focus on the access dimension.

III. TRIPS, The Millennium Development Goals, and Access to Medicines

Several of the Millennium Development Goals are explicitly concerned with increasing access to pharmaceutical products. Goal 6 is to “Combat HIV/AIDS, Malaria, and Other Diseases”.⁴⁷ Target 6.B specifically aims to “Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it.”⁴⁸ Similarly, under Goal 8, “Develop a Global Partnership for Development”, Target 8.E aims to, “In cooperation with pharmaceutical companies, provide access

nearly every drug produced by foreign multinational companies. A booming generic industry drug industry in India ensued.”)

⁴⁵ *Shashikant* at 143.

⁴⁶ *Id.*

⁴⁷ *Goal 6: Combat HIV/AIDS, Malaria and Other Diseases*, UN MILLENNIUM DEVELOPMENT GOALS, <http://www.un.org/millenniumgoals/aids.shtml> (last visited March 31, 2014).

⁴⁸ *Id.*

to affordable essential drugs in developing countries.”⁴⁹ A number of the other Goals and Targets, for instance Target 6.C “Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases” and Goal 4, Target 4.A: “Reduce by two thirds, between 1990 and 2015, the under-five mortality rate”, while they do not explicitly mention access to medications, would conceivably be benefited by improvements in this arena.

Access to medications can be conceptualized in different ways, and factors influencing and interfering with access are multifaceted and complex. A joint report authored by the WTO, WIPO, and WHO defines access as follows: “Lack of access is generally understood to mean the absence of available treatment options for the patient. Appropriate treatment has to be physically available and needs to be affordable for the patient.”⁵⁰

Many different reasons affect why a treatment is not physically available and/or not affordable. As an example, the authors of this joint WTO, WIPO and WHO report note the case of pediatric pneumonia. Pneumonia is “the single largest cause of death in children worldwide....”⁵¹ This is so despite the fact that “it can be prevented by simple interventions, and it can be treated with low-cost, low-tech medication and care. This example of basic and inexpensive medicines that are still inaccessible clearly indicates that barriers to access are more complex than affordability alone.”⁵² The WHO identifies four general determinants of access to medicines: (1) rational selection and use of medicines, (2) affordable prices, (3) sustainable financing, and (4) reliable health and supply systems.⁵³ Successful access to medications requires each of these pieces to be

⁴⁹ *Goal 8: Develop a Global Partnership for Development*, UN MILLENNIUM DEVELOPMENT GOALS, <http://www.un.org/millenniumgoals/global.shtml> (last visited March 31, 2014).

⁵⁰ *WHO, WIPO, WTO Report* at 144.

⁵¹ *Id.*

⁵² *Id.*

⁵³ *Id.* at 145.

simultaneously well-functioning.⁵⁴

While affordability clearly is not the only factor at play in determining successful access to health products, and this determinant itself is multifaceted, it is a feature that intersects most obviously with patent protection and the TRIPs regime. As noted above, patents provide monopolies. Monopolies drive up prices. Patents on pharmaceuticals drive up drug costs and suppress the generic market.⁵⁵ More expensive drugs mean more people are priced out of being consumers. Decreased access to generics, or less expensive drugs, renders individuals and countries unable to purchase the medications that they desperately need.

Problems of affordability and access affect poor people in all countries, but those in developing countries are particularly affected. In low and middle-income countries, “most health care expenditure is paid by patients out of their own pockets.”⁵⁶ Special Rapporteur Anand Grover notes in a report to the Human Rights Council that, “In developing countries, patients themselves pay for 50-90 percent of essential medicines.”⁵⁷ The health of individuals in these countries is therefore “heavily dependent on the availability of affordable medicines.... It is estimated that one-third of the developing world’s people are unable to receive or purchase essential medicines on a regular basis.”⁵⁸

Severe contentiousness surrounding affordability of medications at the intersection of patents and access to generics is perhaps made most vivid by a lawsuit filed against the South

⁵⁴ *Id.*

⁵⁵ Jiraporn Limpananont & Kannikar Kijtiwatchakul, *TRIPS Flexibilities in Thailand: Between Law and Politics*, in ACCESS TO KNOWLEDGE IN THE AGE OF INTELLECTUAL PROPERTY 435, 436 (Gaëlle Krikorian & Amy Kapczynski eds., 2010) (“The impact of pharmaceutical product patents on accessibility to medicines is well recognized. For instance, they cause high prices for patented drugs and delays in the introduction of generic drugs in the market.”) [*hereinafter* *Limpananont & Kijtiwatchakul*].

⁵⁶ WHO, WIPO, WTO Report at 145.

⁵⁷ Grover at ¶ 13.

⁵⁸ *Access to Medicines*, WHO, <http://www.who.int/trade/glossary/story002/en/> (last visited May 22, 2014).

African Government in the late 1990s. At the height of the HIV/AIDS epidemic, antiretroviral (ARV) treatment cost about \$10,000 USD per patient annually.⁵⁹ South Africa sought to amend a national law that would allow increased access to generic medications.⁶⁰ In response, South Africa was placed on the United States Special 301 Watch List,⁶¹ and several multinational pharmaceutical companies filed a lawsuit arguing that these provisions violated TRIPS as well as the South African Constitution.⁶² It was not until 2001, after a public relations nightmare, that the lawsuit was dropped.⁶³ The introduction of generic first generation ARVs eventually brought the annual price per patient down by 99% from \$10,000 to about \$150 or less.⁶⁴

This situation highlights the importance of generic medications for price reductions. The availability of lower cost generic medicines not only impacts individual consumers, but donor-funded purchases.⁶⁵ Médecins Sans Frontières notes this impact:

In the field of health, generic competition saves lives. As a medical treatment provider, MSF relies on affordable, quality generic medicines to treat many diseases, including tuberculosis, malaria, HIV/AIDS and other infections that afflict the poorest and most vulnerable populations.

Major international treatment initiatives and agencies, including the Global Fund to Fight AIDS, Tuberculosis and Malaria, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) program, UNITAID, and UNICEF, also depend heavily on affordable generic drugs to scale up urgently needed treatment programs. For example, more than 98% of the antiretroviral medicines purchased by PEPFAR to

⁵⁹ Grover at ¶ 20.

⁶⁰ *Shashikant* at 143. See also Grover at ¶ 57.

⁶¹ Grover at ¶ 57. The United States' Section 301 provisions allow for the issuing of unilateral trade sanctions against "priority countries" and warnings of impending eligibility for sanctions by being placed on a "watch list" for inadequate intellectual property protections. See e.g. Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of Trips Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1627-28 (2009) [*hereinafter Kapczynski I*].

⁶² Grover at ¶ 57.

⁶³ *Shashikant* at 144.

⁶⁴ Grover at ¶ 20; See also Amy Kapczynski, *Engineered in India—Patent Law 2.0*, 396 N. ENG. J. MED. 497, 497 (2013), available at <http://www.nejm.org/doi/full/10.1056/NEJMp1304400> [*hereinafter Kapczynski II*].

⁶⁵ Brenda Waning, Ellen Diedrichsen & Suerie Moon, *A lifeline to treatment: the role of Indian manufacturers in supplying antiretroviral medicines to developing countries*, 13 J. INT'L AIDS SOC. 1, 5 (2010) ("Countries across sub-Saharan Africa with high HIV/AIDS burdens, as well as India, are heavily reliant on the availability of Indian-produced generic ARVs to support their national treatment programmes.")

treat HIV/AIDS are low-priced, quality-assured generic medicines.⁶⁶

While first generation ARVs have come down in price, many are concerned that high prices due to patent monopolies will again be an issue with newer second and third line medications as well as new ARV regimens recommended by the WHO. Historically, India with its “environment largely void of intellectual property barriers” played an “exceptional role...in providing quality ARVs at low prices to people with HIV/AIDS in developing countries. More than 80% of all donor-funded ARVs purchased since 2006 were supplied by Indian generic manufacturers.” Many of these newer ARVs, however, are still under patent, and this time India will be constrained by compliance with the product patent provisions of TRIPS that went into effect in 2005.⁶⁷

Events in South Africa and elsewhere eventually led to the 2001 WTO Doha Declaration on TRIPS and Public Health.⁶⁸ TRIPS, as detailed below, was designed from the beginning to be sensitive to public health issues through “flexibilities.” The uptake and exercise of these flexibilities, however, has been slow, subject to uneven success, and, at times, fraught with friction.

IV. Increasing Access to Medicines

This section describes several mechanisms and proposals that have been suggested for overcoming barriers to accessing patented medications. These include: (1) compulsory licenses, (2) increases in standards of patentability, and (3) innovations in patent licensing including the Medicines Patent Pool and the Health Impact Fund. Compulsory licensing and increases in

⁶⁶ *Trading Away Health: The Trans-Pacific Partnership Agreement (TPP)*, MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN, available at http://www.msfacecess.org/sites/default/files/MSF_assets/Access/Docs/Access_Briefing_TPP_ENG_2013.pdf (last visited May 22, 2014).

⁶⁷ *Grover* at ¶ 21.

⁶⁸ World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002) [*hereinafter Doha Declaration*].

standards of patentability fall under the rubric of TRIPS “flexibilities.” This section therefore is prefaced by an explanation of what these are.

A. TRIPS Flexibilities

TRIPS has always been cognizant of a balance that must be struck between protecting the rights of both “producers and users of technological knowledge”.⁶⁹ Article 7 of TRIPS which outlines the Agreement’s Objectives, states that:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.⁷⁰

Furthermore, Article 8 explicitly notes that Member states have the authority to “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.”⁷¹ Despite this and other language authorizing “flexibilities,” developing countries had concerns about the precise parameters within which they could legally facilitate access to pharmaceutical products for their people. There was particular concern surrounding the use of compulsory licenses.

In the late 1990s and early 2000s, developing countries, particularly in Africa, were facing public health emergencies in which a lack of access to ARVs was a key issue. As indicated by the MDG 6, lack of access to HIV/AIDS medications remains a major problem. At the time in

⁶⁹ *TRIPS Agreement* at art. 7.

⁷⁰ *Id.*

⁷¹ *Id.* at art. 8.

question, however, language in TRIPS left some developing countries in a bind.⁷²

Under Article 31 of TRIPS, compulsory licenses are permissible. A compulsory license is a license to use “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....”⁷³ Compulsory licenses can be issued in non-emergency situations as well as in “situations of national emergency or other circumstances of extreme urgency” though different conditions apply depending upon the scenario; the underlying requirements are relaxed for emergencies.⁷⁴ The trouble, however, comes along under Article 31(f), which provides that “any such use [of a compulsory license] shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use....”

The meaning of “predominantly” was not explained. There was concern “that the purpose of a compulsory license cannot be to supply a foreign country in need.”⁷⁵ Thus, what does a country do, given TRIPS, if it needs a lower-cost supply of an important drug but lacks manufacturing capabilities itself?

This is one of the major issues addressed and clarified by the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health (hereinafter “Doha Declaration”).⁷⁶ Under Paragraph 6, the Doha Declaration recognized that countries lacking manufacturing capacities could not make full use of the compulsory licensing provisions, and instructed the Council for TRIPS to find an

⁷² Note that the TRIPS Agreement provides for various transitional periods for developing countries and least-developed country members. *See TRIPS Agreement* at arts. 65 and 66. South Africa, for instance, needed to be in compliance by January 1, 2000. Duane Nash, *South Africa's Medicines and Related Substances Control Amendment Act of 1997*, 15 BERKELEY TECH. L.J. 485, 488-89 (2000).

⁷³ *TRIPS Agreement* at art. 31.

⁷⁴ *Id.* at art. 31(b).

⁷⁵ Andrew D. Mitchell & Tania Voon, *The TRIPS Waiver as a recognition of public health concerns in the WTO, in INCENTIVES FOR GLOBAL PUBLIC HEALTH PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES* 56, 61 (Thomas Pogge, Matthew Rimmer & Kim Rubenstein eds., 2010) [*hereinafter Mitchell & Voon*]. The authors go on to note that: “In any case, this requirement means that only a relatively small portion of pharmaceuticals manufactured pursuant to compulsory licenses world-wide may be legitimately exported to countries in need and lacking manufacturing capacity.”

⁷⁶ *Id.* at 61-62.

expeditious solution.⁷⁷ This instruction was implemented in August of 2003. Subject to a number of requirements being satisfied,⁷⁸ WTO members “lacking sufficient manufacturing capacities may now import pharmaceutical products created under compulsory licence.”⁷⁹

Importantly, however, the Doha Declaration also explicitly clarified and reaffirmed that TRIPS is not to prevent member states from taking action to protect the health of their nations: “We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health....we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”⁸⁰ To that end, WTO Members have the right “to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.”⁸¹

TRIPS contains a number of flexibilities.⁸² These include:

- (1) Extended transition periods for developing countries to bring their domestic laws into compliance with TRIPS.
- (2) The ability of member states to define their own specific criteria of patentability in compliance with Article 27.
- (3) The ability of member states to issue compulsory licenses under Article 31.
- (4) The non-interference of TRIPS with the international exhaustion principle and therefore parallel importation under Article 6.⁸³
- (5) Provisions allowing for domestic opposition and revocation of patents under

⁷⁷ *Doha Declaration* at ¶ 6.

⁷⁸ These requirements include: the importing member to notify the Council for TRIPS about the drug and quantities, if not an LDC to have established its lack of manufacturing capabilities for manufacturing the particular pharmaceutical product needed, the compulsory license issued by the exporting member must detail everything being exported and must only export to the requesting member and identified under the paragraph 6 system by using distinctive labeling and coloring, the exporting country must also notify the TRIPS Council, and importing members must try to prevent re-exportation. *Mitchell & Voon* at 64.

⁷⁹ *Id.* at 63.

⁸⁰ *Doha Declaration* at ¶ 4.

⁸¹ *Id.*

⁸² For an enumeration and description of the various TRIPS flexibilities see generally *Grover* at ¶ 28 et seq.

⁸³ Parallel importation involves the importation of “medicines that were legally put on the market in another country by the patent holder (or its licensee) in order to take advantage of price differences across national borders.” Mohammed El Said & Amy Kapczynski, *Access to Medicines: The Role of Intellectual Property Law and Policy*, WORKING PAPER PREPARED FOR THE THIRD MEETING OF THE TECHNICAL ADVISORY GROUP OF THE GLOBAL COMMISSION ON HIV AND THE LAW 8 (2011) [*hereinafter El Said & Kapczynski*].

Article 62.

While each of these flexibilities merits independent discussion, in what follows, the focus will be on compulsory licensing (3) and patentability issues (2).

1. Compulsory Licenses

In theory, compulsory licenses are an important way for developing countries to address their needs for essential medicines. In practice, compulsory licenses are not so easily implemented. Three reasons may hinder the use of this flexibility. First, countries may face internal hurdles. As issuing a compulsory license can require complex expertise and infrastructure, not to mention implementing legislation, some countries may face domestic barriers to utilizing this flexibility. Second, for those countries that lack manufacturing capabilities, this puts them within the Paragraph 6 system above discussed. This system has not been as successful as had been hoped. Third, and significantly, immense external pressure exists from other governments and private actors not to use these rights.

Internal barriers, for some, pose the most significant obstacle to issuing a compulsory license. “In many cases, the most significant barrier to the use of compulsory licensing is the absence of simple, straightforward legislative and administrative procedures, which establishes clear decision-making processes, and responsibilities.”⁸⁴ Other obstacles to the use of TRIPS flexibilities can include a lack of resources, for instance, a lack of technical expertise needed by patent offices to

⁸⁴ Sisule F. Musungu & Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH v (2005), available at http://www.who.int/intellectualproperty/studies/TRIPS_flexibilities/en/ [hereinafter *Musungu & Oh*].

appropriately evaluate applications.⁸⁵

Several countries⁸⁶ have utilized compulsory licensing as a way to increase the access to and affordability of ARVs either through the license itself or as a bargaining tool.⁸⁷ We will consider two examples of the former. Rwanda has been the first and, to our knowledge, the only country to issue a compulsory license under the Paragraph 6 System.⁸⁸ This license was for TriAvir an ARV, and the process involved many problems for both the supplier and the beneficiary.

Thailand is another country that has recently made use of compulsory licensing for ARVs. In contrast to Rwanda, Thailand has manufacturing capabilities. While the implementation of its compulsory licenses was ultimately successful, Thailand serves as an important case study for the intense external pressure it underwent to forgo the use of its rights.

In July of 2007 Rwanda sent notice to the Council for TRIPS that it intended to import an ARV pursuant to the Paragraph 6 system implemented by the WTO General Council Decision of 30 August 2003.⁸⁹ TriAvir was to be supplied by Apotex, a Canadian generic manufacturer. Technically, the Paragraph 6 system involves the waiver of duties under Article 31 (f). In order to waive these duties, amendments need to be made to domestic legislation. Canada amended its

⁸⁵ *El Said & Kapczynski* at 10. See also *Grover* at ¶ 63 (“Many developing countries and LDCs inherited IP laws from former colonizers. As a result, when TRIPS came into force, many countries did not necessarily have the technical expertise to effectively implement the agreement or take advantage of the flexibilities. In some cases, limited institutional capacity led to dependence on developed countries and independent bodies for technical assistance in drafting laws. It should be noted that there have been concerns regarding the qualitative nature of assistance that is typically provided in relation to TRIPS and in some cases LDCs seeking external assistance have adopted TRIPS-plus standards in their national laws.”).

⁸⁶ *Public health innovation and intellectual property rights, Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, WHO 117 (2006), available at <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf?ua=1>.

⁸⁷ *Id.*

⁸⁸ *Grover* at ¶ 41.

⁸⁹ *Mitchell & Voon* at 69.

patent law in 2005.⁹⁰

The pertinent part of its law, the Canadian Access to Medicines Regime (CAMR) involved a more complicated and stringent process than that found in the WTO provisions for allowing exports under a compulsory license.⁹¹ In particular, under Canadian law, a generic producer must “attempt to get a *voluntary* license from the patent holder before Canada can issue a compulsory license.”⁹² Three different pharmaceutical companies had patents triggered by this process. Apotex engaged in unsuccessful negotiations with these companies.⁹³ A compulsory license was eventually issued, but it was not until September 2008 that Rwanda received its first shipment of medicine (the second being in September of 2009).⁹⁴

The Paragraph 6 waiver has not been utilized by anyone other than Rwanda, and the question is why.⁹⁵ Some speculate that it may be due to the necessity of implementing complementary national legislation. Another reason is suggested by the case of Rwanda and Canada. Despite good intentions, and the presence of authorizing domestic legislation, unwieldy domestic and international requirements for accessing this system may prove to be too much of a disincentive for frequent implementation.

⁹⁰ *Canada's Intervention to TRIPS Council: Experience Using the System (Apotex-Rwanda Case)*, Knowledge Ecology International (Oct. 27, 2010), <http://keionline.org/node/1000> (last visited May 21, 2014).

⁹¹ Christina Cotter, *The Implications of Rwanda's Paragraph 6 Agreement with Canada for Other Developing Countries*, 5 LOY. U. CHI. INT'L L. REV. 177, 185 (2008), available at <http://lawcommons.luc.edu/cgi/viewcontent.cgi?article=1067&context=lucilr> [hereinafter Cotter].

⁹² *Id.* at 186. Other alleged problems with the law include: “a complicated application process for countries to undertake, a limited list of eligible medicines, restrictions on NGOs as eligible importers, requirements to declare a national emergency and restrictions that prevent re-exportation to facilitate bulk procurement. Some argue that these restrictions go above and beyond what is required by the WTO Paragraph 6 Decision.” Jillian C. Cohen-Kohler, Laura C. Esmail & Andre Perez Cosio, *Canada's implementation of the Paragraph 6 Decision: is it sustainable public policy?*, 3 GLOBALIZATION AND HEALTH (2007), available at <http://www.globalizationandhealth.com/content/3/1/12>.

⁹³ Cotter at 186.

⁹⁴ Stacey B. Lee, *Can Incentives to Generic Manufacturers Save the Doha Declaration's Paragraph 6?*, 44 GEO. J. INT'L L. 1387, 1403 (2013), available at <http://www.law.georgetown.edu/academics/law-journals/gjil/recent/upload/zsx00413001387.PDF>.

⁹⁵ See generally Mitchell & Voon.

Thailand issued three compulsory licenses between 2006 and 2007.⁹⁶ Two of these licenses were for HIV/AIDS drugs—one a first-line medication named Storcrin and the other a second-line drug named Kaletra.⁹⁷ The third compulsory license was for “clopidogrel, an antiplatelet drug used in the treatment of coronary artery disease, peripheral vascular disease, and cerebrovascular disease, commercially known as Plavix.”⁹⁸ Thailand’s issuance of compulsory licenses is recognized as an important case study. It is “one of the first examples of a developing country with significant manufacturing capacities using compulsory licensing of medicines since the Doha Declaration....”⁹⁹

While many international groups supported Thailand’s use of compulsory licenses, the pharmaceutical industry found these activities to be deeply troubling.¹⁰⁰ Thailand was threatened with potential trade sanctions as it was put on the United States’ Special 301 Priority Watch List,¹⁰¹ smear tactics were engaged in, and one of the involved pharmaceutical companies withdrew all of its pending new drug registration applications in Thailand.¹⁰² This last reaction would effectively remove these drugs from the Thai market.

While Thailand’s use of compulsory licensing was legal, these negative external reactions can discourage countries from exercising their rights. Indeed, some suggest that a key reason Thailand was resolute in exercising its rights was due to an engaged and vocal public calling on its government to improve access to essential medicines.¹⁰³ This kind of support may be crucial for governments to stand up to intense external political and economic pressures. It has been noted, for instance, that despite the established right to issue compulsory licenses, “countries issuing compulsory licences as

⁹⁶ *Limpananont & Kijitwatchakul* at 435.

⁹⁷ *Id.* at 440.

⁹⁸ *Id.*

⁹⁹ *Id.* at 436.

¹⁰⁰ *See generally Limpananont & Kijitwatchakul.*

¹⁰¹ *Grover* at ¶ 58.

¹⁰² *See generally Limpananont & Kijitwatchakul.*

¹⁰³ *Id.* at 441.

part of national drug programmes aimed at providing universal access to HIV/AIDS and other treatments continue to be placed on the United States Special 301 Watch List.”¹⁰⁴

In the background of these debates about compulsory licensing, Thailand was also engaged in contentious free trade negotiations with the United States that involved TRIPS-plus provisions.¹⁰⁵ If agreed to, these provisions would curtail Thailand’s ability to utilize various flexibilities and provide access to medications. As detailed below in Part V, free trade agreements containing TRIPS-plus provisions pose a major barrier to access to medications.

2. Criteria of Patentability and The Problem of “Evergreening”

Though TRIPS provides a substantive floor for patent protection offered by member states, the language of Article 27, as we saw, is quite broad. Patents must be provided for inventions that “are new, involve an inventive step and are capable of industrial application.”¹⁰⁶ The key components of this definition remain to be defined by individual jurisdictions.¹⁰⁷ One country’s standard for what counts as a “new” invention may not be the same as another’s. Indeed WIPO’s Patent Cooperation Treaty program, which facilitates the simultaneous submission of patent applications, makes clear that specific patentability criteria vary across jurisdictions.¹⁰⁸ Article 27 further carves out exceptions to patentability. Diagnostic, therapeutic, and surgical methods, for example, may be categorically excluded from patentability.¹⁰⁹

¹⁰⁴ Grover at n68.

¹⁰⁵ Limpananont & Kijitwanchakul at 438.

¹⁰⁶ TRIPS Agreement at art. 27.

¹⁰⁷ Grover at ¶ 32.

¹⁰⁸ *Protecting your Inventions Abroad: Frequently Asked Questions About the Patent Cooperation Treaty (PCT)*, WIPO (April 1, 2012), <http://www.wipo.int/pct/en/faqs/faqs.html> (last visited May 21, 2014). See also WHO, WIPO, WTO Report at 58.

¹⁰⁹ TRIPS Agreement at art 27.3 (a). See also Grover at ¶ 33.

Defining specific criteria for patentability is of great importance to issues of access. “In the area of patent law, even seemingly minor adjustments in patent scope can have substantial economic effects.”¹¹⁰ Higher barriers to getting a patent weed out protection for inventions that do not merit a patent. This facilitates generic market entry.

India is a recognized leader in making use of TRIPS flexibilities, particularly pertaining to the criteria of patentability. It is primarily known for adopting subject matter exclusions “unknown elsewhere in the world...”¹¹¹ Its “exceptionally high threshold for inventive step (or obviousness)” has also been noted.¹¹² Both of these measures are thought to limit the number of pharmaceutical patents granted in India.¹¹³ Here this paper focuses on India’s leadership in crafting subject matter exclusions.

With respect to subject matter exclusions, section 3(d) of the Indian Patent Act provides that a patent will not be granted for:

the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.¹¹⁴

The important part of this provision is that it excludes from patentability “both new uses of known substances and...new forms of known substances that do not enhance ‘efficacy.’”¹¹⁵ This is an important move given that such discoveries would be granted patents in many other jurisdictions.

¹¹⁰ *Kapczynski I* at 1588.

¹¹¹ *Id.* at 1589.

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ The Patent Amendment Act, No. 15 of 2005, § 3, India Code (2005), available at http://www.wipo.int/wipolex/en/text.jsp?file_id=295102.

¹¹⁵ *Kapczynski I* at 1590.

Indeed, acquiring patents on new uses and new forms of known substances—a technique called “evergreening”—plays a significant role in patent life-cycle management plans.¹¹⁶

Evergreening refers to a set of practices adopted by pharmaceutical companies whereby they effectively extend their monopoly rights on an invention beyond the life of the invention’s original patent. Pharmaceutical companies are able to breathe life into an expired patent by “obtaining new patents on a patented medicine by making minor changes to it.”¹¹⁷ New patents “are obtained on new uses, forms, combinations and formulations of known medicines in a bid to extend the period of the patentee’s monopoly.”¹¹⁸ It is rare that “pharmaceutical compounds are...protected only with a patent on the active ingredient itself. Companies frequently seek other forms of patents, in order to generate or extend their exclusive rights over a medicine.”¹¹⁹ The resulting patent thicket provides pharmaceutical companies with the option of litigation to deter potential infringers as well as potential regulatory system advantages through data exclusivity protections.¹²⁰ Evergreening thus works to prevent generic entry into the market. This strategy preserves monopolistic prices and decreases access to medications.

Stringent subject matter exclusions to patentability, however, work to counteract these practices.¹²¹ This is illustrated by the recent case in the Supreme Court of India probing the interpretation of section 3(d). The case involved Novartis’ Gleevec, “a lifesaving drug used in treating chronic myeloid leukemia.”¹²² The particular Gleevec patent being filed in India was a

¹¹⁶ *Kapczynski II* at 498.

¹¹⁷ *Grover* at ¶ 34.

¹¹⁸ *Id.*

¹¹⁹ *Kapczynski I* at 1591.

¹²⁰ *Kapczynski II* at 498.

¹²¹ *Grover* at ¶ 35.

¹²² *Kapczynski II* at 498.

secondary patent covering a new form of the active ingredient.¹²³

The case hinged on the meaning of “efficacy.” Though the drug “was allegedly easier to store and process, and [was] also 30 percent more bioavailable” this was deemed insufficient.¹²⁴ In the end, the Court opted for an understanding of “efficacy” that requires a showing of improved therapeutic benefits. “[T]he Supreme Court held that, based on the Oxford Dictionary of English, efficacy means ‘the ability to produce a desired result.’ The court concluded that, in the case of a medicine, the desired result is to cure a disease, and thus not all advantageous or beneficial properties are relevant, but only those that relate to its therapeutic efficacy.”¹²⁵

Amy Kapczynski’s commentary on this case highlights at least four important implications of the Supreme Court of India’s ruling on Section 3(d).¹²⁶ First, it means that a generic form of Gleevec can be sold in India “for a fraction of the price.” Second, this interpretation establishes that many patents granted in other jurisdictions will not be granted in India. Third, (implicitly) this result offers encouragement for the adoption of Section 3(d) like provisions elsewhere. Fourth, “if Section 3(d) becomes a model for other developing countries, and such countries become, as some have predicted, a much larger share of the global pharmaceutical market...[this] could...help...innovation, by encouraging companies to focus on the kind of innovation that provides the most health benefit.”¹²⁷

As a footnote to this example, the *New York Times* reported that the Obama Administration as well as the Pharmaceutical Research and Manufacturers of America opposed this interpretation.

¹²³ *Id.*

¹²⁴ *Kapczynski I* at 1592.

¹²⁵ Zoe Lynn Turrill, *Finding the Patent Balance: The Novartis Gleevec Case and the Trips Compliance of India's Section 3(d) Efficacy Standard*, 44 *GEO. J. INT'L L.* 1555, 1567-68 (2013).

¹²⁶ *Kapczynski II* at 498.

¹²⁷ *Id.*

Moreover, the Administration advocates for the issuance of patents like the one sought for Gleevec. This is evidenced by its position in negotiations regarding the Trans-Pacific Partnership Agreement.

The Obama administration and the Pharmaceutical Research and Manufacturers of America, the drug industry's main lobbying group, object to the section in the Indian patent law at issue in the case. And perhaps fearful that the section might be adopted elsewhere, Washington wants the nations negotiating a new Pacific Rim trade agreement, the Trans-Pacific Partnership, to agree to grant patents in situations similar to that involving Gleevec, according to a leaked text of the government's position.¹²⁸

TRIPS-plus provisions will be discussed in Part V.

B. Innovations in Licensing Agreements

While international patent law is the main focus of this paper, it is important to keep in mind that solutions to problems of access and the unaffordability of medications also reside outside of debates about TRIPS flexibilities. In what follows, two such proposals are briefly noted: The Medicine Patent Pool and The Health Impact Fund.

1. The Medicine Patent Pool

Patent pooling is a strategy that involves the “collective management of intellectual property rights.”¹²⁹ A patent pool exists when multiple patent owners come together to license their patents to one another or third parties.¹³⁰ Patent pools have many benefits, and can be tailored to the

¹²⁸ Vikas Bajaj & Andrew Pollack, *India's Supreme Court to Hear Dispute on Drug Patents*, NYT (Mar. 6, 2012), available at http://www.nytimes.com/2012/03/07/business/global/indias-supreme-court-to-hear-long-simmering-dispute-on-drug-patents.html?pagewanted=all&_r=0 (last visited March 31, 2014).

¹²⁹ Krista L. Cox, *The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses*, 4 HASTINGS SCI. & TECH. L.J. 291, 294 (2012) [*hereinafter* Cox].

¹³⁰ *Id.*

particular goals motivating the pool.¹³¹ Benefits include reduced transaction and litigation costs, and, importantly the clearing of patent thickets, which impede innovation and access to generics.¹³²

The Medicine Patent Pool (MPP) is an important example of a patent pool in the pharmaceutical domain. The MPP was created “in response to a crisis caused by lack of access to essential medicines in developing countries...”¹³³ The brainchild of Médecins Sans Frontières and Knowledge Ecology International, the MPP is now supported by UNITAID and is specifically charged with “enable[ing] production and distribution of affordable generic versions of HIV/AIDS medicines.”¹³⁴ It does this by obtaining voluntary licenses from patent holders and then non-exclusively sublicensing the rights to produce a medication to generic pharmaceutical manufacturers for use in developing countries.¹³⁵ The terms of each license are individually determined and negotiated.

As of May 2014, it appears that the MPP has several licenses from patent originators and one price agreement.¹³⁶ The MPP’s first license was from the National Institutes of Health for its patents on darunivir. As the NIH was not the only patent holder for darunivir, these licenses “did not permit the generic production of darunavir for the benefit of HIV/AIDS patients.”¹³⁷ A second license with Gilead Sciences has been more successful. This license covers: “patents for tenofovir (TDF) and emtricitabine (FTC), as well as several pipeline drugs including elvitegravir (EVG), cobisistat (COBI) and a four-drug, fixed-dose combination of these products known as ‘the

¹³¹ See generally Dianne Nichol & Jane Nielsen, *Opening the dam: patent pools, innovation and access to essential medicines*, in INCENTIVES FOR GLOBAL PUBLIC HEALTH PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES 235 (Thomas Pogge, Matthew Rimmer & Kim Rubenstein eds., 2010) [*hereinafter Nichol & Nielsen*].

¹³² *Cox* at 295.

¹³³ *Id.* at 291.

¹³⁴ *Id.*

¹³⁵ *Id.* at 296-97.

¹³⁶ *Licences in the MPP*, MEDICINES PATENT POOL, <http://www.medicinespatentpool.org/licensing/current-licences/> (last visited May 21, 2014) [*hereinafter Licences*].

¹³⁷ *Cox* at 300.

quad.”¹³⁸ Licenses with ViiV Healthcare cover “paediatric abacavir for use in the 118 countries where most children with HIV live” and dolutegravir (DTG), and a license with Bristol-Myers Squibb covers the HIV drug atazanavir.¹³⁹ In addition to these licenses, the MPP has also arranged a price agreement with Roche whereby valganciclovir (a drug to treat a viral infection that causes blindness for those living with HIV) will be made up to 90% cheaper than current prices.¹⁴⁰

While patent pooling has its benefits and the MPP seems to be finding secure footing, this strategy also faces limitations. The most obvious in the case of the MPP is that governments and private companies must opt into the license agreement. The arrangement is voluntary. When the patent pool is designed to serve low and middle-income countries, there may not be enough economic incentives for private actors.¹⁴¹ Other potential limitations might include increases, rather than decreases, in transactions costs, as well as clashes with competition laws.¹⁴²

2. The Health Impact Fund

The Health Impact Fund (HIF) is designed to “stimulat[e] pharmaceutical innovation in the most important therapeutic areas *and* enable[e] widespread access.”¹⁴³ To this end, the HIF rewards innovators on the basis of the health impact of their inventions. The bigger the impact, the bigger the return.

The HIF serves to increase access to medications by making drugs affordable. Innovators register their products with the HIF and opt into receiving a share of a fixed fund. In exchange,

¹³⁸ *Id.* at 302.

¹³⁹ *Licences.*

¹⁴⁰ *Id.*

¹⁴¹ *Nichol & Nielsen* at 253. (“As a general rule, patent holders will need to be convinced that entry into a patent pool will secure return on investment better than working outside the pooling arrangement.”)

¹⁴² *Id.* at 253-254.

¹⁴³ *The Health Impact Fund: A Summary Overview*, Health Impact Fund, <http://healthimpactfund.org/the-health-impact-fund-a-summary-overview/> (last visited May 21, 2014).

innovators must “agree to sell [their] product worldwide at a specified low price” at or below the cost of manufacturing, “and to offer a royalty-free open license for generic versions of the product following the ten-year reward period.”¹⁴⁴ Lower drug costs increase the number of people who will be able to afford medications; it prices fewer people out of the market.

The HIF operates alongside the traditional option of seeking a patent monopoly. Innovators are free to choose either path. As a voluntary mechanism for increasing access, the HIF shares some of the same limitations as the MPP. Money for the HIF is to be provided through partner countries, though a gradual move towards an endowment is also envisioned.

The past year has been an exciting year for the HIF. First, the HIF is now partnering with the Janssen Pharmaceutical Companies of Johnson & Johnson to assess the real-world impact of a new anti-tuberculosis drug. “Not only is Sirturo (trade name of Bedaquiline) the first multi-drug-resistant TB medication, it is also the first novel TB drug developed in over forty years.”¹⁴⁵ As research attests, new TB medications are sorely needed; this partnership is an important development for TB patients. Second, Gordon Brown the UN Special Envoy for Global Education will be creating “an online educational analogue to the HIF.”¹⁴⁶ The Global Education Platform will adopt “performance-based reimbursement principles...reward[ing] educational programs based on impact.”¹⁴⁷ The motivating principles behind the HIF are being used to expand into new areas of salience for poverty alleviation.

¹⁴⁴ *Id.*

¹⁴⁵ *December 2013 Health Impact Fund Newsletter*, HEALTH IMPACT FUND, <http://healthimpactfund.org/newslettercurrent/> (last visited May 21, 2014).

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

V. Free Trade Agreements, the TPP and TRIPS-plus Provisions

Before offering some recommendations, an important barrier to affordable generic medications must be noted. Countries cannot utilize TRIPS flexibilities if they have contracted away their rights to use such provisions. While the U.S. and other developed countries found success in harmonizing patent law through TRIPS, the U.S. soon moved away from this multilateral and relatively open forum to advance a more aggressive intellectual property agenda in “a series of closed-door bilateral and plurilateral trade agreement negotiations.”¹⁴⁸ In exchange for “increased market access [offered] by the United States” the other party would agree to adopt TRIPS-plus provisions.¹⁴⁹ TRIPS-plus provisions are so called because they involve heightened levels of intellectual property protection that go beyond those provisions provided in TRIPS itself. These enhanced protections, “represent[] an attempt to erode flexibilities permitted for developing countries under the WTO regime....”¹⁵⁰

The United States’ practice of negotiating, in secret, bilateral and plurilateral free trade agreements that undermine the use of TRIPS flexibilities and advance more stringent intellectual property protections has come under recent fire with the leaked text of the Trans-Pacific Partnership Agreement. “The Trans-Pacific Partnership (TPP) is a proposed free trade agreement under negotiation between Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam.”¹⁵¹ Many of the proposed TRIPS-plus provisions have important implications for the affordability of medications and access to generics.¹⁵² The TPP is thought to include “some of the harshest provisions against access to medicines ever

¹⁴⁸ Sean M. Flynn et. al., *The U.S. Proposal for an Intellectual Property Chapter in the Trans-Pacific Partnership Agreement*, 28 AM. U. INT’L L. REV. 105, 108 (2012) [*hereinafter Flynn*].

¹⁴⁹ *Id.* at 109.

¹⁵⁰ *Nasu* at 77.

¹⁵¹ *TPP and Access to Medicines*, PUBLIC CITIZEN, <http://www.citizen.org/TPPA>, (last visited May 21, 2014).

¹⁵² *Grover* at ¶ 69 (“TRIPS-plus standards increase medicine prices as they delay or restrict the introduction of generic competition.”).

included in a trade agreement with developing countries, gutting public health safeguards and leaving them unable to take the steps needed to protect the lives and health of their people above the profit of multinational pharmaceutical companies.”¹⁵³

Médecins Sans Frontières provides a very useful table¹⁵⁴ (reproduced below) outlining examples from the TPP draft of TRIPS-plus provisions that are detrimental to access to medications. These provisions include: (1) lower bars to patentability, (2) the ability to patent medical methods, (3) the prohibition of pre-grant oppositions, (4) increases in protection for data exclusivity, (5) extensions in patent terms, (6) the linkage of patent status with marketing approval, and (7) new forms of intellectual property enforcement mechanisms.¹⁵⁵

Table From Médecins Sans Frontières

¹⁵³ *MSF responds to leak of Trans-Pacific Partnership text on Wikileaks*, MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN (Nov. 13, 2013), <http://msfaccess.org/content/msf-responds-leak-trans-pacific-partnership-text-wikileaks>, (last visited May 21, 2014).

¹⁵⁴ *Trading Away Health: The Trans-Pacific Partnership Agreement (TPP)*, MÉDECINS SANS FRONTIÈRES ACCESS CAMPAIGN, available at http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Briefing_TPP_ENG_2013.pdf (last visited May 21, 2014).

¹⁵⁵ *Cf. Flynn* at n245.

	evergreening, for example as India has done with section 3(q) of their patents act.
Patenting of medical methods – require the patenting of surgical, therapeutic and diagnostic methods.	Such measures could increase medical liability and the costs of medical practice, and reduce access to basic medical procedures. Several medical associations have declared patenting of medical procedures unethical, and U.S. law prohibits enforcement of these patents on medical practitioners.
Prohibit pre-grant oppositions – forbid challenges to weak or invalid patents until after they have been granted.	Drug companies routinely file many patents on aspects of the same drug to avoid generic competition for as long as possible, but it's a myth that every patent application filed is valid. Pre-grant oppositions constitute an important form of public oversight that helps reduce over-patenting and evergreening, which can cause unwarranted delays to generic competition. Restricting pre-grant oppositions makes it more expensive and cumbersome to challenge weak or invalid patents.
Data exclusivity – prevent drug safety regulators from using existing clinical data to give market approval to generic or biosimilar drugs.	Data exclusivity grants a distinct monopoly status to medicines, even when patents no longer apply or exist, giving companies a new way to keep prices high for longer and further delay generic competition. In addition, existing generics can be forced off the market when these new backdoor monopolies are created. This is the first time the U.S. has demanded data exclusivity for a newer class of drugs called biologics, which are used to treat cancer and many other conditions. If data exclusivity is imposed, the availability of biosimilars – the generic equivalent of biologic drugs – would be considerably delayed. The UN recommends against data exclusivity for developing countries.
Patent term extensions – require extending 20-year patent monopolies by at least five years to compensate for delays in the regulatory process.	At present, patents on drugs in most countries last for 20 years from the date of filing. There is no more straight-forward way to extend a company's monopoly over a drug than to extend the life of the drug's patent beyond 20 years. The extra years added to the patent are extra years in which the patent holder can maintain a monopoly position and continue to charge artificially high prices for the drug, free from generic competition.
Patent linkage – prohibit national drug regulatory authorities from approving generic medicines until patents have expired.	At present a drug's patent status and its registration status are derived from two separate processes. Linking patent status to the registration of medicines means that the drug regulatory authority is required to withhold marketing approval for a generic version of a patented drug regardless of whether the patent granted is valid or not. Patent linkage not only delays generic competition, but can also undermine the use of compulsory licenses and circumvent normal patent dispute processes in the judicial system. Pharmaceutical companies are responsible for monitoring and defending against potential infringements on their own patents. But patent linkage transfers this burden to governments, making it the responsibility of drug safety regulators to police private patents. WHO has warned developing countries against implementing patent linkage, which is further not required in most European countries.
Require new forms of IP enforcement – grant customs officials new powers to detain shipments, including in-transit shipments, suspected of non-criminal trademark infringements; require mandatory injunctions for alleged IP infringements; raise damages amounts.	Increases the risk of unwarranted interruptions and delays in the flow of legitimate trade in generic medicines and limits the judicial system's capacity to balance commercial and public health interests in patent disputes. These new forms of IP enforcement are reminiscent of the stalled Anti-Counterfeiting Trade Agreement (ACTA), a multinational treaty that sought to impose stringent IP rules. These provisions strip away the ability of governments to define their own enforcement provisions as allowed by international law.

MSF IS ALSO CONCERNED ABOUT OTHER PROVISIONS PROPOSED FOR THE TPP, INCLUDING:

- ❖ provisions in the **Pharmaceutical Pricing Chapter** that would restrict the ability of governments to use reimbursement or price control systems to reduce healthcare costs
- ❖ provisions in the **Investment Chapter** that would give pharmaceutical companies the right to sue governments for regulations that reduce their expected profits in a private, supra-national tribunal whose decisions are usually unappealable

A primary problem with the TPP—and other such free trade agreements—distinct from its worrisome substantive provisions is that these agreements are negotiated in secret. Indeed, “[t]he United States reportedly promoted and signed an agreement with the other TPP member countries that precludes official release of any proposals for the text of the agreement until four years after it is

concluded.”¹⁵⁶ At least with respect to the Office of the United States Trade Representative (USTR), there are severe concerns that this office is “captured” by industry interests.¹⁵⁷ Margot Kaminski points out that the USTR:¹⁵⁸

1. Only shows draft texts of agreements to a select advisory committee comprised of mass media and pharmaceutical industry representatives;
2. Involves a revolving door between government officials and industry;
3. Is exempt from federal transparency laws; and
4. Presents a biased and incomplete picture of U.S. intellectual property law to the rest of the world.

The USTR is allegedly negotiating in the name of the American people¹⁵⁹ and yet it operates largely without public input or oversight. This lack of transparency is a huge problem for both the American people and our trade partners. It likely enables the negotiation of provisions that if negotiated by the light of day would never come to be. There is something very wrong when the public must depend upon WikiLeaks to learn about the terms of its own country’s trade agreements.

¹⁵⁶ *Letter to the President of the United States, Members of Congress, and Ambassador Michael Froman*, INFOJUSTICE.ORG (Nov. 14, 2013), <http://infojustice.org/wp-content/uploads/2013/11/Law-Professors-TPP-11142013.pdf> (last visited May 21, 2014) [*hereinafter Letter*].

¹⁵⁷ Margot Kaminski, *Capture, sunlight, and the TPP leak*, CONCURRING OPINIONS (Nov. 14, 2013), <http://www.concurringopinions.com/archives/2013/11/capture-sunlight-and-the-tpp-leak.html>, (last visited May 21, 2014).

¹⁵⁸ *Id.*

¹⁵⁹ *Mission of the USTR*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, <http://www.ustr.gov/about-us/mission>, (last visited May 21, 2014).

VI. Recommendations for Institutional Reforms

With this background and analysis in mind, ASAP echoes many of the recommendations existing in the literature. Specifically, it recommends the following two Institutional Reform Goals in the area of Intellectual Property and their attendant Targets:

- **Goal 1: Remove external and internal barriers to the use of TRIPS flexibilities.**
- **Goal 2: Increase support for existing south centered organizations and create an international task force composed of legal experts in intellectual property law from developing countries.**

A. **Goal 1: Remove external barriers to the use of TRIPS flexibilities.**

1. **Target 1: Systematically identify the ways in which the activities of foreign states and corporations interfere with the use of TRIPS flexibilities and examine how these activities are ethically or legally problematic.**

Some developed countries, in particular the United States, and industry groups use their more powerful political and economic positions to prohibit the otherwise lawful use of TRIPS flexibilities. As detailed above, TRIPS flexibilities are intended to enhance access to medications and relieve some of the burdens imposed by patent monopolies. Interference with the exercise of these flexibilities therefore impedes access to affordable medications. Thailand's issuance of compulsory licenses was an example in which interference stemmed from immense external pressures attempting to force Thailand to forgo the exercise of its rights. Citizens educated about intellectual property controversies and mobilized social activists played a key role in giving Thailand the domestic public

support it needed to withstand external pressures. Such activities, however, are reactionary rather than preemptory. What can be done to help reduce and eliminate such external pressures in the first place?

As Target 1 suggests, there needs to be a systematic categorizing of the external barriers developing countries face in implementing various TRIPS flexibilities. More importantly, with the aim of crafting justifiable policy, there needs to be an examination of the ways in which these various barriers are or are not morally and legally suspect. Distinguishing between coercion, undue inducements, exploitation and harassment will suggest varying policy implications. It may be desirable ethically and legally, for instance, to proscribe coercive practices, but not necessarily all instances of exploitation. While ASAP recommends a thorough investigation into these issues, brief consideration of how these various issues are manifested via differences between the external barriers of unilateral state pressure and the incorporation of TRIPS-plus provisions in FTAs is illustrative.

a. Unilateral state measures and coercion

As an example of unilateral state measures, consider the Special 301 process in the United States. This mechanism is used to influence the behavior of other states considered to lack sufficient protections for intellectual property.¹⁶⁰ El Said & Kapczynski explain the mechanism as follows:

Countries may also be reluctant to fully deploy the flexibilities allowed to them under TRIPS because of pressure from countries with big IP industries. The US Special

¹⁶⁰ Interestingly, Section 301/Special 301 threats and sanctions hung in the background of and motivated the TRIPS negotiations. *Taylor* at 234-35 (“Over the course of the Uruguay Round negotiations, it became clear that the developing countries ultimately accepted a U.S.-style TRIPs Agreement as a method for limiting Section 301 threats and sanctions.”).

301 process offers the most salient example. It was established by the 1988 *Omnibus Trade and Tariffs Act*, and under it, the US Trade Representative (USTR) must identify “priority countries,” namely those that “*have the most onerous or egregious acts, policies, or practices*” that “*deny adequate and effective intellectual property rights,*” or “*deny fair and equitable market access to United States persons that rely upon intellectual property protection.*” The USTR is permitted, by statute, to retaliate against such countries by imposing tariff or import restrictions, by suspending certain preferential trade agreements, or through other measures within the President’s power.¹⁶¹

The authors go on to note that threats and warnings of this kind “seem to have significant influence in some ministries of trade and finance, leading them to advocate against the use of flexibilities at the local level.”¹⁶²

To the extent that the accouterments of Special 301 prevent developing countries from utilizing TRIPS flexibilities, this appears to be a coercive measure. What counts as coercion? “Most ethicists accept the following definition: A person is coerced when her choices are unfavorably narrowed by someone who is trying to get her to do something she would not otherwise do.”¹⁶³ In other words, “the paradigm case of coercion involves one person (the coercer) threatening to make another person (the victim) worse off if he does not comply with the coercer’s demands.”¹⁶⁴ Importantly, coercion involves one agent purposefully manipulating the options of another, and doing so in a way that “unfavorably” narrows those options.¹⁶⁵ The use of the Special 301 process therefore may constitute coercion. If a country, for example, plans to take advantage of compulsory licensing, but the U.S. threatens trade sanctions in response, the U.S. unfavorably narrows the other country’s options.

¹⁶¹ *El Said & Kapczynski* at 11.

¹⁶² *Id.* at 12.

¹⁶³ Jennifer S. Hawkins & Ezekiel J. Emanuel, *Clarifying Confusions about Coercion*, 35 HASTINGS CENTER REPORT 16, 17 (2005) [hereinafter *Hawkins & Emanuel*].

¹⁶⁴ Joseph Millum, *Consent Under Pressure: The Puzzle of Third Party Coercion*, 17 ETHICAL THEORY AND MORAL PRACTICE 113, 114 (2014).

¹⁶⁵ *Hawkins & Emanuel* at 17.

Why ought we to care whether coercion is present? Coercion centers on “the formation of an agreement”.¹⁶⁶ When two (or more) parties agree to something, consent plays a crucial role. “[C]onsent is typically morally and legally transformative—that is, it changes the moral and legal relationship between parties to an agreement and between those parties and others...”¹⁶⁷ Coercion interferes with this transformation by undermining the validity of the agreement; it renders consent defective.

Given its effect on consent, coercion is often thought to be morally and legally problematic. Coercion, for example, is expressly noted as a source of treaty invalidity under the Vienna Convention on the Law of Treaties.¹⁶⁸ Coercion interferes with a “moralized baseline.” Though our example involves more of a legal than moral baseline, the point is analogous. All WTO members have a right to take advantage of TRIPS flexibilities if they so choose. Threats and actions taken under Special 301 processes interfere with this baseline for the worse. This is essentially a case in which “A proposes to make B worse off relative to B’s moralized baseline if B does not accept A’s proposal.”¹⁶⁹ When, in light of the threat of trade sanctions, a country agrees not to pursue compulsory licenses or more restrictive understandings of patentable subject matter, or what have you, it has been coerced. Its options have been constrained and it has been made worse off relative to the pertinent baseline.¹⁷⁰

¹⁶⁶Alan Wertheimer, *Remarks on Coercion and Exploitation*, 74 DENV. U. L. REV. 889, 896 (1997) [*hereinafter* Wertheimer I].

¹⁶⁷ *Id.* at 890.

¹⁶⁸ See Vienna Convention on the Law of Treaties arts. 51-52, May 23, 1969, 1155 U.N.T.S. 331, available at http://legal.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf. Of note, though the United States signed the treaty on April 24, 1970, it is not a party to this Convention because it lacks Senate approval. *Is the United States a party to the Vienna Convention on the Law of Treaties?*, U.S. DEPARTMENT OF STATE, <http://www.state.gov/s/l/treaty/faqs/70139.htm> (last visited May 21, 2014).

¹⁶⁹ *Wertheimer I* at 900.

¹⁷⁰ Of course, determining the “pertinent baseline” may be up for dispute. One possible counterargument to consider is whether the United States “could argue that they are offering a benefit [through trading privileges] in exchange for compliance rather than threatening a harm in retaliation for non-compliance.” Report Comments from Thomas Pogge to author (April 9, 2014) (on file with author).

If any kind of external interference with the use of TRIPS flexibilities ought to be proscribed, unilateral coercive measures appear to be the low hanging fruit. Indeed, the compatibility of the Special 301 process with the WTO's Dispute Settlement Understanding (DSU) is a matter of debate.¹⁷¹ Though the DSU requires members to settle disputes within the WTO system and forbids determinations of violations and appropriate retaliation outside of the dispute settlement process, complicated questions arise as to when the use of unilateral measures rises to the level of retaliation under covered agreements.¹⁷² It would seem that at least some activities that could occur under the Special 301 are morally and legally impermissible because they are coercive. Echoing the recommendations of others, ASAP therefore recommends an investigation into "the consistency of continued unilateral measures, such as the Special 301 process, with WTO law and human rights norms."¹⁷³ As noted under Target 2, an investigation ought to be undertaken into utilizing existing provisions in the WTO system to address such problematic measures as well as crafting pertinent amendments to TRIPS.

b. FTAs and Undue Inducement

While coercion could be an element attendant to the negotiation of free trade agreements, the inclusion of TRIPS-plus provisions in bilateral FTAs or plurilateral agreements such as the TPP highlight the potential for different ethical concerns. The contracting away of rights to use TRIPS flexibilities is presumably triggered by some kind of attractive offer. As Musungu and Oh note, interference with the use of TRIPS flexibilities through "FTAs pose a great danger to the production

¹⁷¹ *El Said & Kapczynski* at 11.

¹⁷² *Kapczynski I* at 1629-30.

¹⁷³ *El Said & Kapczynski* at 17.

and availability of medicines in developing countries.”¹⁷⁴ Countries recognize these dangers, but consider the risk of harm justified by gains in other sectors. “While these countries accept that they are losing TRIPS flexibilities, they seem to consider that overall there is a net gain for them and the concessions in intellectual property affecting medicines regulation are justified.”¹⁷⁵ Musungu and Oh find this analysis questionable. They write:

However, the net gains analysis presumes that earnings in agriculture or other sectors due to increased market access would translate into ability to afford higher priced medicines. Although increased earnings in these sectors may lead to better earnings for the workers and therefore better ability to afford medicine, it is difficult to see how overall such earnings would improve the ability of citizens to afford higher cost medicines.¹⁷⁶

The extent to which particular tradeoffs are justified has both empirical and normative elements.

In purely economic terms it has been observed that some proposed FTAs including TRIPS-plus provisions may offer developing countries a raw deal. This is especially so for countries with significant disease burdens like HIV/AIDS. Promises of increased “foreign direct investment (“FDI”) and technology transfer, as well as more trade and greater market access”¹⁷⁷ may not in actuality offset the costs of TRIPS-plus provisions.

HIV/AIDS has a distinct economic impact, and many developing countries in sub-Saharan Africa and in Southeast Asia are struggling to fight the disease effectively. For these countries, analysis of the benefits of an FTA with restrictive IP provisions must account for losses in GDP, increased personnel costs, and the burden on its healthcare system. The costs of AIDS significantly offset the benefits of FTAs in these countries, especially in light of the failure of many FTAs to generate the level of FDI and technology transfer that was initially promised. Empirical evidence from past FTAs and a comparison of the proposed U.S.-Thailand FTA to other recently

¹⁷⁴ *Musungu & Oh* at 54.

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ Charles T. Collins-Chase, *The Case Against Trips-Plus Protection in Developing Countries Facing AIDS Epidemics*, 29 U. PA. J. INT’L L. 763, 780 (2008) [*hereinafter Collins-Chase*].

completed agreements show that when AIDS-related costs are included, the benefits of the FTA are minimal.¹⁷⁸

Whether any given FTA is economically beneficial will obviously vary depending upon the specific features of the involved parties as well as the specific provisions under consideration. The economic analysis, however, intersects with a broader set of normative and legal questions pertaining to the nature of these agreements. Absent coercion (or corruption), if FTAs of dubious economic benefit are nevertheless concluded this suggests concerns about the possible presence of an undue inducement or exploitative agreement. Regardless of the economic profile, these issues also raise complicated questions as to whether TRIPS flexibilities are the kind of thing, ethically speaking, that may be bargained with at all.

Undue inducements involve offers that a recipient finds so attractive that it leads to defective decision-making. Bioethicists frequently raise concerns about undue inducements in the context of consenting to participate in clinical research. The point is analogous. Ezekiel Emanuel characterizes¹⁷⁹ the worry as follows: “The core worry seems to be that individuals are offered some good that, against their better judgment, makes them assume substantial risks of harm that compromise their welfare.”¹⁸⁰ He identifies four elements of an undue inducement: (1) a valuable or desirable good offered in order to get someone to do something, (2) the good is “irresistible in the context” which leads to (3) “poor judgment in an important decision” and (4) this decision “exposes them to unreasonable risks...or to forsake deeply held values.”¹⁸¹

¹⁷⁸ *Id.* at 785.

¹⁷⁹ It should be noted that a full investigation of this issue would require the excavation and debate of key terms of this characterization. For instance, the precise meanings of “irresistible” and “poor judgment” would need to be explored.

¹⁸⁰ Ezekiel J. Emanuel, *Undue Inducement: Nonsense on Stilts?*, 5 THE AMERICAN JOURNAL OF BIOETHICS 9, 9 (2005) (citations omitted) [*hereinafter Emanuel*].

¹⁸¹ *Id.*

Ideally, treaty negotiators are sophisticated actors and faithful public officials. Given these assumptions, concerns about undue inducements generally may not be warranted in the FTA context. Problems of this kind, however, could arise if a particular administration has unreasonably skewed trade priorities, is captured by industry, or in some other way represents special interests. To the extent that the interests of government officials diverge from that of the people, a distinction exists between the bioethics context of participating in clinical trials and international negotiations. In the clinical trial context the decision maker and the individual affected are one and the same. By contrast, when nations negotiate, the decision-maker's interests may be distinguishable from those who will be affected. Under far less than ideal circumstances, "The government of the developing country decides, exporting firms are the main beneficiaries and patients are bearing the harms (with some benefits and harms also bleeding outward into the wider population and the government)."¹⁸²

The broader point to keep track of is that states and corporate actors use inducements to influence the behavior of states all the time. The majority of these inducements "are not ethically problematic..."¹⁸³ Only a subset of such inducements may be considered undue: "Undue means that there is something more than a good offered to change our behavior. The something more is that the offered good leads to poor judgment which makes us take unnecessary, unreasonable, and excessive risks of harm, whether physical harm or the harm of violating important values."¹⁸⁴

The key question, in the context of TRIPS-plus provisions, is whether, and under what circumstances, the trading away of TRIPS flexibilities is tantamount to a government unreasonably exposing its citizens to excessive risks of harm to its health and well-being. Such cases might not exist, but reflecting on what separates inducements from undue inducements may be useful to keep

¹⁸² Report Comments from Thomas Pogge to author (April 9, 2014) (on file with author).

¹⁸³ *Emanuel* at 10.

¹⁸⁴ *Id.* (citations omitted).

in mind for the evaluation of external barriers to the exercise of TRIPS flexibilities. If undue inducements are a concern in this context, it will correspondingly suggest the need for a policy fix.

c. FTAs and Exploitation

While coercion focuses more on the formation of an agreement, exploitation “seems to always include reference to the substance or outcome of an agreement.”¹⁸⁵ A prominent conception of exploitation understands exploitation to occur when there is an unfair distribution of benefits and burdens arising out of an interaction.¹⁸⁶ Alan Wertheimer distinguishes between instances of harmful exploitation and mutually advantageous exploitation.

An exploitative transaction is one in which A takes unfair advantage of B. A engages in *harmful exploitation* when A gains by an action or transaction that is harmful to B where we define harm in relation to some appropriate baseline. A engages in mutually advantageous exploitation when, in relation to the same baseline, A gains *unfairly* or excessively by an action or transaction that is beneficial to B.¹⁸⁷

There are many different ways to think about what constitutes benefit, harm, and unfairness, but the definition is structural. When certain relations exist between parties, exploitation occurs.

FTAs, conceivably, could be vulnerable to both kinds of exploitation. An assessment of whether an FTA is exploitative and how particular TRIPS-plus provisions figure into this equation will depend on case specific analyses. Fine-grained assessments of individual TRIPS-plus provisions and their implications for specific countries will play a crucial role in making such determinations.

As a policy matter, however, whereas we might be naturally inclined to prohibit instances of harmful exploitation, cases of mutually advantageous exploitation are trickier. “[I]t is more difficult

¹⁸⁵ *Wertheimer I* at 896.

¹⁸⁶ Rebecca Wolitz, Ezekiel Emanuel & Seema Shah, *Rethinking the Responsiveness Requirement for International Research*, 374 LANCET 847, 847 (2009) (citing Wertheimer).

¹⁸⁷ ALAN WERTHEIMER, EXPLOITATION 207 (1996) [*hereinafter Wertheimer II*].

to explain when and why it might be wrong for A to gain from an action that benefits B and to which B voluntarily consents. And it is certainly more difficult to explain why society might be justified in prohibiting such transaction or refusing to enforce some such agreements.” This is so, because though the transaction is unfair, the exploited party is still made better off than it was pre-transaction.¹⁸⁸

d. May countries permissibly trade away their rights to use TRIPS flexibilities?

The foregoing discussion raises deep questions about a prior issue: is it morally permissible for countries to trade away their TRIPS flexibilities in the first place? Is it legally permissible? There are three logical possibilities in answer to these questions:

1. TRIPS flexibilities are always a permissible bargaining chip.
2. TRIPS flexibilities are never a permissible bargaining chip.
3. TRIPS flexibilities are sometimes a permissible bargaining chip.

The moral and legal permissibility of trading away TRIPS flexibilities are complex problems that merit further study. A brief prima facie case, however, exists for being suspicious of (1). Given the significant relationship that TRIPS flexibilities bear to access to medications, and the connection between access to medications and the fulfillment of the right to health, we should, at the very least question the position that TRIPS flexibilities are, unconditionally, permissible bargaining chips.

Legally (and ethically) a good case may be made that access to medications is intimately tied to fulfilling a human right to health. Suerie Moon observes that, “Access to essential medicines has gradually come to be recognized as part of the human right to health, enforceable under both

¹⁸⁸ *Id.* at 13-14.

international and national laws.”¹⁸⁹ The right to health is recognized in numerous international and regional treaties including the International Covenant on Economic, Social and Cultural Rights (ICESCR).¹⁹⁰ ICESCR is of particular importance because the Committee on Economic, Social and Cultural Rights (CESCR) which monitors the treaty’s implementation issued in General Comment 14 a mandate that the right to health include provision of “essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs”.¹⁹¹ Furthermore, paragraph 50 of General Comment 14 notes that a state violates an obligation of respect when it fails “to take into account its legal obligations regarding the right to health **when entering into bilateral or multilateral agreements** with other States, international organizations and other entities, such as multinational corporations.”¹⁹² Though General Comments issued by CESCR are non-binding, they are considered to offer authoritative interpretations of ICESCR treaty provisions.¹⁹³ In addition to international instruments, a number of national constitutions also include a right to health under which litigation has successfully established some form of access to essential medicines.¹⁹⁴

Given the premise that TRIPS flexibilities are a significant contributor to granting access to pharmaceuticals, and access to medications for some jurisdictions is included in a right to health, the trading away of TRIPS flexibilities therefore may violate a right to health. This is a legal argument contingent upon the national laws of particular jurisdictions as well as their international treaty obligations. It is not universally applicable. From an ethical perspective, however, the argument

¹⁸⁹ Suerie Moon, *Respecting the right to access to medicines: Implications of the UN Guiding Principles on Business and Human Rights for the Pharmaceutical Industry*, 15 HEALTH AND HUM. RTS. 32, 33 (2013) [*hereinafter* Moon].

¹⁹⁰ Hans V. Hogerzeil, Melanie Samson, Jaume Vidal Casanovas & Ladan Rahmani-Ocra, *Is access to essential medicines as part of the fulfillment of the right to health enforceable through the courts?*, 368 LANCET 305, 305 (2006) [*hereinafter* Hogerzeil et al.].

¹⁹¹ UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, ¶ 43 (d), 11 Aug. 2000, E/C.12/2000/4, available at <http://www.refworld.org/docid/4538838d0.html> (last visited May 21, 2014).

¹⁹² *Id.* at ¶ 50 (emphasis added).

¹⁹³ Hogerzeil et al. at 305.

¹⁹⁴ *Id.* at 308.

from a right to health will occupy the same basic structure, and, if successful, presumably would apply across all jurisdictions. This sketch is obviously not a full defense of the position that trading away of TRIPS flexibilities may violate a right to health, nor is it intended to be. Many intricacies still need to be examined.

e. Harassment

The final kind of external barrier to the utilization of TRIPS flexibilities that may be worthwhile to consider, are state and corporate activities deemed “harassing.” In the United States, harassment is often a matter of state law, and many different kinds of activities fall under the umbrella of “harassment”. Statutes have in common, however, that someone is guilty of harassment when he or she intentionally tries to harm or annoy someone. In New York, for example, an individual is guilty of harassment when, “with intent to harass, annoy or alarm another person...He or she engages in a course of conduct or repeatedly commits acts which alarm or seriously annoy such other person and which serve no legitimate purpose.”¹⁹⁵

It would be interesting to explore application of a conceptualization of harassment to the international realm. What would harassing activity in this context look like, and what would be the elements of the claim? Further, should such claims be actionable? Threats under Special 301 to be placed on the Watch List, for example, even if they did not rise to the level of coercion still appear problematic. Perhaps such activities might be appropriately construed as a form of harassment. Similarly, some¹⁹⁶ have suggested that raising unjustified claims might be considered a form of harassment and ought to be sanctioned.¹⁹⁷ A framework of international harassment could fill

¹⁹⁵ N.Y. Penal Law § 240.26 (McKinney) (West, Westlaw through L.2014, chap. 1-22, 50-60).

¹⁹⁶ Annette Kur & Marianne Levin, *Proposals for Amendment of TRIPS*, MAX PLANCK INSTITUTE FOR INNOVATION AND COMPETITION (April 2011), <http://www.ip.mpg.de/en/pub/news/trips.cfm> (last visited May 21, 2014).

¹⁹⁷ The group from the Max Planck Institute proposed the following amendment (among many others) to TRIPS: “*Article 41a [NEW] Remedies Against Mala Fide Use of Intellectual Property Rights* Members shall provide for proportionate, efficient and deterrent remedies against *mala fide* use of intellectual property rights, in particular the making of unjustified

potential gaps and provide explanatory clarity, regardless of whether making such claims actionable is ultimately advisable. Of course, if harassing activities *are* to be taken up as a source for TRIPS reform, the drafting of such provisions must be sensitive to striking a balance between protecting the use of TRIPS flexibilities against the freedom of Members to express their views in opposition to these practices as well as their rights to advocate for and engage in activities that further those ends.

2. Target 2: Explore current mechanisms within the WTO system for curtailing external barriers to the use of TRIPS flexibilities. Craft and advocate for pertinent amendment(s) to TRIPS.

A completed and comprehensive investigation as outlined under Target 1 will set the stage for implementing Target 2. Target 1 involves gathering information about how certain practices may be normatively and legally suspect. This will facilitate informed reform under Target 2. Target 2 involves the utilization of the acquired knowledge to (1) champion reform within existing TRIPS and WTO provisions, and (2) if no such provisions exist to offer draft amendments.

With respect to existing WTO provisions that might be co-opted in the service of curtailing external barriers to the use of TRIPS flexibilities, it may be worthwhile to explore the use of non-violation complaints under GATT Article XXIII. Article XXIII provides:¹⁹⁸

Article XXIII: Nullification or Impairment

1. If any contracting party should consider that any benefit accruing to it directly or indirectly under this Agreement is being nullified or impaired or that the

threats.” *Text of Proposals*, Agreement on Trade-Related Aspects of Intellectual Property Rights (with proposed amendments), http://www.ip.mpg.de/files/pdf1/proposed_amendments_to_trips_20110504.pdf (last visited May 21, 2014). These authors, in a project memorandum, call unjustified threats a form of “unfairly harassing others”. *TRIPS Amendments (work in progress)—background and explanations*, ATRIP, <http://www.atrip.org/Content/Activities/Kur%20AMENDMENT.pdf> (last visited May 21, 2014).

¹⁹⁸ *The General Agreement on Tariffs and Trade*, 1947 WL 55652, 29-30, available at http://www.wto.org/english/res_e/booksp_e/analytic_index_e/gatt1994_08_e.htm (last visited May 21, 2014) (note that the GATT 1947 provisions were incorporated into GATT 1994).

attainment of any objective of the Agreement is being impeded as the result of

- (a) the failure of another contracting party to carry out its obligations under this Agreement, or
- (b) the application by another contracting party of any measure, whether or not it conflicts with the provisions of this Agreement, or
- (c) the existence of any other situation,

the contracting party may, with a view to the satisfactory adjustment of the matter, make written representations or proposals to the other contracting party or parties which it considers to be concerned. Any contracting party thus approached shall give sympathetic consideration to the representations or proposals made to it.

The text goes on to say under section 2 that if problems between parties are not satisfactorily dealt with, the dispute may be referred to the dispute settlement process.

What is interesting about this provision is that if TRIPS flexibilities could plausibly be construed to be benefits under section 1, parts 1 (b) and 1 (c) would seem to provide space for exploring the kinds of claims discussed under Target 1. While coercive, exploitative, and harassing practices might not violate any particular provision of TRIPS, they arguably do impair the benefits that ought to redound under the agreement. Mainly, they interfere with the use of rights protected under TRIPS. Exploring the compatibility of non-violation claims with curtailing external barriers to the use of TRIPS flexibilities has the benefit of drawing upon an already existing infrastructure for dispute settlement.

This particular proposal, however, comes with significant caveats. It is, thus, cautious. These non-violation provisions do not currently apply to TRIPS,¹⁹⁹ and their application is the subject of vigorous opposition by developing countries. By some accounts the United States and Switzerland are the primary, if not only, proponents of lifting the moratorium on non-violation

¹⁹⁹ *Is it possible to have intellectual property disputes in the WTO even if no agreement has been violated? If so, how could they be handled?*, WORLD TRADE ORGANIZATION (Dec. 3, 2009), http://www.wto.org/english/tratop_e/trips_e/nonviolation_background_e.htm (last visited May 21, 2014).

complaints for TRIPS.²⁰⁰ Knowledge Ecology International writes that:

For many WTO members, the application of non-violation and situation complaints to the TRIPS Agreement, as advocated by Switzerland and the United States of America, represent a stealth attack on WTO members' sovereign right to use TRIPS flexibilities such as compulsory licensing to safeguard health and promote access to medicines for all.²⁰¹

Others have discussed the ways in which the availability of non-violation remedies may be troublesome.²⁰²

To suggest an investigation into non-violation provisions is not in any way meant to undermine the validity or persuasiveness of these views. Rather, the suggestion is to explore how these provisions might be made to work to the advantage of developing countries—an exploration that appears to be absent from the literature. Even if these provisions prove promising mechanisms for curtailing external barriers to the use of TRIPS flexibilities, it may be that other considerations nevertheless persuasively counsel in continued support of a moratorium. Still, prior to drafting new amendments from scratch such an exploration would appear worthwhile.

3. Target 3: Demand greater transparency in the negotiation of bilateral and plurilateral free trade agreements.

Steps must be taken to make the negotiations and texts of Free Trade Agreements more transparent. Within the United States this may include making the USTR accountable under several

²⁰⁰ WTO TRIPS Council (February 2014) - India's intervention on Non-Violation and Situation Complaints, KNOWLEDGE ECOLOGY INTERNATIONAL (Feb. 26, 2014), <http://keionline.org/node/1963> (last visited May 21, 2014).

²⁰¹ *Id.*

²⁰² Matthew Stilwell & Elisabeth Tuerk, *Non-violation complaints and the TRIPS Agreement: Some Considerations for WTO members*, CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW ¶ 41 (May 2001), http://www.ciel.org/Publications/Nonviolation_Paper1.pdf (last visited May 21, 2014). The authors argue that, “the non-violation remedy is particularly inappropriate in the context of the TRIPS Agreement. As noted by many WTO Members, its application to the TRIPS Agreement raises a series of practical problems for developing countries, threatens to further imbalance the implementation of the TRIPS Agreement against the interests of the public and developing countries, and gives rise to systemic issues of coherence among WTO Agreements.”

federal laws. Deep consideration ought to be given to making the USTR's trade advisory committees subject to the transparency provisions of the Federal Advisory Committee Act, and its proposals for trade agreements subject to the Freedom of Information Act.²⁰³ Given that the USTR is a "captured" agency, the best avenue to explore for reform may be to alter the USTR's institutional design.²⁰⁴

B. Goal 2: Increase support for existing south centered organizations and create an international task force composed of legal experts in intellectual property law from developing countries.

1. Four Targets

- **Target 1:** Decrease internal barriers to the use of TRIPS flexibilities through changes to national laws.
- **Target 2:** Foster formal and informal collaboration and support amongst developing countries for rejecting TRIPS-plus provisions.
- **Target 3:** Build up and disseminate expertise in intellectual property law from an orientation sensitive to the needs of developing countries.
- **Target 4:** Reduce reliance by developing countries on the training and expertise of developed countries.

2. Addressing these Targets through Research and Collaboration

We currently exist under an intellectual property regime with a "transnational legal culture...disproportionately influenced by high-protection jurisdictions, which have a comparative

²⁰³ *Letter, supra* n157.

²⁰⁴ Margot Kaminski, *The Capture of International Intellectual Property Law Through the U.S. Trade Regime*, __ S. CAL. L. REV. __, 59 (forthcoming 2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2354324 (offering a number of proposals for reform).

advantage in generating, legitimating, and disseminating their writings.”²⁰⁵ This needs to change. Developing countries need to have a more powerful voice in shaping the international intellectual property regime. While several developing country led organizations and joint ventures—including the South Centre, the Third World Network, and the India-Brazil-South Africa Dialogue Forum—work in the area of intellectual property, efforts of this kind need more support and visibility.

In particular, echoing the recommendations of others,²⁰⁶ it may be helpful to explore the creation of an international task force or organization composed of legal experts from developing countries. This task force would have a mandate to, *inter alia*:

1. Draft model intellectual property laws that make optimal use of TRIPS flexibilities.²⁰⁷
2. Generate and articulate legal norms sensitive to developing country concerns.
3. Issue policy papers and promote the Task Force agenda at appropriate international and domestic forums.
4. Facilitate collaboration and coordination across countries to implement a shared agenda.
5. Create, organize and conduct relevant educational trainings.

The potential benefits of such a program would be numerous. As Amy Kapczynski notes, “If countries with similar aims in TRIPS implementation coordinate their legal frameworks, they can reduce the collective administrative costs of adopting an alternative patent regime, create a transnational ‘counter-culture,’ and increase the costs to their opponents of extralegal retaliation.”²⁰⁸

²⁰⁵ *Kapczynski I* at 1623.

²⁰⁶ *Cf. El Said & Kapczynski’s* recommendations for an independent commission and South-South collaboration on technical assistance at 17 and 19.

²⁰⁷ *Cf. WIPO’s Standing Committee on the Law of Patents*, which is comprised of all member states of WIPO. *Standing Committee on the Law of Patents (SCP)*, WORLD INTELLECTUAL PROPERTY ORGANIZATION, <http://www.wipo.int/policy/en/scp/> (last visited May 21, 2014).

²⁰⁸ *Kapczynski I* at 1639.

A group of the kind ASAP envisions could generate legal, economic, political, social, and expressive benefits. It would help to address the four specific targets identified under Goal 2.

The idea is to create a group of legal experts, led by and convened for developing countries, which will emerge as a leader and authoritative source on intellectual property issues. To that end, the group might be modeled after the American Law Institute (ALI). ALI is a prestigious legal organization that:

produc[es] scholarly work to clarify, modernize, and otherwise improve the law. The Institute (made up of 4000 lawyers, judges, and law professors of the highest qualifications) drafts, discusses, revises, and publishes Restatements of the Law, model statutes, and principles of law that are enormously influential in the courts and legislatures, as well as in legal scholarship and education.²⁰⁹

ALI is an independent organization, and it seems desirable that the task force or organization envisioned here ought also to be independent.

To that end, it is worth exploring how such a program could be housed within existing intergovernmental organizations or regional intellectual property organizations²¹⁰ with centralized authority on intellectual property matters.²¹¹ With respect to regional intellectual property organizations in particular, insofar as TRIPS flexibilities are not widely implemented, and TRIPS-plus provisions are being included in FTAs, it would be useful to explore what current, expanded, and/or new role these organizations can or should play in advocating for reforms. If such organizations are unable or limited in their abilities to fill this role, it is also important to determine why this might be.

²⁰⁹ *ALI Overview*, AMERICAN LAW INSTITUTE, <https://www.ali.org/index.cfm?fuseaction=about.overview> (last visited May 21, 2014).

²¹⁰ For instance the African Organization for Intellectual Property (OAPI) and the African Regional Intellectual Property Organization (ARIPO).

²¹¹ *Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks*, WHO (2004), <http://apps.who.int/medicinedocs/en/d/Js4968e/8.2.1.html> (last visited May 21, 2014).

Other practical considerations for creating a new program will, of course, include questions of funding. Assuming the desirability of independence, and more specifically independence from developed country influence, procuring adequate funding raises complicated questions. Since the organization is a legal organization operating in the public interest, one idea to explore would be to fund the program through bar membership in participating jurisdictions. Another possible idea would be to implement additional fees through patent offices, again, in participating jurisdictions. Last, a considerable amount of funding might eventually be procured through educational offerings. 61% of ALI's 2012 Operating and Non-operating revenue, for example, were derived from continuing legal education revenue.²¹²

One of the major criticisms of TRIPS has been that it wrongly imposes a one-size-fits-all intellectual property regime on the entire world.²¹³ The creation of an ALI like task force, or organization, might be seen as yet another kind of project. This charge, however, is mistaken for two reasons. First, developing countries will have ownership over the envisioned program. Its leadership and contributors will be legal experts from developing countries. To the extent that “federalism” type concerns might be raised, the organization can create mechanisms that allow all stakeholders the opportunity for voice and representation. Second, with respect to its legislative activities, the mission is to create *model* legislation and policies. Nothing about this process is binding. This legislation is to be the starting and not the end point for individual developing countries to decide what kind of legislation works best for their own unique needs. The model legislation serves only as an important resource to be individually tailored.

²¹² *The American Law Institute Annual Report 2011-2012*, AMERICAN LAW INSTITUTE 22, http://www.ali.org/doc/ALI_annual-report-2012.pdf (last visited May 21, 2014).

²¹³ *Flynn* at 108 (“A central argument of the opposition was that one size does not fit all in intellectual property policy and that, instead, countries need to take advantage of the flexibilities and ambiguities in the international legal system to craft laws to best serve their own policy goals. An over-expansion of one-size-fits-all intellectual property laws was framed as a threat to numerous vital social and economic objectives, including promoting access to affordable medications, enabling farmers to save and trade their own seeds, and ensuring that students can access affordable learning materials.”).