

Using Publicity to Get Medicine: How Political Participation Can Alter World Trade Policy and Secure Medicines for the Global Poor

by
Robert Howsam

Bachelor of Arts (with Distinction), Simon Fraser University, 2017

Project Submitted in Partial Fulfillment of the
Requirements for the Degree of
Master of Arts

in the
Department of Political Science
Faculty of Arts and Social Sciences

© Robert Howsam 2018
SIMON FRASER UNIVERSITY
Spring 2018

Approval

Name: Robert Howsam

Degree: Master of Arts

Title: Using Publicity to Get Medicine: How Political Participation Can Alter World Trade Policy and Secure Medicines for the Global Poor

Examining Committee:

Chair: Dr. Sanjay Jeram
Senior Lecturer

Dr. David Laycock
Senior Supervisor
Professor

Dr. Endre Begby
Supervisor
Associate Professor
Department of Philosophy

Dr. Genevieve Fuji Johnson
Internal Examiner
Professor

Date Defended/Approved: April 18, 2018

Abstract

Despite HIV becoming a manageable illness due to advancements in pharmaceuticals, over a million people still die every year due to AIDS – most of them poor, in the global South, who cannot afford to pay for treatment. What might allow them to secure medicines? My study of changes in trade policy shows that agreements originally designed to favour pharmaceutical companies can be implemented in ways that lead to increases in access to medicines for the global poor. I argue that domestic and international activism creates global public pressure, and is the key to altering the trajectory of trade policy implementation. Because access to affordable medicines for the global poor is more likely to occur when trade policies face public scrutiny, I call for transparent and accessible trade negotiations and enforcement in the WTO. In essence, I call for a democratization of the international trade regime.

Keywords: trade policy; access to medicines; NGO; WTO; political efficacy; global governance

Table of Contents

Approval.....	ii
Abstract.....	iii
Table of Contents.....	iv
Introduction	1
Literature Review	3
A Theory of a Globalized Political Community	7
Methodology.....	9
Empirical Analysis	9
Ethics and Proposals.....	12
The Case of TRIPS	14
A Narrow Problem Definition	15
Unequal Decision-making Power.....	16
Contested Implementation.....	18
A Proposal for More Effective Participation	22
Current Policymaking Opportunities for NGOs	22
The Proposals	23
Reconceptualising Representation	26
Objections	31
Unacceptable Inefficiencies.....	31
The Incentive Structure Requires IP Rights.....	32
Conclusion	37
References.....	39

Introduction

The intellectual property (IP) rights provisions in the current world trade agreement are contentious due to their negative impacts on access to medicine, which are particularly pronounced for the world's most impoverished. For example, approximately 22 million people with HIV were not receiving antiretroviral treatment in 2015 – most of whom were in economically developing countries – contributing to over a million AIDS deaths per year worldwide. IP rights give pharmaceutical companies a monopoly on the production and marketing of their medicines through patents, prohibiting the production of cheaper generic medicines. Where a generic cannot be produced, prices can remain high and therefore beyond the reach of the world's poor (UNAIDS 2015).

The Secretary-General of the United Nations created the High-Level Panel on Access to Medicines (HLP) to investigate access to affordable medicine. Its final report finds that the goals of two international regimes are in conflict with each other. The World Trade Organization's (WTO) treaty on IP rights, the 1994 *Agreement on Trade-Related Aspects of Intellectual Property Rights* (known as TRIPS) seeks to spur innovation and economic growth through monopolies for intellectual property creators, primarily through the use of patents. Meanwhile, international human rights law – and much of the work of the international community – is dedicated to promoting human well-being and development. This results in “incoherencies” in the policy goals between the trade regime and the rights regime (High-Level Panel 2016). But my case study will show IP rights holders like the pharmaceutical industry played a leading role in developing TRIPS while IP users – those seeking access to medicines – were largely excluded. I argue that while the WTO should strive to increase access to medicines, such goals are only likely to be achieved by creating more opportunities for effective political participation for IP users and their allies within the WTO.

To make my case, I first show how to conceptualize the political community in global politics. It differs significantly from the domestic realm, not least because there is no one government that people can appeal to for justice. As Nancy Fraser (2008) argues, our global governance structures, like TRIPS, will only be just when they embrace the ideal that everyone who is subjected to their rules and effects has an opportunity to understand the implications of the system and shape its development.

After laying out these philosophical arguments, I describe how TRIPS was constructed and negotiated. I use a policymaking analysis framework developed by Howlett, McConnell, and Perl (2016) to perform a case study in two parts. Through their framework, which combines stages and spheres of influence, I first show TRIPS is the result of a policymaking process that was dominated by powerful states and interests. I show that it excluded IP users, denied them political participation, and developed a system that provides patents for the pharmaceutical industry but little protection for IP users.

Using the same framework, I then show how IP users and their allies pressured the United States to reverse trade actions designed to punish countries that produced generic medicines. I show how the course of TRIPS' implementation and interpretation was changed through the actions of a global coalition that exposed the US government's tactics to public scrutiny for the first time, and eventually made TRIPS more flexible. This will demonstrate how publicity is an effective means of changing powerful actors' responses, and can lead to greater access to medicines for the world's poor.

To prevent the exclusion of IP users in the future, and thus give them an equal opportunity to shape the rules that shape their lives, I propose changes to the WTO that would make it more susceptible to democratic inputs. Using Fraser's insights along with Iris Marion Young's, coupled with the empirical evidence produced in the case study, I offer three proposals. Each is designed to increase efficacy of IP users, at different stages of the policymaking process, through increased publicity within the WTO. Before concluding, I consider important objections regarding the impact such changes might make on policymaking at the WTO, and whether or not innovation might be harmed by greater access to medicine.

Literature Review

There is widespread and longstanding agreement that amongst human rights, a right to health exists. In addition to its presence in the 1943 World Health Organization Constitution, the 1948 Universal Declaration of Human Rights and the 1966 International Covenant on Economic, Social and Cultural Rights, “every state has ratified at least one international human rights treaty recognizing the right to health” (OHCHR and WHO n.d., 1) and it is “recognized in at least 115 constitutions” (OHCHR and WHO n.d., 10).

That the right to health should include access to medicines is also widely accepted. The Special Rapporteur on the right to health reported to the UN Human Rights Council that TRIPS has “had an adverse impact on prices and availability of medicines, making it difficult for countries to comply with their obligations to respect, protect, and fulfil the right to health” (Grover 2009, 28). Further, in the economically developing South, far fewer people have private health insurance or access to government-subsidized medicines, so they pay 50 to 90 per cent of the costs of their medicines themselves. This drives 100 million people into poverty every year (Grover 2009, 7). The Special Rapporteur later urged states to address this, and “shift the dominant market-oriented paradigm on access to medicines towards a right-to-health paradigm” (Grover 2013, 5).

Access to medicines, many argue, must be balanced against IP rights (e.g., Helfer as cited in Helfer and Austin 2011; High-Level Panel 2016; Pogge 2010; WHO 2006; WIPO 2007). But where legal protections for IP rights holders have been clearly specified in TRIPS, rights for IP users are not (Sell 2003). Among the set of core principles that “run throughout” the WTO’s legal documents is a commitment to protect public health (WTO n.d.), but human rights are not acknowledged. And though a 2001 Ministerial Declaration – a non-binding document from the organization’s highest body – says “no country should be prevented from taking measures for the protection of human, animal or plant life or health” (WTO 2001), this does not express or affirm an individual right to health and does not assure access to medicines for IP users. Instead, the current TRIPS agreement grants states the option to override patents in public health emergencies. States can grant licenses for the production and sale of patented medicines to entities other than the patent holder – that is, to allow for the production of

generic medicines – if a government determines that public health requires it (Sell 2003). However, as my case study will show, countries face economic and legal pressures from the US, the European Union and the pharmaceutical industry when they attempt to invoke the public health provisions in TRIPS.

IP users and their allies then respond to this pressure and attempt to reverse government and industry positions. Domestic civil society organizations (CSOs) and international non-governmental organizations (NGOs), often alongside poorer Southern governments, use both formal and ad-hoc networks (Hosseini, 2010; Pianta 2014; Reitan 2012; Wibulpolprasert et al. 2011) to draw various publics' attention to the negative impacts of the pressure, and often secure concessions on a case-by-case basis (Hallas 2006; Hoekman and Kostecky 2009; Sell 2003). This has led some to suggest that TRIPS could balance IP rights holders' and IP users' interests if powerful countries stopped launching WTO challenges and trade actions when poorer countries use the public health provisions within TRIPS (Hernández-Truyol and Powell 2009).

These controversies have led to a discourse linking the right to health to access to medicines. Driven by CSOs and NGOs, a number of findings and motions adopted by UN bodies indicates a change in international norms toward a link between access to medicines and the right to health (Alkoby 2012, Hosseini, 2010; Pianta 2014; Reitan 2012; Wibulpolprasert et al. 2011). But it is still in flux (Alkoby 2012), so some have argued that human rights still need to be legitimized and clarified by describing their relationship to the international trade regime (Alkoby 2012; Harrison 2007; Hestermeyer 2007; OHCHR 2001).

Others examine the roles of the state and the market. Market proposals focus on developing different funding systems for IP knowledge generation, and thus intend to make discoveries accessible to more people (see Fisher and Syed 2010; Goldin and Reinert 2012; Knowledge Ecology International 2008; Love 2016; Pogge 2010). States can also keep IP laws but create a more competitive environment – and thus lower prices more quickly – through laws that promote rapid development of generics as patents end and limit “evergreening” of patents, where pharmaceutical companies make small changes that allow for the extension of patents on existing medicines (Grover 2013; High-Level Panel 2016; OHCHR 2001; WHO 2006; WIPO 2007). And Northern governments are called upon to speed up and build up the transfer of technology and

domestic technical and legal expertise in less-developed countries to reduce the inequality in access to medicines TRIPS exacerbates (Goldin and Reinert 2012; High-Level Panel 2016; WHO 2006; WIPO 2007).

Some focus on the role of the pharmaceutical industry, and call on it to build on the limited actions taken in recent decades to meet the needs of IP users. They negotiate price discounts with countries that are considering issuing compulsory licenses – the legal mechanism that allows the production of generic medicines still under patent protection (Glaser and Murphy 2010). They sometimes voluntarily provide “equity pricing” for poor countries so that medicines are affordable (WHO 2006). They negotiate bulk discounts (Rosenberg 2014), or in cases of public health crises, issue voluntary licenses, which allow their patents to be used for free (Hoekman and Kostecki 2009). They pursue partnerships with governments in less economically developed countries and NGOs to ensure widespread distribution of medicines (Illingworth 2012; Ng 2010; Werhane and Gorman 2005; WHO 2006). But some argue that for these ad hoc measures to lead to lasting and consistent access to medicines— regardless of country or illness – corporations must develop an ethical position that recognizes their unique responsibility to provide health care technologies (Illingworth 2012; Ng 2010; Werhane and Gorman 2005).

Others call for greater involvement by civil society and health service providers both domestically and internationally. These organizations can defend the human right to health and pursue meaningful change in both the interpretation of rights and the delivery of services (Farmer 2003) while also monitoring the current trade regime for rights violations – and indeed anticipate such violations in the policy formulation stage (Harrison 2007; OHCHR 2001).

The WTO is criticized for its close-knit “club culture.” When the WTO was formed in 1995, there was no input by NGOs or other non-state actors who might represent the interests or perspective of the global poor (Charnovitz 2000; Scholte 2004; Steffek and Kissling 2006). It was common practice to allow only those adept in international trade to participate in policymaking, because they were best able to act in interests of the common good, it was presumed (Esty 2002; Steffek and Kissling 2006).

This kind of culture depoliticizes important issues like access to medicines, hiding them behind technical and confidential negotiations that privilege those who have access. The many who do not participate lack not only a voice, but knowledge as to what is being considered, negotiated and implemented (McMichael 2012, Esty 2002). To rectify this, some argue that the WTO should create more opportunities for public participation (Wilkinson 2014) by making it clear who has influence and how decisions are being made (Esty 2002) and publishing drafts of trade agreements (Scholte 2004). Others call for the creation of mechanisms akin to legislative oversight, either within the WTO or through domestic legislatures (Esty 2002; Charnovitz 2000). Such mechanisms might allow issues like access to medicines to reach decision makers more quickly.

In summary, the discourse on access to medicines considers a range of options from rights claims to policy changes to institutional changes. Rights claims can only succeed where mechanisms to enforce obligations exist, and policy changes only succeed with solid plans for implementation.

While all of the proposals might have merit, they have yet to be brought together within a comprehensive proposal, as I will now do by investigating two questions: (1) On what basis can anyone claim a right to participate in the makings and machinations of a trade agreement and (2) what institutional alterations, supported by a claim to participate, will make it more democratic? Put another way, how can we conceptualize political participation without – or perhaps above – the single nation state? And what does that tell us about how to reform the WTO? To answer the former question, which informs the latter, I next explore Nancy Fraser's theory on a globalized political community.

A Theory of a Globalized Political Community

To translate what have traditionally been domestic political rights – and violations of them – to a globalized political-economic structure like TRIPS, we need to re-conceptualize the political community. Fraser (2008) argues that prior to the establishment and growth in power of international organizations like the International Monetary Fund (IMF), the World Bank and the WTO, most of our claims for redistribution of valuable goods or recognition of our equal moral standing could be advanced through direct political participation and formal and informal representation within the state. But international rules and systems that create globalized governance structures are not controlled by any one nation-state. Instead of defining our political community around the nation state, the right to political participation should be organized around the “all-subjected principle” (65): All who are subjected to the rules of a structure have moral standing to participate in the development and decisions of that structure. If people live under a shared set of rules, systems or institutions that are “shaping their respective life possibilities” (24), these structures allow them to make claims against one another, through both legal means and political discourse. They thus form a political community.

A just political community enables “parity of participation” (Fraser 2010, 16) in political discourse. Everyone in a political community should have the ability to participate equally in three connected areas: economic redistribution, cultural recognition and political participation. A key element of equal political participation is efficacy. That is, equal political participation is only possible if competing parties are not only heard, but have some chance of seeing their agenda met. For Fraser, political efficacy can be demonstrated when a public’s will is “translated ... into binding laws” and then implemented into programs and regulations (Fraser 2010, 96).

While we are unlikely to ever have complete equality in participation, one element that is available to those who have less access to the formal mechanisms of power is the “critical function of publicity” (Fraser 2010, 93). Through public scrutiny and debate, “a relationship” develops among all political participants that exposes everyone to a “plurality of points of view” (Young 2000, 169). While this can lead to greater understanding, publicity can also constrain public officials in the domestic sphere and “put pressures on state institutions to address” neglected issues (Young 2000, 177).

My case study will demonstrate that publicity is central to effective participation for IP users in the international sphere. For IP users in South Africa, the case under study, it was only when they were able to use publicity that they were able to adjust and clarify TRIPS regarding their government's options around public health, both through their direct actions, and through those of international NGOs. However, the ongoing battles around the use of generics show that the legal clarifications were not enough. The US government and the pharmaceutical industry often punish states that issue compulsory licences through trade sanctions and economic actions.

These actions then meet with a globally-organized response by IP users and their allies. This is a complex dynamic. It involves international trade rules and attempts by the US, the pharmaceutical industry and other powerful allies to enforce a particular interpretation of them; the publicizing of these attempts in an effort to use publicity to shame these actors into changing their positions on them; and the coordination of these efforts across states and domestic and international activists. This means the global poor have often been represented by international NGOs on the world stage, and by US domestic activists within the United States to advance their interests.

Thus, for publicity to work in the global trade regime, the global poor are dependent upon a form of representation that allows for NGOs and domestic actors in other countries to articulate their interests, perspectives and policy prescriptions. This is akin to what Iris Marion Young describes as a democratic "process that *connects* 'the people' and the powerful" in the public sphere" (Young 2000, 173, author's italics). Civil society actors, both domestic and international, "transmit information about ... harms" through public discussions, contentious politics and dissemination through news media (Young 2000, 177-8). As my case study will show, political participation for the global poor is generally limited to the domestic sphere, but when they align with international NGOs, they are able gain representation by these actors who can transmit information to the publics that can affect US policy and pharmaceutical industry policy.

In sum, some of the injustices of political exclusion of the global poor – which have led to real harms – can be mitigated through increased participation. For this participation to be effective, it will require a stronger role for publicity in WTO policymaking, and for NGOs as representatives in the international realm.

Methodology

Empirical Analysis

I will first perform a case study to show that IP users were excluded from the political process of TRIPS' creation, and then I will show how they developed an effective response. I will first perform a case study, using existing literature, to show that IP users were excluded from the political process of TRIPS' creation. I will show that TRIPS' agenda setting stage was a process internal to the US in the 1980s and was primarily designed to address trade deficits and IP industries' — pharmaceuticals, entertainment and computer technology — profits (Sell 2003). In the second phase of my case study, I will focus on South Africa's attempt in 1997 to produce generics to address the public health emergencies of HIV/AIDS, tuberculosis and malaria. I will show that those that shaped TRIPS — the US government and its industries — attempted to restrict South Africa's actions. This triggered a global movement against TRIPS, bringing the agreement into focus – and contention (Kelly 2007; Mowjee 2003).

My case selection is designed to “exemplify a common pattern” as Gerring puts it, (2017, 56) and so the case is chosen because it is typical. The pattern I examine is which political actors are able to influence policy at different phases of the policymaking process, specifically how publicity, generated by domestic and international civil society actors, reverses US policies on trade. What began in South Africa has become a typical pattern in the international political economy: a country attempts to use generics for public health purposes; the US and the pharmaceutical industry attempt to prevent the country from doing so; a coalition of domestic activists and international NGOs raises alarms. I will show it is representative of this dynamic by briefly describing the case of Thailand's attempt to produce generic medicines, which, though it began years after the South Africa case resolved in 2001, follows the same pattern.

I selected this early phase of the TRIPS agreement because it allows me to apply Gerring's “manipulable-in-principle” (2017, 199) concept. Prior to the South Africa case, there was very little interaction between NGOs and the policymakers in the international trade regime; only as TRIPS became public did NGOs begin to grasp the implications for access to medicines (Hanegraaff et al. 2011). With greater civil society involvement

came greater publicity, and eventually shifts in US trade policy and greater access to medicine.

Even though I cannot manipulate the key independent variable — political participation by IP users — I will be able to measure its effect in the case study. The dependent variable, US trade policy, had been altered from the decision-making stage to the implementation stage, providing a treatment effect for analysis. In the implementation phase of the case — what we might call the treatment period — there is much stronger involvement by NGOs and domestic activists. This led to widespread awareness of the effects of TRIPS and to changes in US policy. This reflects the political efficacy of the global Access to Medicines movement. Thus, only this single case is available to show a pre-treatment period and a post-effect period. And a focus on a single case allows for an in-depth analysis that spans approximately a decade.

For the pre-treatment period, Susan Sell's account of how TRIPS came to be will be central, and for the post-treatment period I will draw on a variety of accounts of political action from various disciplines, particularly political economy and sociology. I will examine the nature and effects of several independent variables: the pharmaceutical industry's role; US government's actions; domestic activists' role in the US and South Africa; and international NGOs' role.

I will operate deductively, using Fraser and Young's ethical frames to demonstrate that equal participation was not available at the early stages of TRIPS. To do this, I will apply a policymaking analysis framework that allows me to explain why US and pharmaceutical industry policy shifted after the introduction of IP user participation.

I will use an approach recently developed by Howlett, McConnell, and Perl (2016). It synthesizes two major policy analysis frameworks, policy cycle-stage models and policy stream models. Models that use cycles to explain policy outcomes break the process into a number of stages, each of which contains a series of events and participants with their own dynamic. Between each stage, a critical juncture creates an opportunity for the process to change direction. Timing thus becomes a critical element in determining events. The authors argue that while cycle models offer an effective analytical tool for breaking down the stages through which an idea becomes an implemented policy, it presents "an idealized image of policymaking" that makes it

difficult to detect power or explain why a stage ends and a new one begins (277). Multiple streams models are able to analyze different actors operating in different spheres – politics vs policy development for example – and explain how their interactions eventually create policy. While this latter model is effective at explaining why an idea moves off the drawing board and into political consideration, it tends to focus on the early part of the policymaking processes, missing out on how decision processes themselves can be designed and manipulated in favour of a preferred outcome.

Howlett, McConnell and Perl (2016) bring these two effective yet incomplete frameworks together in their “threads metaphor” framework. They identify five stages that echo policy-cycle models: agenda setting, policy formulation, decision making, implementation and evaluation. Five spheres of activity or “threads” weave through the stages: problems, policies, politics, processes, and finally a program thread emerges, when decision-making shifts to implementation. Because this model can “capture the political and power dynamics of public policy” (275), it not only helps explain the initial formulation and adoption of IP rights, but it is an excellent tool for explaining how TRIPS evolved.

Because it uses a stage model, I will use it to detect changes in power for the different actors as the cycle progresses. And the threads moving through the stages help to explain why these changes in power occur. The authors theorize that being able to identify which thread is dominant at different stages of the cycle provides insights into why a policy emerged. Different actors can have greater influence if they can succeed in mastering the dominant thread (Howlett, McConnell, and Perl 2016). I will describe each stage and thread in more depth as they become relevant to the case study. I will detail who dominates individual threads, and which threads are dominant at different stages, which will help explain the political efficacy of different groups. In doing so, I will highlight different means of efficacy, and the power of publicity for IP users will become apparent.

This empirical work allows me to address my own bias, and those of some of my chosen theorists. An empirical, deductive approach limits the possibility that my desire to align with a critical interpretation of events will draw me toward an incorrect conclusion. By using a policymaking framework, and this one in particular, I am able to focus on actual events to check my interpretation, rather than only normative accounts of how the international sphere does or should function. One place this will be particularly important

is the role of the pharmaceutical industry. It has been vilified for decades, as the case study will show, for asserting its patent rights, even in poorer countries. Thus, it is important to use an analytical method that will allow me to determine if the pharmaceutical industry is merely responding to a set of rules that they too are living under, or if they play some larger role in the creation of these rules, and thus are themselves powerful players.

Ethics and Proposals

Proposals founded in normative theory, as these are, are most relevant to real world problems when they comprehensively move from ethical principles to implementable policy. This means going from an ideal vision of justice – complete parity of political participation for example – to what can be implemented in the here and now. This is accomplished by bringing in empirical evidence (Gerring and Yesnowitz 2006) and understanding current political and economic systems (Hamlin and Stemplowska 2012). I use the case study evidence to demonstrate that IP users' political efficacy can be enhanced through alterations to the current policymaking/trade negotiation processes. By showing how the principles of political participation can manifest in policymaking process changes, I tie the theoretical elements to an implementable solution. In sum, I recognize that the injustice of little to no political participation for the world's poor is both morally untenable and only incrementally alterable.

Note that I choose to focus on only a few possible changes, so that I can elaborate on and explore each one. The discourse provides a range of ideas, but I highlight those that both closely align with the ethical goal of parity of political participation, and are most likely to be most efficacious for IP users.

And I am not suggesting that my proposals, even fully implemented, will solve the problem of access to medicines for the world's poor. It is widely recognized that access is also inhibited by a lack of domestic production capacity (e.g., Joseph 2011) and insufficient health infrastructure to adequately distribute medicines (e.g., High-Level Panel 2016). This proposal does not address those countries with such limited capacities. Nor does it suggest a solution for the problem Pogge (2011) proposes to solve: the structural lack of incentives for researching medicines that treat diseases that predominantly afflict the world's poor – neglected tropical diseases.

Finally, I do not attempt to resolve the conflicting objectives and philosophies between the trade regime and rights regime. I look specifically at one gap created by this conflict – the problem of life- and health-saving medicines out of reach due to cost for the poor in the global South – and attempt to minimize the incoherencies to resolve it.

The Case of TRIPS

In this section, I show how industries that profit from IP rights dominated the policymaking process within the US government, who then advanced that agenda and perspective at the international trade level. I then show how IP users' international and domestic response changed the direction of TRIPS' implementation. IP users and their allies applied political pressure to change US trade policy and thus reduced pressure on poorer countries to accede to a US interpretation of TRIPS.

The case study will show that the pharmaceutical industry actors, along with other IP-related industries, first dominated the agenda setting and policy formulation stages within the US. The US, EU and Japanese governments then aligned with the pharmaceutical industry (for the purposes of brevity, I will refer to this coalition of actors as Pharma going forward) and were able to advance their agenda when the policy thread dominated TRIPS' decision-making phase at the negotiations. The policy thread is the realm of "experts and analysts in a policy community" (Howlett, McConnell, and Perl 2016, 278) who both help shape and interpret the problem in early stages of policymaking. In the threads metaphor, it is expected to dominate during the formulation stage when solutions are being examined closely, and during the decision-making stage if the decision is being made in less visible political realms. The policy thread is the world of technical details, where the general public might have difficulty understanding the subtle variations among different proposed policy solutions. It is in this setting, when public scrutiny is minimal, that Pharma has proven most successful.

However, as the political thread dominated the implementation and evaluation stages of the policymaking process, the case study will show that IP users and their advocates successfully altered TRIPS. IP users' advocates, including international NGOs like Médecins Sans Frontières (MSF) and Consumer Project on Technology, and domestic CSOs like Treatment Action Campaign in South Africa and ACT-UP in the US (all of whom I will refer to collectively as the Access coalition), are highly effective when the political thread dominates a policymaking stage. The political thread is characterized by engagement with and persuasion of publics, and public debate that can influence policymakers and their aligned interests' responses. Depending on the policy issue, politics can dominate the agenda setting stage, where a problem comes to the attention

of politicians via public outcry, and during more open aspects of the legislative process, if floor debates and votes present an opportunity to “influence and alter policymaker behaviour” (Howlett, McConnell, and Perl 2016, 278). Any elements of policymaking that are more available to public scrutiny and understanding are more susceptible to domination by the political thread.

A Narrow Problem Definition

TRIPS’ agenda setting stage, where policymakers decide an issue requires attention and a problem is often defined (Howlett, McConnell, and Perl 2016), was a process internal to the US in the 1980s. The US trade deficit had grown by 309 per-cent between 1980 and 1985. This deficit was due in large part to growing merchandise imports; copyrighted and patented goods – intellectual properties like medicines, software and entertainment – on the other hand, accounted for \$1.2 billion surplus in 1982 (Sell 2003).

The International Intellectual Property Alliance, formed to promote the interest of intellectual property industries, set the agenda for IP rights by arguing that better global IP protections would reduce the US trade deficit. Presenting their case to Congress throughout the early 1980s, they argued the IP profits were “a fraction of what could have been earned” if IP rights protections had been in place around the world (Henriques as cited in Sell 2003, 86).

TRIPS’ policy formulation stage, involving the “discovery of which policy solutions are most suited to addressing the problem” (Howlett, McConnell, and Perl 2016, 281), also occurred in the US, later in the 1980s. The IIPA sought legislative changes and trade policy actions that would, as a founding member of the IIPA put it, “forge the necessary legal tools ... to convince foreign nations to take action against ... piracy” (Veliotes as cited in Sell 2003, 84-85). Through leadership positions on the Advisory Committee for Trade Negotiations (ACTN), a body consisting of industry leaders appointed by the executive branch of the US government, IIPA members continued to lobby for both legal instruments and for the US to enforce its interpretation of IP rights (Sell 2003).

The US Trade Representative (USTR), an executive branch office that investigates trade issues, began responding. The IIPA put forward a number of cases

against countries it believed to be infringing and proposed suspending their Generalized System of Preferences benefits to apply economic pressure (the GSP allows the US to lower tariffs on goods from less economically developed countries and aid their economic growth and development [Cohn 187]) (Sell 2003). In 1987, after Mexico refused to comply with American demands to provide greater patent protections for pharmaceuticals, the US suspended its GSP, eventually costing Mexico \$500 million (Mowjee 2003). In 1993, Brazil was placed on the USTR Watch List for its production of generic medicines. Placement on the Watch List tells investors that a country is not following free trade practices, and so is a higher risk of investment and unlikely to provide favourable terms; investment with it should thus be avoided (Mowjee 2003). The Brazil-US dispute was not resolved until eight years later; even as Brazil made some concessions, it refused to stop distributing free generics to those with HIV (Mowjee 2003; Sell 2003). There is little evidence of NGO involvement in the trade realm prior to the agreements that created the WTO in 1995. The rare exception to this is a 1990-91 dispute where a US NGO attempted to use US law to stop environmentally harmful fishing practices in Mexico, Venezuela and Vanuatu. The US banning of Tuna from these countries was ruled incompatible with international trade liberalization goals by the WTO's predecessor, and reversed by the US government (Robertson 2003, 1124).

The above demonstrates that this was a policymaking process that garnered little public attention. It was a technical discussion about the link between trade deficits, and copyright and patent laws. This highly technical aspect of law and trade was only of concern to IP corporations, and to the US government for its ability to reduce its trade deficit. It was not open to the kinds of pressures that public attention can create, nor did it involve the inputs from either domestic or international IP users. As the following sections show, the issue of IP law and access to medicines only began to emerge as an area of concern as the TRIPS agreement was announced.

Unequal Decision-making Power

While the trade actions were underway, the USTR consulted the IIPA on IP rights for the Uruguay round of trade talks, which commenced in 1986. The industry determined that it wanted three things in an international IP rights agreement: minimum standards for domestic laws that enshrine IP rights; enforcement procedures through trade sanctions and a dispute settlement mechanism (Sell 2003).

However, middle-income and least-developed countries from the global South, led by India and Brazil, remained opposed to the introduction of IP rights into the negotiations. “Since the vast majority of developing countries consume rather than produce intellectual property,” any commitments would likely not be of benefit to them (Sell 2003, 108). Southern countries eventually agreed to IP rights inclusion for a number of reasons. Greater technological investment was possible with proper IP rights in place, they were told, and there promises of greater exportation of agriculture and textile goods for Southern countries. It was also expected that a TRIPS agreement would end US unilateral actions and create a single regime where countries could settle IP rights disputes (Hoekman and Kostecky 2009).

But Southern countries faced a massive power imbalance in the negotiations. In addition to the threat of new, intensifying and ongoing US trade sanctions, Northern countries had a number of economic mechanisms available to them: “Their much greater political and economic muscle” meant they could issue threats and promises, “to provide or withhold (and very largely to ensure that international agencies provide or withhold) technical assistance, financial aid, ... debt relief and preferential trade agreements” (Jawara and Kwa 2004, 149).

Pharma also dominated the technical aspects of the negotiations. Multinational corporations with a stake in IP rights acted as counsel to the US, who claimed greater IP law expertise over poorer countries. And indeed, the South was ill prepared for the negotiations, whose government representatives had little knowledge of IP and the implications of agreeing to implement such laws (Jawara and Kwa 2004). Early in the IP negotiations, the US had brought the EU and Japan – other countries that create IP – on side, and together they rejected most attempts by India and Brazil to reduce IP rights requirements (Sell 2003). When the final TRIPS agreement was reached in 1994, it contained “95%” of what the IP industry had sought (Sell 2003, 115). Amongst other provisions designed to protect the products of the entertainment, software and pharmaceutical industries, the agreement requires countries to establish laws that protect pharmaceutical patents for 20 years. It provides enforcement mechanisms if countries fail to institute or enforce these laws, including trade actions like tariffs, and the US retained the use of the Trade Watch List and GSP benefits, though it is now required to take a dispute to the WTO before implementing them. The WTO provides dispute

settlement and determines if a state has failed to implement or enforce the TRIPS provisions (Hoekman and Kostecky 2009).

Throughout the confidential negotiations, there was no comment from NGOs (Sell, 2003). They lacked both the expertise and access; only as TRIPS became public did NGOs begin to grasp the implications for access to medicines (Hanegraaff et al. 2011). Indeed the UN Development Programme (as cited in Alkoby 2012) supports the idea that very few people anticipated the legal implications or Pharma's reaction.

In terms of effective political participation then, assuming all the governments of the world's poor were entirely committed to consulting with their populations, they would still not have been able to represent their IP users' interests. They lacked the expertise to negotiate, had the threat of economic sanctions dangling over them if they walked away, and were participants in a global economy that made them reliant on Northern states in a number of socio-economic areas. In these ways, the global poor were denied political participation because they lacked both a direct role and adequate representation. IP users' interests and perspectives were given little to no consideration throughout the policymaking process, as though they had no investment in the policy outcomes. They thus lacked an opportunity to participate in the shaping of a global governance structure that the next section will show directly affected their lives.

Contested Implementation

As TRIPS implementation began, the restrictions and requirements it would place on countries began to come into focus – and contention. In 1997 South Africa passed the Medicines and Related Substances Control Amendment Act (the Medicines Act), which would allow for the production of cheaper generic medicines for HIV/AIDS, malaria and tuberculosis (Kelly 2007). The South African government believed provisions in TRIPS gave it the right to respond to these public health situations with such legislation (Sell 2003).

Pharma disagreed. The USTR applied economic pressure on South Africa by placing it on the Trade Watch list (Mowjee 2003), and later imposed tariffs on South African goods, immediately making South African products more expensive in the United States (Sell 2003). Next came legal actions. In February, 1998, the South African

Pharmaceuticals Manufacturing Association sued the South African government to overturn the Medicines Act, temporarily suspending the law while it was before the courts, thereby preventing the widespread distribution of cheaper generics (Mowjee 2003). The US simultaneously registered a formal complaint against South Africa with the WTO (Kelly 2007). If the US government was successful, it would be allowed to further punish South Africa with more trade sanctions. And if the pharmaceutical industry was successful, it would not only limit the South African government's options, but send a message that it could successfully contest issuing compulsory licenses for public health emergencies (Mowjee 2003).

The newly-forming Access coalition began bringing public attention to the dispute. While the US and the pharmaceutical industry faced regular protests by South African activists throughout 1997 (Mowjee 2003), in 1998 US Vice President Al Gore was repeatedly confronted by US ACT-UP activists at home. They demanded an end to the trade actions. As the Vice President declared his intention to seek the Democratic nomination for president in June 1998, the US government eased sanctions but maintained its complaint at the WTO (Sell 2003).

In the weeks leading up to ministerial-level trade talks in Seattle in 1999, the growing Access coalition called on the WTO to endorse the use of generics, and to interpret TRIPS through the lenses of access to medicines and public health promotion. On the eve of the conference, then-President Bill Clinton announced that US policy would now prioritize access to HIV/AIDS treatments in Africa and would consider public health issues when enforcing intellectual property provisions (Sell 2003). However, this did little to ease tensions, until, a year later, President Clinton prohibited retaliation against African countries attempting to use TRIPS protocols to use generics to treat HIV/AIDS (Mowjee 2003).

And the pharmaceutical industry responded to the growing pressure by lowering prices on some drugs – essentially eliminating the price difference compared to generics (Hoekman and Kostecky 2009). These were small concessions on the part of the pharmaceutical industry – MSF called them the equivalent of “an elephant giving birth to a mouse” (Sell 2003, 153-4) – especially in light of its ongoing lawsuit in South Africa, which was still keeping generics out of production. On March 5, 2001, Access coordinated a global day of action, with protests in 30 cities around the world. It drew

international coverage and led to a 250,000-signature petition, urging governments to pressure the pharmaceutical industry to withdraw the suit. The Pharmaceuticals Manufacturing Association withdrew its suit shortly thereafter (Mowjee 2003). This demonstrates that the policy options available to the Pharma coalition were shrinking, due to growing public concern.

Where the pharmaceutical industry had defined a problem for US trade policymakers, the Access coalition's actions had defined the problem for the public: people were dying due to lack of readily available medicines. The pharmaceutical industry was characterized by the coalition as a group of "greedy multinationals," and was "juxtaposed ... against images of the sick and dying in developing countries" (Bubela and Morin 2010, 128). By 2001, the intensely negative publicity forced US policymakers to reset the agenda: the US government had to respond to the AIDS crisis in Africa by providing access to medicines.

With a new problem for policymakers to respond to, governments commenced the November 2001 Doha Round of trade negotiations to clarify the meaning of TRIPS, amongst other things. There had been extensive media coverage leading up to the talks, generated by organizations like MSF. "Public pressure was huge," in the words of one negotiator (Jawara and Kwa 2004, 100), on Northern governments to make a commitment on access to medicines. Despite this, once confidential negotiations began the US and the EU put forward a strict interpretation of TRIPS that would have further limited states' abilities to produce generics. Through a unified position, and by consulting with NGOs who provided legal expertise and negotiation support, Southern countries were in a stronger negotiating position.

The final Ministerial Declaration leaned toward the Access position on TRIPS (Jawara and Kwa 2004). The Doha Declaration affirmed that TRIPS "does not and should not prevent members from taking measures to protect public health," and that states have a "right to protect public health and, in particular, to promote access to medicines for all," including "the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted" (WTO 2001). This shows that Access had begun to develop some capacity to at least protect its position in the complex negotiation stages dominated by policy expertise. While the letter of the trade

law remained unchanged – no new bill of rights for users – the declaration seemed to have protected existing options around generics.

This was no doubt a victory for Access, demonstrating that publicity can translate public will into binding law in the international realm. But a more recent case in Thailand shows the difficulty in implementing the law consistently.

In 2006, Thailand began allowing the production of generic drugs to treat HIV, after attempting to negotiate price reductions with the pharmaceutical industry for two years. The initial impetus to develop the generics came from those domestic CSOs comprised of people living with HIV who could not afford treatment (Wibulpolprasert et al. 2011). In 2007 the impacted pharmaceutical companies sued in Thai courts to stop production, and the US government initiated a series of escalating trade sanctions, beginning with its placement on the USTR Watch List. Both claimed that Thailand was not in compliance with TRIPS. NGOs and domestic activists combined with government agencies to form the Committee to Support Government-Use Implementation; it responded to the legal, international and political actions of the US and the pharmaceutical industry. The dispute eventually led to an investigation – supported by MSF, CSOs and the Thai government – conducted by the World Health Organization, but including involvement from the WTO, which found that Thailand was in compliance with TRIPS (Wibulpolprasert et al. 2011).

As a result of ongoing and punishing sanctions, Thailand agreed to begin renegotiating with pharmaceutical companies in 2009. Eventually, the Thai government agreed to stop issuing new compulsory licenses, but insisted on keeping the ones it had already issued. This was regarded as capitulation to the US and the pharmaceutical industry amongst many Thai activists (Glaser and Murphy 2010).

This suggests that US government trade policy is still likely to push for an implementation of TRIPS' that interprets public health provisions in a narrow way. It further suggests the pharmaceutical industry will resist attempts by countries to use TRIPS' public health provisions. Against economic sanctions and lawsuits, the Access coalition continues to rely on publicity and its broad coalition to secure gains country by country – and then fights to keep them.

A Proposal for More Effective Participation

In this section, I will propose means by which greater participation for IP users in the global south might be achieved within the WTO. Before offering my proposal, I will describe the ways NGOs and other non-state actors (e.g., industry organizations) currently connect to the WTO. After I offer my proposals, which anticipate a strong role NGOs, I will describe when NGOs can act as representatives of the global poor. These proposals will to not lead to the kind of just global political participation through representation in a global democratic forum that Fraser might want us to eventually achieve (2010); however, they serve to reduce the injustice of unequal political participation through means that Fraser identifies as central to effective participation.

Current Policymaking Opportunities for NGOs

The WTO's guidelines for NGOs say it "would not be possible for NGOs to be directly involved in the work of the WTO or its meetings," pointing such actors back to their state (WTO General Council 1996). Since that guidance was issued, however, the WTO has started to hold an annual Public Forum, "the only dedicated, officially sanctioned non-state venue" (Hannah 2018, 119) wherein non-state actors, including business groups, NGOs and academics can interact. The entire process is driven by the WTO Secretariat, which picks the themes for the conference, reviews proposals and determines who will speak. Rejected proposals are not made public, and the venue itself is not designed to provide a direct feedback mechanism on trade policy or negotiations (Hannah 2008).

However, opportunities for direct feedback are available at Ministerial Conferences. These are the highest level of talks, and are only held when an agreement seems imminent. NGOs are given the same kind of access as the news media, with no more access to information or decision makers than journalists. The exception to this is when a state includes an NGO or industry interest group in its official delegation. Even then, such groups are not permitted to participate in or even observe the actual negotiations, but do gain access to early drafts – which they are bound to keep secret, limiting their ability to openly criticize their contents (Hanegraaff et al. 2011).

Perhaps the most substantive area of involvement for non-state actors has been in the dispute settlement processes. The WTO's Dispute Settlement Body and Appellate

Body have, since the late 1990s, accepted amicus curiae briefs from NGOs (Hannah 2018). But “NGOs are still excluded from almost all meetings of WTO bodies, even at the level of specialized committees” (Steffek and Kissling 2006), which administer and amend the current WTO agreements, including TRIPS. And while NGOs might be invited for informal discussions regarding their work, the WTO decides when, how or if such discussions will take place (Scholte 2004; Steffek and Kissling 2006).

The Proposals

The following proposals are designed to increase effective political participation by IP users throughout the trade policymaking process, and thus increase access to medicines by creating more balanced agreements, amendments, interpretations and implementations. Overall, the goal is to increase the role of publicity – the tool most likely to increase IP users’ effectiveness.

While Fraser worries that publicity is not as effective in a globalized political community because it is not clear to whom we direct our public will (2010, 95), the case demonstrates that the use of publicity can move the policymaking process into public view. The South Africa and Thailand cases show that political efficaciousness is available to the world’s poor, but it is through a combination of international NGO and local activist publicity, combined with state action. Indeed, these non-state actors are widely accredited with providing the support and pressure that enabled weaker states to secure the Doha Declaration (e.g., Harrison 2007; Jawara and Kwa 2004; Joseph 2011; Sell 2003). Thus, there are a number of audiences that the Access activists can effectively influence, depending on which stage of the policymaking is at play, and where the activist is located.

Thus, to increase the efficacy of the publicity function during the policy formulation stage, I propose:

- 1) *that the WTO allow interested parties to see early drafts of trade agreements.*

Just and legitimate policymaking processes allow equal participation throughout and “must be in principle be open to all” (Fraser 2010, 93). They do not favour actors who have access to confidential government information, nor do they rely on governments to pick and choose to whom that information is released.

But trade negotiations happen behind closed doors – something that many in the Access coalition would no doubt agree “violate[s] the basic democratic norms of publicity” (Young 2000, 54). While the average person cannot interpret trade agreement texts or anticipate their impact, NGOs like MSF have become expert at understanding their implications and raising public awareness (Scholte 2004). Thus, the more technical aspects of WTO trade negotiations, where a legal turn of phrase can create unexpected results – and where the pharmaceutical industry has dominated – should be made more open to public scrutiny. This would allow for broader understanding and multiple analyses, allowing the political elements of the policymaking process to influence the subsequent negotiation and decision stages more effectively.

Second, to increase the efficacy of the publicity function during the decision-making stage, I propose:

2) that the WTO parties should accept public submissions and/or testimony, at regularly scheduled intervals, from non-state actors during high-level negotiations and deliberations.

First, we can recognize that Ministerial Conferences of the WTO, where agreements are finalized, and the General Council, which is the highest-level decision-making body for the WTO, act similarly to legislative bodies (Charnovitz 2000): they consider a variety of policy options, deliberate and eventually settle on a binding solution. But banning non-state actors from these meetings limits their power to report on negotiations and shine a light on a state’s negotiating position. The experience of the Doha negotiations show that even though the US had committed to ensuring treatment for Africans with HIV/AIDS, behind the closed doors of the trade negotiation room, it pushed for even stronger protections for pharmaceuticals.

An important element of publicity is the “right to criticize one another’s proposals” (Young 2000, 23), so it is important that arguments, analyses and positions be made in public for others to question and challenge. Not only would this change allow for greater dialogue and critique amongst different actors, it would also increase IP users’ efficacy. NGOs rely on understanding policy and the timing of decision-making to develop and articulate their position and influence public opinion (Forsythe 2006), so the ability to

submit and review other submissions will likely help them direct their resources and coordinate their responses.

But allowing non-state actors greater access and a stronger voice is the smallest incremental change toward parity. Even if the WTO adopts the above proposals, the people that most need access to affordable medicines – the global poor – will need a form of representation that some states cannot provide. Therefore, I propose:

3) that the WTO develop a system to both solicit and accept direct inputs from NGOs and CSOs as consultants.

Effective political participation can be exceedingly difficult – even more so for the impoverished. Besides struggling for the resources to participate (the time and money for example, to address WTO proceedings directly), they often lack the technical skills to participate. The current WTO agreements are exceedingly complex: “30,000 pages consisting of about 30 agreements” (WTO, n.d.). Indeed, even assuming full literacy, and imagining them fully equipped to appear before something akin to a government committee for example, the ability of the poor to participate equally with IP rights holders, who are represented by IP law experts will still be unequal. So while the global poor might be experts on their own condition – and critical to the successful implementation of increased access to medicines– most of the poor lack the technical knowledge to interpret the agreement and comment on it. Most of us in the global North have a plurality of representatives that can effectively represent our varied interests: different levels of governments and their political opponents, along with CSOs operating on each level of government. For the poor in the global South, international NGOs offer one opportunity to increase their effective political participation through a plurality of representatives.

Just as the UN grants some NGOs consultative status (Kent 2018), the WTO should develop a similar procedure. Because the purpose of such status in this proposal is to amplify the voice of the politically marginalized, NGOs should be able to show direct contact with domestic CSOs (I explore this connection in depth below). While the WTO might place other conditions on consultative status, for now it is important to emphasize that any formal role for NGOs must be assessed through the lens of an NGO’s relationship to those they claim to represent.

As consultants, NGOs and CSOs should have a presence throughout implementation, amendment and interpretation processes, for example, as policy analysts. The General Council could ask NGOs to perform public health impact assessments to “verify that the increased trade and economic benefits are not endangering ... human rights” (High-Level Panel 2016, 28). Formally recognized NGOs would not have to wait for an invitation from the WTO to investigate but could raise issues directly to the General Council and the various specialized committees. There is a long history of NGOs monitoring international organizations’ performance and effects, including tracking progress toward goals; adherence to policy, mandate and constitution; and impact of policy (Scholte 2004). While the WTO is “a repository of expert knowledge,” and does provide some technical support for least developed countries, it does not provide assistance in policy assessment (Higgott and Ermin 2010, 468-9). Specialized expertise in the impacts of trade would add an important means for the least developed countries to understand how trade is affecting them, and might strengthen their negotiating position.

This final proposal addresses participatory inequality in a unique and potent way. Evaluation processes lead naturally back to agenda setting by highlighting the failures or gaps in an existing policy. A substantial increase in the parity of political participation for the global poor emerges if they are not merely responding to the priorities of IP rights holders, but identifying their own sets of problems and solutions related to access to medicine. So while this proposal increases efficacy at the evaluation stage, more importantly, it enables a stronger agenda setting function for NGOs.

Reconceptualising Representation

Because these policy conflicts are happening across and above nation states, where the Access activist is located affects who can be addressed by the activist and how. While both NGOs and CSOs wield discursive power to coalesce and convince people around issues (Montanaro 2012), they address different publics. While domestic CSOs can coordinate their activities within the traditional nation-state and perhaps with a few of their international allies, international NGOs can coordinate a response across a number of states and publics. They not only activate their own international network, but as this study shows, they can coordinate within a larger coalition of like-minded groups and generate hundreds of thousands of responses.

International NGOs also do a different job than domestic CSOs. The former organize global political action, fund smaller service providers, and provide expert technical advice to governments and advocates (Steffek et al. 2010, 100). This range of skills and services, the credibility it lends them, along with the resources at their disposal to do research and develop policy, mean they are well equipped to effectively influence public will in the global North. Some have called this a “division of labour” (Sutherns, as cited in Nyamugasira 1998, 299), where domestic CSOs “effectively hear and represent the authentic voices of the poor, while Northern NGOs are better able to articulate ... their concerns to Northern governments, multinational corporations, and global institutions” (Nyamugasira 1998, 299).

Domestic activists should not be excluded from direct participation in WTO policymaking. Indeed, NGOs that claim to represent marginalized groups should be working to advance their participation. They should be working “to integrate the poor into the global mainstream in a manner that maximizes their benefits and minimizes their exploitation” (Nyamugasira 1998, 303). We can see evidence of this in the Thailand case, where CSOs, along with MSF were part of the committee that aided a WHO investigation into Thailand’s production of generic medicines (Wibulpolprasert et al. 2011). The CSO’s presence is a positive indicator that MSF was not trying to speak for them, but to work with them.

Is this enough for NGOs qualify as representatives? Young (2000) draws on Hanna Pitkin to tell us that healthy representative relationships rely on “moments of authorization and accountability” (129) – mechanisms not available to the global poor as they relate to NGOs. But people can enjoy “a plurality of representatives” (133), which provide different modes of representation. Representation of shared interests can be provided by those who are affected the same way by a set of circumstances, and are trying to achieving the same ends (134), as demonstrated with the domestic organizations in South Africa and Thailand. An NGO shares opinions with the represented – “principles, values, and priorities” (Young 2000, 135) that they can represent, as seen by MSF’s campaigns in the South Africa case. So while the global poor cannot hold international NGOs to account, through their public alliances with them, they provide a form of authorization.

We can call this “*discursive authorization*” (Montanaro 2012, 1101, author’s italics). Just as publicity can be a source of efficacy, it can also be a source of authorization. When we see South African or Thai activists coordinating their activities with international NGOs, and delivering the same message and demands, we can take this as a sign of authorization by the domestic group. Through this we can infer authorization to speak for the domestic group to international publics and organizations that the domestic organizations might not be able to reach or might be poorly equipped to navigate. And in a best-case scenario, domestic actors will state clearly that they are aligned with an international NGO, making the nature of the relationship clear to outside observers.

So while direct authorization and accountability are not possible under these circumstances, some criteria by which to measure the likelihood of an NGO’s ability to represent politically marginalized groups are available to us. There should be clear connections to domestic activists characterized by empowerment. The activist voice is not silenced, but enhanced by an NGO that shares the same principles; the NGO brings domestic activists into direct contact with international organizations whenever possible; and the NGO can demonstrate its deep ties of collaboration and coordination to domestic groups. None of this suggests the kind of accountability and authorization we would ideally see in a representative relationship, but these factors provide indicators as to whether or not NGOs’ claims of representation are credible.

There might not always be a plurality of representatives, especially in repressive states with no independent civil society. If there is no NGO/CSO relationship that would provide evidence that the NGO is acting on behalf those they claim to represent, it is the responsibility of the NGO to demonstrate that such domestic organizations do not exist. A claim of representation might still be legitimate, particularly if it is supported by the diaspora of represented.

Using NGOs to act as political representatives is far from ideal. They can simultaneously provide overlapping services while leaving gaps in services, both through error and active omission (Wenar 2010). And there are concerns about the role and legitimacy of NGOs who “regard themselves as accountable only in terms of their political responsibility to global democracy” but use the world’s need to hide “their political ambitions” (Robertson 2000, 1122).). Attempts at accountability “upward to

patrons,” “internally to ... mission” and “downward to clients” might encourage NGOs to “privilege” accountability to funders over the communities they serve (Ebrahim 2007, 195). And even this accountability is questioned; researchers have ranked many NGOs as less transparent than multi-national corporations (MNCs) and, ironically, the WTO (Kovach 2006).

These are deeply imperfect representatives, no doubt. But where the pharmaceutical industry can rely on support from EU, Japanese and American governments, the global poor cannot always rely on their own state. NGOs can give the global poor a voice that is not dependent upon a (perhaps disinterested, despotic or embarrassed) government or a weak state that has limited capacities. It means the global poor do not rely solely on a less powerful state that has limited options due to the “much greater political and economic muscle” of the US and the EU to issue threats and promises, “to provide or withhold (and very largely to ensure that international agencies provide or withhold) technical assistance, financial aid, ... debt relief and preferential trade agreements” (Jawara and Kwa 2004, 149).

Ideally, Fraser’s vision of global fora of political deliberation would allow all of the world’s peoples to choose their own representatives through democratic processes. But we should remain aware that even if such conditions existed, we would still have imperfect representatives. So as we set very high standards for NGOs to act as representatives for the global poor, we should not disqualify them to take on the role for either for individual actor’s impropriety or for their collective imperfections. These are not standards that we hold elected representatives to – and they wield much greater power over their citizens’ lives than NGOs.

Further, three mitigating factors allow us to give NGOs a voice for the global poor. First, since NGOs lack the coercive power of the state, relying instead on discursive power, their claims of representation do not allow them to make binding decisions for the world’s poor. Second, we already accept in the domestic sphere that a representative claim by a non-state actor does not mean it represents a unanimous opinion – no one would claim that the National Action Committee on the Status of Women is the sole voice for women on abortion in Canada. Finally, plural representation means we might often have access to a number of accounts of what the poor desire and need. These proposals allow for the WTO and its member states to access more of

these accounts, and thus reach conclusions based on a number of inputs. They do not tie a poor or marginalized group's fate to the will of a single, distant NGO.

Objections

Unacceptable Inefficiencies

The current round of world trade negotiations is stalled, so adding more variables to an already complex and difficult multilateral process is unlikely to make things any easier. Fifteen years after the launch of the Doha Development Round the completion of talks are “nowhere in sight” (Verma 272). And when small successes were won at the Bali 2013 and Nairobi 2015 Ministerial Conferences, member states focused on areas of low contention in an effort to revive the talks (Flentø and Ponte 2017). Some have gone as far as to say that Doha is dead, replaced by a preference for regional trade agreements like the Trans-Pacific Partnership (Martin and Mercurio 2017) and isolated agreements under the auspices of the WTO that do not bind all members (Winslett 2017). Surely the last thing these talks need is more involvement by a plurality of interests that – given a status that could make them agenda setters – will be quick to demand even more of countries already straining to maintain progress on trade liberalization. Indeed, giving in to demands for greater participation would lead to “so many layers of consultations ... almost nothing could be achieved” (Robertson 2000, 1126).

One can respond to these objections in several ways. First, evidence suggests that there would not be a near-endless growth of groups. The number of participants at the WTO Public Forums fluctuates from year to year, depending on where the talks are in their progression (Hannah 2018). This suggests that there is demand for greater involvement by non-state actors with the WTO, but not an infinite clamouring to be heard. Research also suggests that, much like the domestic sphere, interests groups might proliferate around a new issue, but stabilize within the “interest group system” as it matures (Hanegraaff et al. 2011, 454). The number of interest groups attending WTO Ministerial Conferences does in fact remain stable (Hanegraaff et al. 2011).

And it is not guaranteed that such changes would create inefficiencies. A formal, standardized role for NGOs might strengthen the policymaking processes in a way that creates benefits for the entire organization. While the total number of participant organizations remains stable, there are “high levels of volatility” amongst the organizations that participate in Ministerial Conferences. This suggests that in the current system “only a small number of organizations are capable of continuing their

lobbying in the long run” (Hanegraaff et al. 2011, 449). For example, only half of the 686 non-state organizations at the Seattle Ministerial Conference attended a future conference – but the total number of groups that attended future conferences remained stable (Hanegraaff et al. 2011). So a number of organizations attempt to interact, and then drop off, never to return.

Such instability might be due to changing issues or changing venues (getting into the United States was far easier for many NGO actors than getting into Qatar, for example) (Hanegraaff et al. 2011). It also suggests ineffectiveness for non-state actors in two ways. Groups are unable to maintain their presence due to venue-related constraints and so do not develop the skills and networks to develop efficacy, and/or there are limited opportunities to impact the discussions at such meetings, leading groups to redirect their efforts.

The WTO could stabilize this situation, and create reliable partners that develop strong expertise and capacity to assist all states, using standardized processes of interaction. “The more stable the pattern of representation is,” the more capable NGOs will become at “constructing long-lasting policy networks with key policymakers” (Hanegraaff et al. 455). Thus, a stable and predictable system for interaction between non-state actors and the WTO would likely increase efficacy and create a stable core of NGOs upon which the organization could rely. Less powerful countries would likely welcome such a development. “Developing countries have a strong preference for formalised, rule governed processes of decision-making” (Higgott and Ermin 2010, 463). This is because they rely heavily on standards and rules to constrain the actions of powerful countries and create predictable systems (Hoekman and Kostecki 2009). Clearer rules that allow for participation for the global poor through international NGOs and domestic activists are likely to be both welcome and efficacious.

The Incentive Structure Requires IP Rights

Returning to the core question – how to increase access to medicines for the poor – some might find the very premise of this paper flawed. This proposal does not address the structural conditions under which the pharmaceutical industry operates, and so does not change the incentives that use patents to reward innovation. Pharmaceutical companies have fought for IP rights enforcement to protect their industry because the

current system allows them to gain revenues and thus continue innovating through these rights. Diminishing patent protections would not only reduce the incentives to innovate, but could drive pharmaceutical companies out of business (Merges 2011).

Further, there are no other methods, beyond patents, available for the pharmaceutical industry to generate sufficient revenue to even keep the doors open, let alone take the risks on costly innovation. The costs of production of medicines are cheap for generic pharmaceutical producers, while the costs of creation are high – sometimes up to 15 years of research (Hawthorne 2003; Pogge 2010). The pay-offs are far from guaranteed, and such risk taking must be richly rewarded if we are to continue to incentivize medical research. But IP rights do more than incentivize these massive investments, which some economists have pegged at an average of \$800 million per drug developed (Hawthorne 2003). They actually enable research to continue by providing funds from yesterday's discoveries for research into future medicines.

There are a number of fallacies in the pharmaceutical industry's arguments about the links between revenues and innovation that must be addressed. First, TRIPS is not necessary to maintain a profitable pharmaceutical industry. From the 1970s through the 1980s, the industry's profits outperformed the Fortune 500 companies' average (Tyfield 2008), proving that the industry was already healthy and profitable. And as of 2016, the pharmaceutical industry was enjoying a 20 per-cent profit margin – approximately 8 points higher than the average of the S&P 500 (*The Economist* 2016). All of this suggests that pharmaceutical companies are not in need of greater levels of profit to develop drugs.

Second, much more needs to be done to determine how much of a pharmaceutical company's expenditures are related to research and development (R&D), and how much is related to political and public relations efforts. Industry lobbying spending was worth \$140 million in 2003, and much of its legal spending was dedicated to prolonging and enforcing existing patents (Tyfield 2008). And as of the mid-2000s, marketing and public relations spending ate up a greater share of industry budgets than research (Tyfield 2008). For example, the industry put "hundreds of millions" into a 2016-2017 public relations campaign to restore the industry's battered image in the US (Karin-Smith 2016), after the news media began reporting on massive spikes in prices for drugs that had long been on the market (see for e.g. Kaplan 2016; Kliff 2016;

Sidahmed 2016). In one example, the pharmaceutical company Turing increased the price on a drug that treats an infection amongst those with a compromised immune system by 5,556 per-cent (*The Economist* 2016). These kinds of price increases vividly illustrate the lack of relationship between the price pharmaceutical companies charge and the cost of development.

Indeed, these spikes in prices highlight their monopoly position. Robert Merges (2011), who advocates for strong IP rights for creators on deontological grounds, says that if the marketplace “confers truly disproportionate leverage” on IP rights holders (163) by virtue of their monopoly, then we can limit some aspect of their rights. TRIPS confers a 20-year monopoly on patent holders, in an industry where actors are willing to use their monopoly to raise prices to the outermost limit of what consumers are able to pay – and beyond. Thus, this is a case where a “disproportionate reward” is being conferred, which might justify a reduction in patent protections (Merges 2011, 279). And other areas of TRIPS might not be as damaging to human health as withholding pharmaceuticals – entertainment, for example. But because of both the disproportionate leverage conveyed on the pharmaceutical industry, and because the pharmaceuticals themselves are required to enjoy basic rights – the rights to life and to health – the use of generics for the poor are justified.

Merges would also argue that we need to take into account the needs of future generations. A strict consequentialist account might ask us to consider if “the total supply of medicine is greater ... when developed countries devote substantial resources to drug innovation while temporarily putting off access to the poor to a later date” (2011, 278). Put another way, allowing greater access for the poor now denies future generations access to medical advancements because the pharmaceutical industry might lack the income to develop new drugs.

Enforcement of IP rights in low- and middle-income countries contributes little to innovation. Because “countries that cannot afford high-priced drugs” simply do not purchase them, “they are not important in generating the R&D incentives” to develop new drugs (Hoekman and Kostecky 2009, 396). To highlight how little revenues from poor countries matter, Pogge (2010) explains that the therapies that would primarily save the lives of the poor in the global South are not even in development because there is no financial incentive to do so.

The Thailand case shows us why. Prior to the government issuing compulsory licenses for medicines that prevent HIV from progressing into AIDS, and eventually an early death, only 3,000 people had access to the medicines. After the price decrease that allowed for widespread government distribution, 100,000 people were on treatments (Glaser and Murphy 2010, 221-2). The pharmaceutical industry did not miss out on the profits from the 97,000 people who began receiving life-saving therapies; those people could not afford to buy the drugs at market prices – nor could their government.

And the pharmaceutical companies involved could have made a small profit on the production of medicines in Thailand. The government offered pharmaceutical companies a five per-cent markup over the price of the generics in negotiations that preceded the introduction of compulsory licenses (Wibulpolprasert et al. 2011). This “high volume-low margin” business model for the South (Joseph 2011) is viable to some: while Abbott Laboratories decided not to sell their HIV medicines to Thailand (participating in a lawsuit instead), the makers of a drug called Imatinib agreed to the five per-cent markup, ensuring access for 1,850 patients with chronic intestinal diseases (Wibulpolprasert et al. 2011). Not only is the industry not relying on the global poor to fund its research – Africa only accounted for 1.3 per-cent of the total global medicines market in 2000 – it seems some companies are so financially healthy they can forego a smaller profit margin if they find conditions unfavourable. In short, “there’s limited evidence to show that spurring innovation requires [the current] level of profit” (Gal as cited in *The Economist* 2016).

But even if pro-IP arguments were correct, TRIPS would still be deeply ethically flawed. Imagine a counterfactual where the world’s poor, engaged in equal political participation, agreed that medical advancements are only available if pharmaceutical companies can charge whatever they like. The 97,000 HIV-positive Thais now receiving treatment might then gladly relinquish their right to health so that their grandchildren could get better treatments tomorrow. But they have not been given the choice to make that sacrifice for future and distant others because they have been excluded from the political processes that shaped TRIPS.

That is to say that we are not dealing merely with commodities of intellectual property. If a trade agreement only limited access to pirated music, and thus only minimally affect the enjoyment of life of those affected by the agreement, it might not be

open to the same kind of scrutiny to affected publics. But pharmaceuticals directly affect one's life possibilities. Indeed, it is because they are so essential to life, health, the ability to work and provide for oneself and one's family, that the industry is given its disproportionate leverage through its monopoly. For the industry to be given such a huge advantage without the political participation of those whose life chances depend on the industry is a political injustice that requires rectifying.

Conclusion

In sum, greater access to medicines is possible, but only if the policies of the US government, the pharmaceutical industry, along with the current and anticipated effects of trade agreements are widely known. My proposals for greater political participation can support greater access to medicines because they make publicity more central to the functioning of the WTO. This makes WTO administration, enforcement and negotiations more vulnerable to the public will that supports wider distribution of medicines. It reduces the ability of the US, EU and Japanese governments to take negotiating positions that are unpopular at home, and thus reduces the likelihood of further restrictions on generic medicines production. And this is a significant threat. More recent regional trade agreements have included “TRIPS-plus” provisions that “prolong monopolies, support high prices and frustrate entry of generic medicines,” (Lopert and Gleeson 2013, 199).

For the global poor, their governments are particularly vulnerable to large and powerful states and multinational corporations. This has led to the need to ensure a plurality of representation for the poor in the global South. NGOs and domestic activist organizations provide additional representation that fills a niche: unencumbered by pressures from powerful states and MNCs, these civil society actors enable the participation of the global poor in the global political community by publicly criticizing the systems and structures that limit access to medicines. They are most effective when trade issues are in the minds of various publics. Thus, increasing access to medicines requires these actors to be effective. I have argued they can be more effective by integrating them more fully into the WTO.

The benefits of increased participation and publicity might be generalizable to other trade agreements under negotiation, like NAFTA, and to other global governance institutions like the World Bank and the International Monetary Fund. My research provides one way to investigate more precisely how non-state actors have been included in policymaking processes, and to more clearly state how we might want these non-democratic institutions to pursue parity of political participation.

While many doubts have been raised about NGOs’ motives, efficacy and accountability, we do have a means to establish a link between NGOs and the interests

and values of the people they claim to represent. These actors are not perfect – none of our representatives are – but a plurality of representatives, the limited authority of NGOs and the function of publicity offers some reassurance that greater NGO integration into the WTO does not mean allowing them to bind the poor or the WTO to a particular course of action.

It is also fair to worry that these changes might make for less efficient processes at the WTO. And it is possible that they will, to some extent. But not to the extent anticipated, and there are likely previously unforeseen benefits, which I have highlighted. Finally, arguments that greater access to medicines for the world's poor will somehow diminish innovation have been made for the better part of 20 years. The research suggests that the global poor are not currently central to the revenue streams of highly profitable multinational corporations that expend hundreds of millions of dollars on marketing and lobbying.

I have argued that IP rights holders had outsized power in the development of TRIPS, and that to ensure access to medicines, a greater emphasis should be put on the needs of IP users who cannot afford to pay for patented medicines. This proposal asks only for an incremental increase in the ability of IP users to participate in existing policymaking processes to achieve this end. However, it is important to recognize that I have provided only a broad outline of how direct participation and representation could be both more just and effective in the WTO; many details remain to be worked out and negotiated, including how grants of consultative status might be practically implemented. Making quick progress on this urgent work not only begins to undo an injustice, it modifies a process that literally determines whether the poor live or die.

References

- Alkoby, Asher. 2012. "Improving Access to Essential Medicines: International Law and Normative Change." In *Access to Medicines as a Human Right: Implications for Pharmaceutical Industry Responsibility*, edited by Lisa Forman and Jillian Clare Kohler, 46–74. Toronto: University of Toronto Press.
- Brown, L. David. 2007. "Multiparty Social Action and Mutual Accountability." In *Global Accountabilities: Participation, Pluralism, and Public Ethics*, edited by Alnoor Ebrahim and Edward Weisband, 89–111. Cambridge: Cambridge University Press.
- Bubela, Tania, and Jean-Frederic Morin. 2010. "Lost in Translation: The Canadian Access to Medicines Regime from Transnational Activism to Domestic Implementation." *Health Law Journal* 18 (2010): 113–58.
- Charnovitz, Steve. 2000. "Opening the WTO to Nongovernmental Interests The World Trade Organization, Globalization, and the Future of International Trade: Essay." *Fordham International Law Journal* 24 (2000): 173–216.
- Cohn, Theodore H. 2012. *Global Political Economy*. 6th ed. Boston: Pearson Longman.
- Ebrahim, Alnoor. 2007. "Towards an Effective Accountability of NGOs." In *Global Accountabilities: Participation, Pluralism, and Public Ethics*, edited by Alnoor Ebrahim and Edward Weisband, 193–224. Cambridge: Cambridge University Press.
- Esty, Daniel C. 2002. "The World Trade Organization's Legitimacy Crisis." *World Trade Review* 1 (1): 7–22. <https://doi.org/10.1017/S1474745601001021>.
- Farmer, Paul. 2003. *Pathologies of Power: Health, Human Rights, and the New War on the Poor*. California Series in Public Anthropology 4. Berkeley: University of California Press.
- Fisher, William W., and Talha Syed. 2010. "A Prize System as a Partial Solution to the Health Crisis in the Developing World." In *Incentives for Global Public Health: Patent Law and Access to Essential Medicines.*, edited by Thomas Pogge, Matthew Rimmer, and Kim Rubenstein, 181–208. Cambridge: Cambridge University Press.
- Flentø, Daniel, and Stefano Ponte. 2017. "Least-Developed Countries in a World of Global Value Chains: Are WTO Trade Negotiations Helping?" *World Development* 94 (June): 366–74. <https://doi.org/10.1016/j.worlddev.2017.01.020>.
- Forsythe, David P. 2006. *Human Rights in International Relations*. 2nd ed. Themes in International Relations. New York: Cambridge University Press.

- Fraser, Nancy. 2010. *Scales of Justice: Reimagining Political Space in a Globalizing World*. Reprinted. Cambridge: Polity Press.
- Gerring, John. 2017. *Case Study Research: Principles and Practices*. Cambridge: Cambridge University Press.
- Gerring, John, and Joshua Yesnowitz. 2006. "A Normative Turn in Political Science?" *Polity* 38 (1): 101–33. <https://doi.org/10.1057/palgrave.polity.2300054>.
- Glaser, Mishka, and Ann Marie Murphy. 2010. "Patients Versus Patents: Thailand and the Politics of Access to Pharmaceutical Products." *Journal of Third World Studies* 27 (1): 215–34.
- Goldin, Ian, and Kenneth Reinert. 2012. *Globalization for Development: Meeting New Challenges*. Oxford: Oxford University Press.
- Grover, Anand. 2009. "Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health." United Nations Human Rights Council.
- . 2013. "Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, on Access to Medicines." United Nations Human Rights Council.
- Hallas, Roger. 2006. "The 'Face' of AIDS: Commodity Compassion and Global Pandemic." In *What Democracy Looks like: A New Critical Realism for a Post-Seattle World*, edited by Amy Schrager Lang and Cecelia Tichi, 88–113. New Brunswick, N.J.: Rutgers University Press.
- Hamlin, Alan, and Zofia Stemplowska. 2012. "Theory, Ideal Theory and the Theory of Ideals." *Political Studies Review* 10 (1): 48–62. <https://doi.org/10.1111/j.1478-9302.2011.00244.x>.
- Hanegraaff, Marcel, Jan Beyers, and Caelesta Braun. 2011. "Open the Door to More of the Same? The Development of Interest Group Representation at the WTO." *World Trade Review* 10 (4): 447–72.
- Hannah, Erin, Amy Janzwood, James Scott, and Rorden Wilkinson. 2018. "What Kind of Civil Society? The Changing Complexion of Public Engagement at the WTO." *Journal of World Trade* 52 (1): 113–41.
- Harrison, James. 2007. *The Human Rights Impact of the World Trade Organisation*. Studies in International Trade Law, v. 10. Oxford: Hart.
- Hawthorne, Fran. 2003. *The Merck Druggernaut: The inside Story of a Pharmaceutical Giant*. Hoboken, New Jersey: J. Wiley & Sons.

- Helfer, Laurence R., and Graeme W. Austin. 2011. *Human Rights and Intellectual Property: Mapping the Global Interface*. New York: Cambridge University Press.
- Hernández-Truyol, Berta Esperanza, and Stephen J. Powell. 2009. *Just Trade: A New Covenant Linking Trade and Human Rights*. New York: New York University Press.
- Hestermeyer, Holger. 2007. *Human Rights and the WTO: The Case of Patents and Access to Medicines*. Oxford: Oxford University Press.
- Higgott, Richard, and Eva Erman. 2010. "Deliberative Global Governance and the Question of Legitimacy: What Can We Learn from the WTO?" *Review of International Studies* 36 (2): 449–70.
<https://doi.org/10.1017/S0260210510000100>.
- High-Level Panel. 2016. "Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies." United Nations Secretary General's High Level Panel on Access to Medicines.
- Hoekman, Bernard M., and Michel M. Kostecki. 2009. *The Political Economy of the World Trading System: The WTO and Beyond*. Oxford: Oxford University Press.
- Hosseini, S. A. Hamed. 2010. *Alternative Globalizations: An Integrative Approach to Studying Dissident Knowledge in the Global Justice Movement*. London: Routledge.
- Howlett, Michael, Allan McConnell, and Anthony Perl. 2016. "Weaving the Fabric of Public Policies: Comparing and Integrating Contemporary Frameworks for the Study of Policy Processes." *Journal of Comparative Policy Analysis: Research and Practice* 18 (3): 273–89. <https://doi.org/10.1080/13876988.2015.1082261>.
- Illingworth, Patricia. 2012. "Corporate Social Responsibility and the Right to Essential Medicines." In *Access to Medicines as a Human Right: Implications for Pharmaceutical Industry Responsibility*, edited by Lisa Forman and Jillian Clare Kohler, 75–89. Toronto: University of Toronto Press.
- Jawara, Fatoumata, and Aileen Kwa. 2004. *Behind the Scenes at the WTO: The Real World of International Trade Negotiations: Lessons of Cancun*. Updated ed. New York: Zed Books.
- Joseph, Sarah. 2011. *Blame It on the WTO? A Human Rights Critique*. Oxford: Oxford University Press.
- Kaplan, Thomas. 2016. "Hillary Clinton Unveils Plan to Address 'Excessive' Increases in Drug Prices." *The New York Times*, September 2, 2016.
<https://www.nytimes.com/2016/09/03/us/politics/hillary-clinton-epipen-mylan.html>.

- Karlin-Smith, Sarah. 2016. "Drug Lobby Plans Counterattack on Prices." *Politico*. August 4, 2016. <https://www.politico.com/story/2016/08/drug-lobby-gears-up-for-massive-pr-campaign-226646>.
- Kelly, Trish. 2007. *The Impact of the WTO: The Environment, Public Health and Sovereignty*. Northampton, MA: Edward Elgar.
- Kent, Melissa. 2018. "Politicized UN Committee Using 'repeated and Arbitrary Deferrals' to Block NGOs, Critics Say." CBC News. January 21, 2018. <http://www.cbc.ca/news/world/un-ngo-committee-politics-1.4494291>.
- Kliff, Sarah. 2016. "EpiPen's 400 Percent Price Hike Tells Us a Lot about What's Wrong with American Health Care." *Vox*. August 23, 2016. <https://www.vox.com/2016/8/23/12608316/epipen-price-mylan>.
- Knowledge Ecology International. 2008. "KEI Proposal: A WTO Agreement on the Supply of Knowledge as a Global Public Good." Washington, DC: Knowledge Ecology International.
- Kovach, Hetty. 2006. "Addressing Accountability at the Global Level: The Challenges Facing International NGOs." In *NGO Accountability: "Politics, Principles and Innovations,"* edited by Peter van Tuijl and Lisa Jordan, 95–210. London: Routledge.
- Lopert, Ruth, and Deborah Gleeson. 2013. "The High Price of 'Free' Trade: U.S. Trade Agreements and Access to Medicines." *The Journal of Law, Medicine & Ethics* 41 (1): 199–223. <https://doi.org/10.1111/jlme.12014>.
- Love, James. 2016. "Contribution to the United Nations Secretary General's Panel on Access to Medicines: Trade Agreements and the Supply of Public Goods." Washington, DC: Knowledge Ecology International.
- Martin, Antoine, and Bryan Mercurio. 2017. "Doha Dead and Buried in Nairobi: Lessons for the WTO." *Journal of International Trade Law and Policy* 16 (1): 49–66. <https://doi.org/10.1108/JITLP-01-2017-0001>.
- McMichael, Philip. 2012. *Development and Social Change: A Global Perspective*. 5th ed. Los Angeles: SAGE.
- Meier, Benjamin Mason. 2007. "Advancing Health Rights in a Globalized World: Responding to Globalization through a Collective Human Right to Public Health." *The Journal of Law, Medicine & Ethics* 35 (4): 545–55. <https://doi.org/10.1111/j.1748-720X.2007.00179.x>.
- Merges, Robert P. 2011. *Justifying Intellectual Property*. Cambridge: Harvard University Press.

- Montanaro, Laura. 2012. "The Democratic Legitimacy of Self-Appointed Representatives." *The Journal of Politics* 74 (4): 1094–1107. <https://doi.org/10.1017/S0022381612000515>.
- Mowjee, Tasneem. 2003. "Campaign to Increase Access to HIV/AIDS Drugs." In *Globalizing Civic Engagement: Civil Society and Transnational Action*, edited by John Clark, 66–85. New York: Zed Books.
- Ng, Elizabeth Siew-Kuan. 2010. "Global Health and Development: Patents and Public Interest." In *Incentives for Global Public Health: Patent Law and Access to Essential Medicines*, edited by Thomas Pogge, Matthew Rimmer, and Kim Rubenstein, 101–32. Cambridge: Cambridge University Press.
- Nyamugasira, Warren. 1998. "NGOs and Advocacy: How Well Are the Poor Represented?" *Development in Practice* 8 (3): 297–308. <https://doi.org/10.1080/09614529853594>.
- OHCHR. 2001. "Economic, Social and Cultural Rights: The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights." Report of the High Commissioner. Office of the High Commissioner on Human Rights, United Nations Economic and Social Council.
- OHCHR and WHO. n.d. "The Right to Health: Fact Sheet No. 31." Office of the United Nations High Commissioner for Human Rights and World Health Organization. Accessed December 10, 2017.
- Pianta, Mario. 2014. "Slowing Trade: Global Activism Against Trade Liberalization." *Global Policy* 5 (2): 214–21. <https://doi.org/10.1111/1758-5899.12116>.
- Pogge, Thomas. 2010. "The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices." In *Incentives for Global Public Health: Patent Law and Access to Essential Medicines*, edited by Thomas Pogge, Matthew Rimmer, and Kim Rubenstein, 135–54. Cambridge: Cambridge University Press.
- Reitan, Ruth. 2012. "Theorizing and Engaging the Global Movement: From Anti-Globalization to Global Democratization." *Globalizations* 9 (3): 323–35. <https://doi.org/10.1080/14747731.2012.682364>.
- Robertson, David. 2000. "Civil Society and the WTO." *The World Economy* 23 (9): 1119–34. <https://doi.org/10.1111/1467-9701.00322>.
- Rosenberg, Stephanie T. 2014. "Asserting The Primacy of Health Over Patent Rights: A Comparative Study of the Processes That Led to the Use of Compulsory Licensing in Thailand and Brazil." *Developing World Bioethics* 14 (2): 83–91. <https://doi.org/10.1111/dewb.12050>.
- Scholte, Jan Aart. 2004. "Civil Society and Democratically Accountable Global Governance." *Government and Opposition* 39 (2): 211–33. <https://doi.org/10.1111/j.1477-7053.2004.00121.x>.

- Sell, Susan K. 2003. *Private Power, Public Law: The Globalization of Intellectual Property Rights*. Cambridge: Cambridge University Press.
- Steffek, Jens, Ralf Bendrath, Simon Dalferth, Kristina Hahn, Martina Piewitt, and Meike Rodekamp. 2010. "Assessing the Democratic Legitimacy of Transnational CSOs: Five Criteria." In *Evaluating Transnational NGOs: Legitimacy, Accountability, Representation*, edited by Jens Steffek and Kristina Hahn, 100–125. New York: Palgrave Macmillan.
- Steffek, Jens, and Claudia Kissling. 2006. "Civil Society Participation in International Governance: The UN and the WTO Compared." *TranState Working Papers*. Bremen: University of Bremen. <http://edoc.vifapol.de/opus/volltexte/2012/4083/>.
- The Economist*. 2016. "Seizure-Inducing," September 3, 2016. <https://www.economist.com/news/business/21706347-row-over-mylans-epipen-allergy-medicine-raises-fresh-questions-about-how-drugs-are?fsrc=scn/tw/te/pe/ed/seizureinducing>.
- Tyfield, David. 2008. "Enabling TRIPs: The Pharma–biotech–university Patent Coalition." *Review of International Political Economy* 15 (4): 535–66. <https://doi.org/10.1080/09692290802260555>.
- UNAIDS. 2015. "How AIDS Changed Everything — MDG6: 15 Years, 15 Lessons of Hope from the AIDS Response." http://www.unaids.org/en/resources/documents/2015/MDG6_15years-15lessonsfromtheAIDSresponse.
- Verma, S. K. 2018. "WTO and the Regulation of International Trade Law." In *Contemporary Issues in International Law*, edited by B.C. Nirmal and Rajnish Kumar Singh, 263–72. Singapore: Springer. https://doi.org/10.1007/978-981-10-6277-3_17.
- Weisband, Edward, and Alnoor Ebrahim. 2007. "Introduction." In *Global Accountabilities: Participation, Pluralism, and Public Ethics*, edited by Alnoor Ebrahim and Edward Weisband, 193–224. Cambridge: Cambridge University Press.
- Wenar, Leif. 2013. "Poverty Is No Pond: Challenges for the Affluent." In *Giving Well: The Ethics of Philanthropy*, edited by Patricia Illingworth, Thomas Pogge, and Leif Wenar, 104–32. New York: Oxford Univ. Press.
- Werhane, Patricia H., and Michael E. Gorman. 2005. "Intellectual Property Rights, Access to Life-Enhancing Drugs, and Corporate Moral Responsibilities." In *Ethics and the Pharmaceutical Industry*, edited by Michael A. Santoro and Thomas M. Gorrie. New York: Cambridge University Press.
- WHO. 2006. "Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health." Geneva: World Health Organization Commission on Intellectual Property Rights, Innovation and Public Health.

- Wibulpolprasert, Suwit, Vichai Chokevivat, Cecilia Oh, and Inthira Yamabhai. 2011. "Government Use Licenses in Thailand: The Power of Evidence, Civil Movement and Political Leadership." *Globalization and Health* 7 (September): 32. <https://doi.org/10.1186/1744-8603-7-32>.
- Wilkinson, Rorden. 2014. *What's Wrong with the WTO and How to Fix It*. Cambridge: Polity Press.
- Winslett, Gary. 2017. "Critical Mass Agreements: The Proven Template for Trade Liberalization in the WTO." *World Trade Review*, July, 1–22. <https://doi.org/10.1017/S1474745617000295>.
- WIPO. 2007. "The 45 Adopted Recommendations under the WIPO Development Agenda." Provisional Committee on Proposals Related to a WIPO Development Agenda, World Intellectual Property Organization. 2007.
- WTO. 2001. "WTO Ministerial Conferences - Doha 4th Ministerial - TRIPS Declaration." https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.
- . n.d. "The WTO Agreements." *The WTO in Brief*. Accessed March 15, 2018. https://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr03_e.htm.
- WTO General Council. 1996. "Guidelines on Relations with Non-Governmental Organizations." World Trade Organization. https://www.wto.org/english/forums_e/ngo_e/guide_e.htm.
- Young, Iris Marion. 2000. *Inclusion and Democracy*. Oxford Political Theory. Oxford: Oxford University Press.