This is MINE.

No, this is OURS:

Holding “Big Pharma” To Account

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Executive Summary

This report examines the World Trade Organization’s (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and pharmaceuticals, “Big Pharma’s” role in defining the initial agenda, and the social and political activism that emerged to fight for access to medicines. Using Nancy Fraser’s multifaceted public sphere perspective as a theoretical lens, the report analyzes the roles of relevant actors through her differentiations of “strong” publics, “weak” publics, and “subaltern counterpublics.”

Central Findings

*It’s all about balance: intellectual property rights and the ‘Common(s)’*—The ethical questions that the issue of TRIPS and pharmaceuticals raise are part of a much broader phenomenon of public concern—the commodification or expropriation of the ‘Commons.’ In recent years, there has been a steady influx of privatization, which has allowed private/corporate interests to take hold of things that were not previously classified as commodities. A “commodity fiction” was formulated so that water resources could be privatized, so that the genetic code could be owned, and so that information regarding essential medicines could be restricted solely for Big Pharma’s commercial purposes. As a staple of market economies, the private property rights system is held in high regard for good reason; however, as the TRIPS issue clearly illuminates, there must be an appropriate balance between the sanctity of private property and the health of the Common(s). It is imperative to keep these more fundamental concerns in mind when addressing these issues because it helps one see beyond the “red tape” of these laws and helps one deconstruct who is manufacturing them for their own benefit.
Underlying significance of the WTO’s initial implementation of TRIPS ~ The inclusion of pharmaceuticals in the TRIPS Agreement successfully legislated an agenda with Big Pharma ideology at its core – namely big rules and big money. The result of its implementation was a constructed ‘ideal’ market for both the corporate interests of Big Pharma as well as those of the developed nations in which these corporations operate (“stronger publics”). Therefore, with little consideration of larger global public health concerns, the agenda that TRIPS set completely neglected the poor in developing nations who are unable to access essential medicines. These “weaker publics” were given no voice let alone a thought in the WTO’s agenda.

“Big Pharma” as a star player ~ The Big Pharma industry has been granted such a ‘larger than life’ position of power that the corporations which have been frantically mapping out the human genome, have actually been allowed to patent what they discover. In other words, Big Pharma has been given the right to own the genetic codes of life. Patents are a lucrative business and therefore, when TRIPS was written, Big Pharma lobbied for a standardized international regime that would protect its patents irrespective of the country. Naturally, when governments of developing nations (like South Africa and Brazil) began challenging the monopoly on the utilization of these patents, Big Pharma, along with the developed nations in which these corporations are based, brought costly lawsuits against the challengers. Thus, not only did Big Pharma play a major role in writing the agenda, it also acted as an enforcer of it as well.
“Subaltern Counterpublics”: A force to be reckoned with – In addition to the governments of a few developing nations that took a stand against Big Pharma and the TRIPS regime, there were also numerous NGOs (like Oxfam, Médecins sans Frontières (MSF), and the Treatment Action Campaign (TAC) and social movements (such as the ‘Battle at Seattle’) which took up the fight for access to medicines. These entities represent “subaltern counterpublics.” Their actions came together to construct a counter-discourse that eventually influenced the WTO to reframe its agenda and adopt the Doha Declaration on TRIPS and Public Health. The successes of the political and social activism taken within these subaltern counterpublics reveal an exciting change in the geopolitical landscape of power. The global public sphere is recognizing an increasingly diverse number of publics whose opinions and needs were previously unacknowledged in the dominant discourse. This transformation is empowering people who traditionally did not have a voice in matters of global governance. As these relations are changing before our eyes, we must try to reconceptualize how we perceive global power relations. We must challenge ourselves to adapt our conceptual tools for the contemporary landscape, and that is why Nancy Fraser’s multifaceted public sphere perspective has been invaluable to the deliberations in this report.

Key Concepts

The ‘Common(s)’: spaces, resources, and goods that are not expropriated by the private property rights system, meaning that they are not owned by any particular private body. In addition to the Common(s) signifying traditional goods like water for example, it can also signify more abstract things such as the communicative practices and collaboration
between individuals. This is further elaborated upon in Michael Hardt and Antonio Negri’s book *Multitude*.

*Neoliberal*: an ideology that promotes profit-driven, bottom-line thinking and free market economic principles (privatization, deregulation, liberalization of trade, etc.).

“*Big Pharma*”: this is now a popularized term which represents the multinational and multimillion dollar pharmaceutical industry and the corporations that are a part of it.

*Public sphere*: “a body of ‘private persons’ assembled to discuss matters of public concern or ‘common interest’” (Fraser, 112). “It is the space in which citizens deliberate about their common affairs, and hence an institutionalized arena of discursive interaction” (Fraser, 110).

*Globalization*: characterized by national economies becoming increasingly integrated, ever-increasing flows of communications and financial activity around the globe, and a growing presence of multinational and transnational corporations, organizations, and social movements. Different actors with conflicting agendas utilize these conditions creating fascinating power relations as illustrated throughout the contents of this report. The most prominent tension discussed here exists between those who promote a neoliberal vision of economic globalization versus those of the “anti-globalization” movement who are opposed to the neoliberal agenda.
“This is MINE”

As you settle in to read this paper, you bring with you an often-overlooked assumption. You naturally assume that the author – that is, me, owns every paragraph and page. It is just understood that in being my mind’s creation, this paper is my private property and therefore, it is my right to restrict its use as I see fit. There is an assumption that it is the reader’s duty to respect that. However, what if this paper held information that would save a life? Would the rules still be the same? What if this paper held information that could save one million lives? Would my right to its restriction still be respected? What if there was an international regime that prevented the effective sharing of information that might save your life?

When the World Trade Organization (WTO) decided to include pharmaceutical drugs and processes in its Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, it made an unsettling choice. The TRIPS regime called on WTO Member-states to regulate pharmaceutical patents according to a homogenized neoliberal framework; one that was constructed to privilege the interests of multinational pharmaceutical corporations (Big Pharma) as well as those of the developed nations in which they operate. This follows a familiar trend in how economic globalization has facilitated a concentration of political and economic power into ever-larger international social institutions. Nation-states are more malleable to the policies and norms set by international institutions, and multinational corporations have become a prominent beacon of influence whose control spreads not only geographically to all corners of the globe, but also to all corners of what can be considered the ‘global Commons’ by commodifying more aspects of our lives.
In an increasingly global information economy, the corporate hand extends its reach further with the intellectual property rights system. In relation to TRIPS and access to medicines, the dissemination of information can be, quite literally, a matter of life and death, thus raising fundamental philosophical questions about balancing private property rights and the health of the Common. Fortunately, there is a strong subaltern power that is creating a counter-discourse that does just that – cuts through the red tape of a legislated “industrial fatalism”\textsuperscript{1} to tackle the more fundamental questions and fight for an agenda that takes into account more than profits as the bottom line. Nongovernmental organizations (NGOs), the governments of developing nations, and transnational social movements are accumulating power through a backlash against a market-driven, neoliberal economic globalization. In these subaltern counterpublics, people escape from their ‘communities of fate’ (no matter what their geographical location, no matter what their class or ethnicity) to mobilize together into ‘communities of choice,’ which strive for a common goal and achieve social change.

When analyzing the issue of global intellectual property rights and access to essential medicines for the world’s poor, one sees how something as supra-structural as the WTO’s international agenda can be reset by concerned citizens working in unison. This report will examine how the efforts of subaltern counterpublics have pressured Big Pharma in order to hijack power away from the industry and the WTO by demanding more accountability and protection for global health concerns.

\textsuperscript{1} The concept of “industrial fatalism” is a term used by Ulrich Beck to describe a prevailing mentality that rationalizes everything to the extreme so that things seem more functional, calculated and reasoned. This can lead to the rationalization of larger risks and hazards that have no accountability to human interests. “Industrial fatalism” is linked with the standard critiques of ideological notions of “progress.”
“Once upon a time there was a market . . .”

As much as some place the ‘self-regulating’ market on a pedestal, it is people who have created that story, and people who revere that neoliberal image. Market economies are cultural constructs just like the laws manufactured to govern them. One of the main themes that Karl Polanyi emphasizes in, The Great Transformation is that “man’s economy, as a rule, is submerged in his social relationships” (Polanyi 48). Despite attitudes to the contrary, items that are bought and sold on the market do not have an inherent quality that rationalizes their becoming commodities. The necessary justification for any commodification is what Polanyi calls a “commodity fiction.”

Polanyi argued that the rendering of things not originally produced for sale as commodities required their reconceptualization, and thus their fictionalization, as “property” . . . A story needed to be told about these resources which was not necessarily linked to their existence or social production but rather narrated as a propensity to be organized through market relations (May 124).

This “fictionalization” continues to dictate the commodification of more and more elements of our lives further entrenching our social relations within the rules of the market – providing further specifications on what is considered ‘property’ and what is not. The deep-rooted conception of private property rights and their justification can be traced back to the theories of liberal philosopher, John Locke and the post-Kantian idealist, Georg Wilhelm Friedrich Hegel.

For Hegel, property rights represented the creation and protection of individuality; they “protect the individual from the state and competing individuals in society by
carving out a sovereign space” (May 126). Locke’s thoughts on private property are especially significant since he initiated a long line of liberal thinkers who have continuously adopted his theories. Locke said, “He by his labour does, as it were, enclose it from the Common … where there is enough and as good left in the Common for others” (Andreasson 5). Interestingly, somewhere along the way, liberal thinkers ‘forgot’ Locke’s assertion about balancing private property rights with the need to ensure that there is enough left in the Common for others. Again, this omission was not ‘natural’; it was chosen and the choice was rationalized by pragmatic or economic arguments, which are now inseparable from ideas of private property.

One of these central economic arguments is that a scarcity of any resource drives innovation. When goods are scarce, the costs of attaining them are high so that, theoretically, people are inspired to innovate in order to avoid the costs. The other main rationalizing argument is that “efficient resource use is established through the use of markets in which property is exchanged and transferred to those who can make the best use of it” (May 127). Therefore, property rights are supposed to regulate an “efficient” use of limited resources and simultaneously guard against what Garret Hardin describes in his article as “The Tragedy of the Commons.” Hardin claimed that if the Commons were not regulated, individuals would use its resources for their own self-interest to the point of depletion. The basic idea behind this tragedy scenario is that: “Freedom in the Commons brings ruin to all” (May 128).

From this perspective, enclosing the Commons through a private property rights system is justified for the social good because, as Hardin declares, “while it replaces merit or justice with wealth as the key allocation mechanism, ‘injustice is preferable to
Putting a Price-Tag on Ideas: Intellectual Property Rights

The commodification of information and ideas presents interesting nuances regarding the issue of private property rights since there is a unique relationship between information and the Common:

The production of ideas, images, and knowledges is not only conducted in [the] common – no one really thinks alone, all thought is produced in collaboration with the past and present thought of others – but also each new idea and image invites and opens new collaborations (Hardt and Negri 147).

The collaboration involved in the production and dissemination of information and knowledge not only functions through the Common, but it also creates more ideas for the Common which others, in turn, can use as a resource to produce yet even more ideas. Intellectual property rights (IPRs) are “legal and institutional devices to protect creations of the mind such as inventions, works of art and literature, and designs” (Dutfield 533). They are the legal means through which ideas are commodified and their use restricted.

Scholars such as Manuel Castells assert that currently the dominant ‘mode of development’ is “informationalism” in which “the source of productivity lies in the technology of knowledge generation, information processing, and symbol communication” (Castells 17). Complementary to this, Hardt and Negri identify the
“historical tendency” of our time as a “hegemony of immaterial production,” which means that “immaterial labour” (labour related to information processing, generation, and dissemination) essentially frames all other existing labour relations (Hardt and Negri 141). Since information is the most valuable economic resource in “informationalism” and “immaterial production,” it is not surprising that the most sophisticated forms of property rights in existence are now intellectual property rights.

The origination of intellectual property right laws in the West is rooted in the ‘privileges’ granted to inventors in fifteenth century Venice and sixteenth century England along with other places in Europe. These privileges, granted as part of a package, required the inventors to commit to teaching apprentices and to publicizing their new method and/or technology. Thus, along with the attached economic benefits of the granted privilege, the inventors had a duty to make their innovations accessible to as many people as possible (May 132). “The subsequent history of intellectual property has reversed this logic to make intellectual property itself the right which benefits society. This has been a political reversal, not some ‘natural’ development, or refinement of law” (May 132).

When it comes to knowledge and information, these arguments regarding scarcity as a driver of innovation do not seem to hold true. This thereby presents a problem for justifying the commodification of the social good. As Christopher May so eloquently puts it: “If the social good served by knowledge and information is related to availability … then the enforced scarcity of intellectual property becomes problematic” (May 130). When people can use the same knowledge without damaging the benefits that can be taken from that knowledge simultaneously, how does one justify the use of patents and
copyrights to construct a false scarcity of information, which imposes harmful costs to so many people because that information is being restricted? What if this dilemma leads to a tragedy of the “anti-commons”? Here the under-utilization of resources leads to “universal ruin” (May 141).

Whether we choose to pay attention or not, the private property rights system progressively encloses more and more of what is referred to as the ‘global Commons’ – including lifesaving knowledge and information. As the institution of private property extends its reach to new geographical territories and commodifies important aspects of our lives, one should question, who is setting the agenda for the development of these laws and who is benefiting from that agenda?

Look Who’s Talking: A Struggle of Publics in a Global Marketplace

Jürgen Habermas’ “public sphere” is paraphrased by Nancy Fraser as being: “a body of ‘private persons’ assembled to discuss matters of public concern or ‘common interest’” (Fraser 112). Habermas’ view of the public sphere is characterized as being an overarching public sphere made up of one large body, to which, theoretically, all ‘citizens’ should have access. Yet, Fraser argues that multiple publics exist: “strong publics,” “weak publics,” and “subaltern counterpublics.” What differentiates these publics, she theorizes, is their location within power relations of dominance and subordination and by how much decision-making influence each public holds.

Although it is sometimes argued that global capitalism operates through a ‘seamless’ mechanism of adjustment and price-setting, the rules of this mechanism have been constructed by international organizations like the WTO. Therefore, groups that
have the power to influence the agenda of the WTO construct international policies that have an impact on the global community in a profound way.

When considering the issue of global intellectual property rights and access to medicines, the weaker public would be the disadvantaged people of developing countries, who are deprived of essential medicines and whose voices are ignored in the negotiations for their rights to these medicines – the group Paul Collier coins “the bottom billion.” The stronger public is composed of multinational pharmaceutical corporations (Big Pharma) and developed countries, which traditionally have more influence in the decision-making of the dominant discourse; that is, in ‘writing the rules of the game’ – the WTO’s legislation. NGOs, and the governments of some developing countries involved in this battle, embody Fraser’s subaltern counterpublics since they are “parallel discursive arenas where members of subordinated social groups invent and circulate counterdiscourses to formulate oppositional interpretations of their identities, interests, and needs” (Fraser 123). They have less enforceable decision-making powers than multinational corporations or the governments of developed countries, but their impressive strength stems from their ability to establish a counter-discourse against the “powers that be.”

WTO conferences and the official legislation documents that result from these conferences set the international legal parameters for the patentability of medicines for all WTO Member-states. Picture the WTO legislative process as a conversation. The stronger publics attempt to frame the WTO’s legislative discourse in terms of protecting private intellectual property rights. The subaltern counterpublics attempt to reframe the issue so that the protection of global public health is not governed by market principles as
the overarching guideline; these groups hold the humanitarian interests of the world’s poor as the primary focus. The stronger public sets the agenda to create laws that construct a neoliberal marketplace, and the agenda is subsequently reset by subaltern power.

We can trace the first significant move in the WTO’s legislative conversation regarding international intellectual property rights and access to medicines back to the WTO’s Uruguay Round in 1994. This was where the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement was discussed and subsequently, implemented. This Agreement sets out the minimum standards of patent protection that all WTO members must meet, creating an international regime governing copyrights, patents, trademarks, and any other issues relating to intellectual property. The patentability of pharmaceutical processes and products was included in the Agreement as well. Through the creation of TRIPS and its inclusion of pharmaceuticals, the stronger publics of the WTO extended a neoliberal arm out into the global Commons to grab hold of invaluable information. To understand the impact of NGOs in establishing a counter-discourse to Big Pharma, it is first necessary to recognize how the interests of Big Pharma were written into the ‘dominant’ discourse of the WTO’s original global intellectual property rights regime.

**Big Rules, Big Money, Big Pharma Ideology**

Pfizer Chairman Emeritus, Edmund Taylor Pratt Jr.’s speech in 1995 to the U.S. Council for International Business:
The [Intellectual Property Committee, which Pfizer helped found] helped to convince U.S. officials that we should take a tough stance on intellectual property issues, and that led to trade-related intellectual property rights being included on the GATT agenda when negotiations began in Punta del Este, Uruguay, in 1986. ... The current GATT victory, which established provisions for intellectual property protection, resulted from the hard-fought efforts of the U.S. government and U.S. businesses, including Pfizer, over the past three decades. We’ve been in it from the beginning, taking a leadership role (Wallach and Woodall 94-95).

Multinational corporations (MNCs) are fond of “global rules” that they can take advantage of in any country in which they choose to operate. Therefore, MNCs are efficient at exerting pressure in order to shape the global rules set by international institutions like the WTO. They rally support from the governments of the countries in which they operate, as these governments often “see their national interests linked to the competitive position of the large firms that operate there” (Tansey 1). From the government’s perspective, if a big pharmaceutical firm earns more profits from patents in foreign countries, the GDP of the home country will increase and, in turn, the home country will have a more competitive position on the world market.

The pharmaceutical industry endorses and justifies strong patent systems internationally because “if copying is allowed in developing countries, these drugs will be exported to developed country markets, where the industry makes most of its profits” (Roffe, Spennemann and von Braun 12). If an original, brand-name drug is the only one available to consumers, then consumers are left with no choice but to spend the money
and purchase that drug. When drugs are copied and produced as generic drugs, as happens when a patent runs out or when a compulsory licence is issued, the generic drugs can be sold at a cheaper price undermining the price of the original brand-name drug. To employ standard economic theory, an increase in supply decreases demand and prices should be reduced accordingly.

Therefore, drugs copied in developing countries and exported to developed countries at a reduced price are problematic for the pharmaceutical industry. The presence of a generic drug undermines their ability to set prices, and further undermines their profits. Not surprisingly, Big Pharma makes the greatest profits in developed countries where the markets can usually bear substantially higher prices coinciding with the ability of consumers to afford it – as opposed to the price being set in relation to the actual production costs of the drug.

The most popular argument put forth by Big Pharma to explain why the industry puts so much pressure on keeping these patent systems strong is that its research and development (R&D) would significantly suffer from the lack of funding that would result without these protection systems. Lack of funding, in turn, impedes the development of new drugs – new drugs which, according to Big Pharma, will benefit everyone in the end. The validity of the argument that R&D would be disadvantaged by loosening the grip on these patent systems can be scrutinized for a number of reasons: (1) considering how much R&D really costs when compared to other expenses, such as the money directed towards the marketing strategies of pharmaceutical companies; (2) there is a substantial role played by public funding in R&D, which is often unaccounted for; and (3) there is no evidence that policies like compulsory licensing have in fact reduced investment in
R&D (Roffe, Spennemann and von Braun 15). Funding loss to R&D is also the basis for the pharmaceutical industry’s arguments against the implementation of price controls.

In 2005, “a Tanzanian worker would have to earn 500 hours of wages to get a course of first-line tuberculosis treatment, compared with the one hour of wages necessary for a Swiss worker” (Gathii 347). Activists from prominent NGOs, like MSF and Oxfam, argue for pharmaceutical companies to adopt a “systematic and transparent tiered-pricing policy, where prices for all essential medicines are set according to people’s ability to pay” (Oxfam press release, 2007-11-24). A tiered-pricing system, they argue, would have a significant impact on increasing the level of access to medicines for the world’s poor without severely cutting profits for the pharmaceutical companies. Yet, Big Pharma views tiered-pricing with scepticism.

From Big Pharma’s viewpoint, this is price control, and price controls harm shareholders, employees, suppliers, and the public because, again, less money goes towards developing new drugs and treatments. As Richard A. Epstein writes:

The pharmaceutical business may feature patents that create monopoly, but so long as these are not acquired by a wave of the hand, everyone will cut back investment to reflect the low valuation that any system of price controls, however convoluted and indirect, imposes on the system. It is a mug’s game that cannot be won here any more than with price controls on gasoline or rent controls on apartments (Epstein 81).

In any case, a key question must be raised: how much R&D funding is actually put towards improving healthcare treatments for the world’s poor?
A great deal of R&D is conducted primarily to investigate illnesses and conditions that affect people in industrialized countries; these results are of no significance to the poor. This focus obviously disadvantages people in developing nations. “Between 1975 and 1999, 1393 new drugs were developed, of which only 13 were for tropical diseases…90 per cent of investment into health-related R&D has focused on concerns that only affect 10 per cent of the global population” (Roffe, Spennemann and von Braun 13). Diseases like malaria and tuberculosis, which continue to be serious health issues in developing countries, are marginalized in the R&D agenda while issues like obesity (a major condition for industrialized nations) dominate. James Orbinski (former president of the International Council of MSF) states that no new drugs have been developed for the treatment of tuberculosis since 1967 and 95 per cent of active tuberculosis cases occur in developing countries – not a surprising correlation.

Of course, there have been various instances where Big Pharma’s philanthropy has shone through – pharmaceutical companies have reduced drug prices in developing countries, companies have offered substantial discounts on ARVs (antiretroviral drugs), and there have even been instances when companies have provided drugs and health infrastructure for free. However, many agree with Carsten Fink, that even though “such actions are laudable, they are not systematic and depend on the good will of private firms. Clearly, the scale of the health crisis in the developing world is too large to be solved by private philanthropy alone” (Fink 187). The global public health crisis is not an issue that can be handled based on various acts of ‘good will,’ it needs to be permanently present in the agenda itself; it needs to be a priority.
Where is the “Progress” here? Where is the “Development”? 

The logic of Big Pharma and industrialized nations largely reflects the rhetoric of the old “modernist paradigm” of development initiated in the 1940s and 1950s – the ideology of “modernization” and the traditional view of “progress.” This ideology presumed that “only through material advancement could social, cultural, and political progress be achieved. This view determined the belief that capital investment was the most important ingredient in economic growth and development” (Escobar 39). Robert Goldberg, former director of the Manhattan Institute’s Centre for Medical Progress, summarizes the logic of this concept of development in one phrase: “wealth begets health.” Goldberg argues that the main method of bettering healthcare is to make poorer countries wealthier: “improving health in poor countries requires a combination of improved protection of property rights… [including] protection of intellectual property rights” (Goldberg).

This viewpoint – that private wealth leads to the betterment of all – is inherent in the neoliberal development initiatives put forth by prominent international institutions like the World Bank and the International Monetary Fund. Their development programs are set up so that developing nations will privatize public services such as healthcare and education. The central aim is for these countries to ‘free’ their economies in order for the market to rule. The vision behind the ‘self-regulated’ market is the ideal that the benefits from the accumulation of private wealth will ‘trickle-down’ to everyone; but “the history of increasing reliance on neo-liberal development strategies suggests that the expected benefits do not materialize for most of the world’s poor” (Andreasson 16). This awareness is spreading even within mainstream economics.
Jeffrey Sachs, a world-renowned economist, has focused his career on collaborating with governments and NGOs alike on matters of economic development, global poverty, the cancellation of debt for developing countries, environmental sustainability, and global health concerns. \(^2\) A constant thread throughout Sachs’ career has been his interest in examining the relationships between poverty, health, and development. In 2001, he led a WHO commission of macroeconomists and public health specialists in producing the influential report called *Investing in Health for Economic Development*. One of the simplest yet crucial findings of this report, which gets to the heart of the correlation between development and global health issues, is that: “Poor health causes poverty and poverty causes poor health” (Sachs 204).

Sachs elaborates on this concept in his book *The End of Poverty: Economic Possibilities for Our Time* when he discusses the “poverty traps” that many of the extremely poor countries in the world are caught in such as climate stress, environmental degradation, and/or disease.

Even though life-saving solutions exist to increase their chances for survival – whether in the form of new farming techniques, or essential medicines, or bed nets that can limit the transmission of malaria – these families and their governments simply lack the financial means to make these crucial investments (Sachs 1).

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\(^2\) Jeffrey Sachs works at Columbia University where he is the Director of The Earth Institute, a Quetelet Professor of Sustainable Development, and a Professor of Health Policy and Management. He was the chairman of the World Health Organization (WHO) Commission on Macroeconomics and Health (CMH) from 2000 to 2001. Currently he holds the esteemed position of Special Advisor to the United Nations Secretary-General Ban Ki-moon, and from 2002 to 2006, he acted as the Director of the UN Millennium Project and was Special Advisor to the United Nations Secretary-General Kofi Annan on the Millennium Development Goals.
These poverty traps can severely inhibit any of the market reforms or good governance strategies implemented to aid development.

Sachs discusses malaria as a prime example of a “poverty trap” in poor countries. Although malaria is a treatable disease, “it still claims up to three million lives per year, mostly young children, about 90 percent of whom live in Africa … Low cost treatments exist, but they do not reach the poor” (Sachs 196). Not only is malaria devastating for the individuals and families that suffer from it, but malaria can also devastate a country’s macro-development. An outbreak of malaria can prevent the development of investment projects like new tourist sites, mines, or farm regions (Sachs 197). Access to items such as insecticide-treated bed-nets and anti-malarial medicines would significantly reduce the number of people that die of malaria every year but, “malaria sets the perfect trap: it impoverishes a country, making it too expensive to prevent and treat the disease. Thus malaria continues and poverty deepens in a truly vicious cycle” (Sachs 199). The same can be said about the painful impacts of AIDS. Sachs makes it clear that although aid initiatives, trade policies, and good governance may all be working towards the same objectives of “development” and “progress,” one strategy may defeat another if the actual harsh realities of the poor are not taken into account. We can, in the name of development and progress, ‘free’ the markets, impose the strongest intellectual property rights system possible, and construct an ‘idyllic’ marketplace for global trade, but if the people are dying from the rampant spread of treatable diseases, they will be unable to function properly in any market.
Setting Global Rules: The ‘Nitty-Gritty’ of the WTO TRIPS Agreement

The large number of specific obligations defined in the legal framework of TRIPS marked a significant shift from past WTO agreements. The TRIPS Agreement was also far more “controversial because it seemed to favour the interests of exporters (mostly industrialized countries) more than the interests of importers (most developing nations)” (Gallagher 93). Although many developing countries expressed resistance to putting intellectual property rights into WTO agreements, they felt there was no choice since they wanted continued market access to developed countries in other areas of trade, such as agriculture and textiles.

What’s more, the TRIPS Agreement did not merely outline ‘suggested’ international norms that nation-states should follow in regards to intellectual property rights. It implemented an enforceable regime under the Dispute Settlement Understanding (DSU) through which “[O]nce the existence of a violation has been determined, the affected country can apply cross-retaliations to the non-complying country, in any area covered by the World Trade Organization (WTO) Agreement” through sanctions (Correa 2). Thus, with the TRIPS Agreement, WTO Member-states lost much of the power they possessed prior to TRIPS when they were able to consider the welfare of their own particular national interests and use their own discretion in determining which matters they wanted to cover under intellectual property rights laws. In fact, a study published by the United Nations in 1975 shows that many countries, developing and developed alike, did not allow the patentability of pharmaceutical products. This ensured a lower cost of access for the country’s population, and/or allowed
the government to protect the national pharmaceutical sector from competition with more advanced sectors in other countries (Roffe, Spennemann and von Braun 13).

There are, however, “flexibilities” within the TRIPS Agreement that provide Member-states with some power over how they exercise patents in their own countries. Members have the freedom to “define the broad parameters of a patentable invention,” and can implement measures to sidetrack a patent owner’s monopoly of a patent in specific situations as outlined in the Agreement. One such measure that allows for this kind of flexibility is the research exception. Countries will implement this exception so that researchers can use a patented invention to understand it better for the purposes of advancing science and technology.

TRIPS also includes the “Bolar” or “regulatory” provision which is employed when governments want to allow generic drug manufacturers to use a patented product before the patent has expired so that they can get marketing approval from the necessary public health authorities. This provision enables generic manufacturers to release their generic version of the drug on the market as soon as the patent licence expires. A patent owner’s monopoly over a patented product or process might also be superseded in cases where the owner is partaking in anti-competitive practices; meaning that the intellectual property right is being used in a way that inhibits competition and obstructs trade or technology transfer. TRIPS also allows for the use of parallel importation, which means that companies can import the cheapest-priced drug from another country where a patent exists. This can effectively drive down the prices of pharmaceuticals (Roffe, Spennemann and von Braun 14).
The one flexibility measure in TRIPS that runs into the most controversy with Big Pharma is compulsory licensing. A compulsory license enables a third party to use a patent without the patent owner’s authorization. A government can use this compulsory licence to give one of its own agencies or a private company the right to produce drugs under a generic label. Royalties are paid to the patent owner on each sale but these will be minimal in order to keep the drug price as low as possible. Big Pharma’s main problem with these flexibility measures is that they undermine its monopoly power and price-setting ability – to use compulsory licensing as an example, it can successfully “lower the price of medicines as much as 95%,” severely cutting into profits (Wallach and Woodall 95). It is not surprising then that certain conditions were attached to the flexibilities outlined in TRIPS to ensure that their usage would be minimal.

Under the TRIPS Agreement, compulsory licensing could only be enacted under certain stipulations. Consideration for a compulsory licence was on an individual basis, and negotiations were required between the party wanting the licence and the patent holder to ensure at least an attempt to agree on a voluntary licence prior to the issuance of a compulsory one. TRIPS did state that negotiations would not be required if the country were in a state of “national emergency,” or if the government needed to correct anti-competitive practices. Once a compulsory licence was issued, it could only be applied within the parameters set when it was authorized; and the licence could only be used for the domestic market (Roffè, Spennemann and von Braun 15-16). These flexibilities made TRIPS “unlike many other WTO agreements, [because] within the TRIPS Agreement there [was] space to manoeuvre. However, as with all WTO issues, the ability to access this flexibility [came] down to issues of power” (Wallach and Woodall 95).
Despite such provisions, there was justified fear in how TRIPS would affect the welfare of the weaker publics of developing nations – the bottom billion. “Intellectual property rules create monopolies for medicines sold by multinational pharmaceutical companies, keeping inexpensive, generic medicines, which can reduce the cost of medicine in a sustainable way, off the market” (Oxfam Briefing Paper). In Egypt, the increase in the price of drugs after TRIPS was estimated to be five to six times the price of non-patented products (Correa 35). One economist from the traditionally ‘neoliberal-conservative’ World Bank even estimated that “the minimum welfare loss to a sample of developing countries (Argentina, Brazil, India, Mexico, Korea and Taiwan) would amount to a minimum of US$3.5 billion and a maximum of US$10.8 billion, while the income gains by foreign patent owners would be between US$2.1 billion and US$14.4 billion” (Correa 35). The interests privileged by the inclusion of pharmaceuticals in the TRIPS Agreement seem to be quite clear – they are those of Big Pharma and the developed countries in which these multinational pharmaceutical companies are based.

**TRIPS as “Organized Irresponsibility”**

The actions and overall ideology of Big Pharma as legislated through the TRIPS Agreement perfectly reflects what Ulrich Beck has labelled proof of the “industrial fatalism” and “organized irresponsibility” which govern the practices of modern-day global capitalism. Beck asks, “What good is a legal framework that prosecutes technically manageable small risks, but legalizes large-scale hazards on the strength of its authority, foisting them on everyone, including even those multitudes that resist them” (Beck 69)? Beck raised this question about global ecological concerns; however, it is
easy to apply the question to global health issues and the legislation of TRIPS. Looking beyond all of the flexibilities, stipulations, and other legal technicalities in the TRIPS Agreement, the issue of intellectual property rights and the accessibility of medicines is quite literally a matter of people’s health or illness, of increased standards of living or poverty – of life or death. While Big Pharma argues for maintaining high levels of R&D funding to save the lives of future generations, in the interim millions of lives are lost because of a lack of access to medicines.

The previous points may sound dramatic and radical, as if uttered by a person solely appealing to emotions as the basis for argument. However, how ‘radical’ are these statements? Are we really “imprisoned by our dependence on [the] rationality” of the industrial fatalism which Beck cautioned us about (Beck 58)? Perhaps we can be so ‘rational’ in following the organized standards of ‘red tape,’ that we are incapable of seeing beyond it; and therefore, incapable of deconstructing issues with a simpler rationality and responsibility – which would be saving lives versus not saving lives.

Is there a remedy to this dangerous industrial fatalist illness? The actions on the ground of subaltern counterpublics and their demand for more accountability from Big Pharma demonstrate how this illness is being successfully combated. In his book, *The Bottom Billion: Why the Poorest Countries Are Failing and What Can Be Done About It*, Paul Collier remarks that the WTO’s trade policies, structured essentially as a marketplace, neglect the needs of the “bottom billion” and thus, help perpetuate their poverty:

The WTO trade policy is determined by national trade representatives who see their role as negotiating a deal. Within this framework there is no
scope for using trade policy as an instrument for development. For trade policy to become an instrument of development, ministries of trade have to be ordered to change their priorities from extracting the best bargain to fostering development in the bottom billion. But ordered by whom? (Collier 187)

The people who are currently ordering the change in priorities that Collier discusses have risen out of their ‘communities of fate’ and joined together in ‘communities of choice’ to form subaltern counterpublics which fight against the demands of Big Pharma. The TRIPS Agreement may have established the strong publics’ dominant discourse in the WTO’s legislation; but it is evident that the efforts and successes of subaltern counterpublics have created a forceful counter-discourse as seen in the South African Government’s Medicine Act (1997) controversy, Brazil’s ongoing fight to maintain a good level of accessibility for its citizens, the ‘Battle of Seattle’ (1999), and the Doha Declaration (2001).

**South Africa: The Protests of AIDS Activists’ are Heard**

“One in five adult South Africans, one in seven Kenyans, and one in three Zimbabweans has HIV/AIDS,” which is why some liken HIV/AIDS to the plague that devastated Europe in the 14th century (Wallach and Woodall 94). In response, the South African government implemented the Medicines and Related Substances Control Amendment Act (1997) in order to help its citizens gain better and more affordable access to anti-AIDS drugs and other essential medicines. The Act:
encourage[d] the use of generic drugs, prohibit[ed] pharmaceutical companies from paying doctors bounties for prescribing their products … and institute[d] parallel importing as a means to control pharmaceutical costs. The Medicine Act also allow[ed] the government to require compulsory licensing. Under Article 31 of the TRIPS Agreement, such compulsory licensing [was] legal if royalties [were] paid to the patent holder (Wallach and Woodall 96).

Although both compulsory licensing and parallel importing are provisions supported by the TRIPS agreement, the U.S. government claimed that South Africa was infringing on international patent rights because of the wording of the new legislation. The disputed portion of legislation, Section 15C, was “designed to override the exhaustion of rights problem by giving the Minister of Health new over-riding administrative discretion” (Cleary and Ross 450). The United States feared that a “broad interpretation of 15C would allow the government to bypass the Patents Act and issue ‘fast track’ compulsory licenses on pharmaceutical patents” (Cleary and Ross 453).

U.S. Secretary of Commerce Richard Daley took up the matter with his South African counterpart. This led to a revision of South Africa’s proposed legislation, addressing some of the U.S. industry’s concerns. The U.S. still was not satisfied, and engaged in a ‘full court press’ in late 1997 to persuade South Africa to suspend the law entirely (Wallach and Woodall 96).
Consequently, the U.S. Office of the Trade Representative (USTR) labelled South Africa as a “Special 301 ‘watch list’ country – a status that could lead to trade sanctions” (Roffe, Spennemann and von Braun 16).

The Pharmaceutical Manufacturers’ Association of South Africa (PMA) would also use WTO obligations as their basis for challenging the Act. In February 1998, “39 international [pharmaceutical] firms, including the South African Pharmaceutical Manufacturers Association (PMA) brought legal action against Nelson Mandela and the South African Department of Health” (Roffe, Spennemann and von Braun 16-17). The PMA withdrew its case against the South African government in late 1998 due to international public pressure, only to bring the same lawsuit back again in January 2001 (von Soest and Weinel 215). The PMA’s representatives claimed that it was the “arbitrary power” of the Minister of Health that was at issue, but the allowance of compulsory licensing was more at the core of the problem – that is, the money that would be lost from these patents was the real issue at hand.

Subaltern counterpublics raised a massive and unified global outcry to counteract the legal action brought against the South African government by the United States and the pharmaceutical companies. “Intellectual property rights activists tended to demonize the large pharmaceutical companies as a core part of their political strategy, and linkage of this campaign to the southern African HIV/AIDS epidemic clearly enhanced popular interest in the case” (Cleary and Ross 453). This enabled these cases to attain a significant amount of exposure in the popular media. NGOs and other movements introduced “counter-concepts” into the public consciousness like “no patents on life” and “patents kill.” Developing nations later adopted these concepts when formulating their
proposals to the WTO and the World Intellectual Property Organization (WIPO) (Dutfield 538). Leading NGOs, like MSF, employed and continue to employ “counter-experts” in the battle against Big Pharma, using academic consultants with legal experience and hiring staff to concentrate solely on intellectual property rights issues (Dutfield 538).

Campaigns were organized in South Africa by the Treatment Action Campaign (TAC), the country’s main advocacy group for increased levels of access to anti-retroviral drugs. In the United States, American AIDS activists organized mass demonstrations, particularly against the Al Gore presidential campaign, which had a significant impact (Cleary and Ross 453-454). While Gore formally announced that he was running for president, AIDS activists were chanting “Gore’s Greed Kills” and “after two of Gore’s next three speeches were similarly disrupted, the White House began reaching out to activists, indicating that it was looking at changing its position” (Wallach and Woodall 96). The U.S. government dropped the trade pressures it had issued against South Africa, and Vice Presidents Al Gore and Thabo Mbeki came to a resolution in 1999. “During the November-December WTO Ministerial in Seattle, the Clinton administration announced it would offer special treatment for health-related intellectual property disputes, taking into account health issues as well as commercial concerns” (Wallach and Woodall 96). AIDS activists successfully shifted U.S. policy and secured an interpretation of TRIPS that would support similar actions taken by governments of other developing countries.

The United States government had changed its position; however, the PMA did not drop the lawsuit. Demonstrations took place in front of the headquarters of several
major pharmaceutical companies in Europe and North America (von Soest and Weinel 215-216). In the spring of 2001, “300,000 people from more than 130 countries signed an international petition launched by MSF calling on the companies to drop the case” (MSF press release), and there was continued international public pressure and negative media attention for the PMA. “Interestingly, the government, HIV/AIDS activists, scientists, and other previously divided stakeholders joined hands to win the court case against the TNPCs [transnational pharmaceutical companies], although they followed different agendas” (von Soest and Weinel 216). These diverse publics emerged from their ‘communities of fate’ to find kinship and the power to enact social change for an important ‘community of choice.’ Because of this communal activism, the 39 pharmaceutical firms finally dropped their lawsuit on April 18, 2001.

There was a definite moment of crisis in the WTO over discourse and how different parties were interpreting the conditions and uses of the TRIPS Agreement. The strong publics put forward one discourse, while the subaltern counterpublics proposed an alternative. As a result, the lawsuits brought against the South African government were diverted, and the Medicines and Related Substances Control Amendment Act (1997) remained largely unaltered. The only “concession” made by the government was to reaffirm that it would adhere to the stipulations of TRIPS (von Soest and Weinel 216). Similar success occurred in the case of Brazil where subaltern counterpublics again held Big Pharma to account.
Brazil’s Crusade Against Big Pharma

The government of Brazil has a history of balancing international trade laws and national social policies for the benefit of its people. Therefore, when Brazil, as a Member-state of the WTO, had to shape its laws to suit the TRIPS agreement in 1994, it obliged, but with certain conditions attached to safeguard the welfare of its citizens. The Industrial Properties Law signed on May 14, 1996 by President Fernando Henrique Cardoso provided a high level of protection for pharmaceutical patents, yet the legislation was written in a way to allow for a liberal interpretation of TRIPS obligations.

Over the years, Brazil has developed a strong pharmaceutical manufacturing base composed of many private and public manufacturers. Because of this local industry, the prices of drugs are lower than they would be if Brazil had to import the same drugs. Brazil’s manufacturing capacity also provides the government with a powerful weapon against the pharmaceutical industry since it can use the threat of compulsory licensing to negotiate with Big Pharma. In 1997, the Brazilian government was able to include anti-retroviral therapy in its universal access to healthcare policy which “guarantee[d] the entire population prevention and treatment for HIV/AIDS, the right to diagnosis, and the right for universal and free access to all resources to treat the disease” (Wallach and Woodall 99). As part of this program, the government provides seventeen anti-retroviral drugs to its citizens free of charge – eight are generic drugs produced in Brazil and nine are brand-name drugs imported from other countries (Cohen I-17). These healthcare policies led to “a sharp decline in AIDS morbidity, mortality, opportunistic infection rates, and hospitalizations” (Cohen, I-17).
In June 2000, the U.S. government brought legal action against Brazil through the DSU system arguing that the Brazilian government violated the TRIPS Agreement through its legislation permitting “local manufacturers to produce products [when] a patent holder does not produce them locally.” This legislation allowed for the authorization of compulsory licences and parallel imports in circumstances where some of the production for the required pharmaceuticals was based in another country (Wallach and Woodall 98). The U.S. government claimed that Brazil was violating the TRIPS condition that all manufacturing under a compulsory licence must be done only in and for the domestic country’s market (Roffe, Spennemann and von Braun 17). The U.S. was concerned that Brazil’s production of cheap generic versions of anti-retroviral drugs weakened the U.S. pharmaceutical industry.3 Due to international pressure from activist groups, the “USTR [United States Trade Representative] announced a consultative mechanism to promote cooperation with Brazil on HIV/AIDS issues in June 2001,” and in the end, the U.S. government dropped its complaint against Brazil (Wallach and Woodall 99).

The Brazilian government further exemplified success in improving accessibility to medicines with actions just prior to the Doha Conference of 2001. Brazil’s Minister of Health, Jose Serra, threatened to issue the first compulsory licence for an HIV/AIDS drug after negotiations failed between the Brazilian government and the pharmaceutical company, Hoffmann-La Roche Inc. Serra argued the Hoffman-La Roche had, in effect, left the country in a state of emergency because the price of pharmaceuticals were so

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3 Ironically or not, “in 2001, [when] faced with a mere handful of cases of anthrax, the US government threatened to override Bayer’s patent on ciprofloxacin by endorsing compulsory licensing” (The Lancet). The U.S. government demonstrated blatant hypocrisy since it habitually discourages other countries from using compulsory licensing but threatened to use this measure when their own citizens’ health was at risk.
high. Brazil could easily have followed through on the threat to issue a compulsory licence, since they had the manufacturing capacity to do so, but instead, the Brazilian government used the threat of compulsory licensing to bargain with Hoffmann-La Roche Inc. so that in the end the company reduced the price of the anti-retroviral drug Nelfinavir by 40% (Cohen I-17). Brazil’s lessons for other developing countries observing the negotiations were telling and clear. Despite pressures from Big Pharma, the United States, and the TRIPS intellectual property rights regime, social activism and the governments of developing nations had the power to put saving people’s lives first on the agenda.

The Battle at Seattle: An “Icon of Dissent”

Cases like the Brazilian and South African fight against Big Pharma and the U.S. raised awareness as to how WTO legislation, multinational corporations, and some industrialized nations utilized the discourse of globalization to construct a neoliberal economic agenda solely for the benefit of the stronger publics. For many members of the weaker publics and subaltern counterpublics, globalization came to signify a dystopian direction for the world, a direction that would only serve to marginalize further the world’s poor and further destroy the environment.

In response, the subaltern counterpublics mobilized together to create a powerful counterdiscourse known as the ‘anti-globalization movement.’ Although anti-globalization protesters have worked against neoliberal globalization, they are not opposed to using the communicative tools that globalization advanced, such as the Internet. The anti-globalizers’ use of this tool demonstrates how “the continuous
movement of people and information feeds a cycle of dissent with far-reaching consequences” and as a result, “paroxysms of public demonstration have intensified in an age of globalization” (Drache, Clifton and Froese). This intensification was evident as the anti-globalization movement’s cycle of dissent came to a climax with the Seattle protests in 1999.

Throughout 1999, … people got plenty of chances to join the anti-WTO campaign. A main rallying point was the StopWTORound distribution list … [which] enabled many to receive detailed information on different aspects of the WTO. The communication was facilitated even more by various sites on the Internet, the umbrella website of the anti-WTO coalition being the most famous … While groups with local ties concentrated on mobilization and direct action, more transnational-based groups provided information and frames to feed the action (Van Aelst and Walgrave 468).

This networking led up to November 30, 1999 and the massive street protest demonstration in front of the Seattle Center where the WTO’s Ministerial Conference was set to take place.

The tens of thousands of protesters and members of NGOs present voiced their concerns regarding the environment, labour issues, consumer protection, and most particularly, free trade. The protesters wanted to take a stand against unfair trade arrangements (such as the inclusion of pharmaceuticals in the TRIPS Agreement) which continued to privilege the interests of industrialized nations and multinational corporations while simultaneously ignoring the needs of developing nations. This
monumental event, etched into the collective memory as the ‘Battle of Seattle,’ was and still is the anti-globalization movement’s signature “icon of dissent.”

These controversial cases involving developing countries and the anti-WTO protests did not go unnoticed. The next WTO ministerial meeting on November 14, 2001, in Doha, Qatar, took into account the claims made against Big Pharma; as a result the discourse around WTO legislation regarding intellectual property rights and access to medicines shifted. The subaltern counterpublics had made themselves heard and the dominant discourse shifted because of it.

**A Reframed Agenda: The Doha Declaration**

The Doha Ministerial Conference was a pivotal event in the WTO’s history for a few different reasons. It was the “first comprehensive negotiating mandate in the global trading system since 1986, it incorporated the most NGO involvement to date, and, finally, the needs and concerns of developing countries seemed to be placed at the forefront of the agenda (Gallagher 100).

In the months leading up to the Conference, it was clear that the WTO wanted to forge better relations with NGOs to avoid another ‘Battle of Seattle.’

The WTO organized presentations by selected NGOs to Members in Geneva, held briefings and workshops with NGOs, established a public discussions forum (still in place) on its website for organized and self-initiated discussion, circulated NGO views and papers to Members and published a monthly bulletin on NGO/WTO contacts and events of interest to NGOs (Gallagher 105).
By encouraging open communication, the WTO not only tried to ensure that NGOs were aware of WTO activities, the organization also attempted to remain informed of any NGO concerns that should be addressed in the preparation process to the upcoming Conference to avoid potential conflicts.

These communication efforts continued throughout the Conference itself. The 365 NGOs present were provided with “office and workshop facilities for conferences including press conferences in an NGO centre adjacent to the main conference centre.” In addition to this, NGOs “were briefed daily by senior WTO officials and by some ministers on the progress of the discussions” (Gallagher 105). With the creation of a better information-loop between NGOs and the WTO, the actors of global civil society were given more agency in the legislative process. They were provided with greater knowledge and more forums through which to voice their opinions – leading to more power to implement change.

In the weeks leading up to the Doha Round, conflicts of interest arose over the interpretation of certain elements of TRIPS. Brazil, Thailand, and African countries among others “sought legally binding language stating that the TRIPS Agreement ‘shall’ be interpreted and implemented to allow compulsory licensing and other public health measures” (Wallach and Woodall 100). These countries wanted to make it clear that countries without the manufacturing capacity to produce drugs under compulsory licence should be able to import the necessary drugs from a country with the capacity to do so. Therefore, the developing nations came together to draft a proposal for their desired interpretations (Option One), and in it, they asked that the language allow for as much flexibility as possible. On the other side of the debate, developed countries such as the
U.S. and Switzerland drafted their own proposal (Option Two). They demanded that the parameters for the use of compulsory licensing be as narrow and restrictive as possible. For example, they wanted to block any country from importing medicines produced under compulsory licences, and they wanted to specify that a compulsory license should only be issued in cases of extreme emergencies and only for HIV/AIDS pandemics (Wallach and Woodall 100). Ultimately the discussions that took place at the Conference resulted in the WTO’s adoption of the Doha Declaration on TRIPS and Public Health.

In light of previous legal cases, like those brought against South Africa and Brazil, the Doha Declaration stressed the importance of:

Implement[ing] and interpret[ing] the TRIPS Agreement in a way that supports public health – by promoting access to existing medicines and the creation of new medicines – and that the TRIPS Agreement does not and should not prevent Member governments from acting to protect public health (Gallagher 102).

Moreover, the Declaration specifically emphasized that circumstances of national emergency should be left to the discretion of each WTO Member-state. In relation to this, the Declaration explicitly talked about how tuberculosis, HIV/AIDS, and malaria would be deemed reasonable grounds for declaring a national emergency. Overall, the general impression was that each Member-state should feel free to use the flexibilities of TRIPS to the fullest extent when deemed necessary – including using compulsory licensing and being “free to establish their own regimes on parallel imports or ‘exhaustion of intellectual property rights’” (Doha Declaration 2001, paragraph 5(d))” (Roffe, Spennemann and von Braun 18).
The Doha Declaration also acknowledged unresolved issues that had not been covered in the TRIPS Agreement, which would need to be addressed in the future. One of the main outstanding issues was that some developing countries lacked the manufacturing capacity to produce their own drugs, therefore in a state of emergency, another country would have to be issued a compulsory licence to produce the necessary drugs for the country in need. Although TRIPS allowed for compulsory licensing, one of the major conditions for its use was that the drugs produced under compulsory licence remain within the domestic market, thus exports under these licences would be prohibited (Gallagher 89). After all the negotiations at the Doha Round, there was no resolution around what the legal boundaries would be for countries unable to produce drugs locally nor what the rights would be in terms of importing compulsory licensed drugs from other countries (Wallach and Woodall 101).

In the absence of a resolution, the Declaration appropriately assigned two tasks to the TRIPS Council. The first was “to find a solution to the problems countries may face in making use of compulsory licensing if they have too little or no pharmaceutical manufacturing capacity”;4 and the second, “to extend, the deadline for least-developed countries [LDCs] to apply provisions on pharmaceutical patents until 1 January 2016”\(^5\) (Gallagher 102).

The Doha Conference was an official turning point for the weak publics and subaltern counterpublics. Not only did they express their needs but also, through legislation, they showed how to protect and advance their interests, ensuring for the

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4 An original deadline for this task was set for December 31, 2002 but a solution was not actually agreed upon until the Geneva WTO Round on August 30, 2003.
5 The original deadline for LDCs to change their patent systems to coincide with the TRIPS agreement was January 1\(^{st}\) 2006.
future that attention must be given to them. Following the Doha Declaration, Oxfam and MSF fought for the expansion of Article 30 in the TRIPS Agreement so that generic drug manufacturers could acquire compulsory licences that would permit them to produce drugs solely for exportation to other countries lacking the capacity to produce the drugs themselves (Loff, MSF press release, 23.11.2002, www.msf.org).

Once again, the calls for expansion were answered by the WTO and the spirit of Doha maintained its momentum. At the WTO General Council meeting in Geneva on August 30, 2003, the Council agreed upon the “Waiver Decision” which waives all restrictions prohibiting the exportation of drugs under compulsory licensing on the condition that the exporting member manufactures only enough drugs to meet the emergency conditions of the importing member. Other conditions actualized in this meeting included permitting LCDs to use the flexibilities of the TRIPS Agreement in regional arrangements so they could take advantage of economies of scale. It was also conceded that Members would no longer be required to get advance authorization for compulsory licence but would only have to “notify their intentions to use the export or import side of the waiver” (Gallagher 113). At this WTO Council meeting, Director-General Supachai Panitchpakdi optimistically stated that, “The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO’s intellectual property rules in order to deal with the diseases that ravage their people” (Gallagher 112). The Doha Declaration and subsequent addendums were significant moves towards placing human interests above the market principles of Big Pharma; however, by no means was the fight over.
The Current Tribulations of TRIPS

For developed countries, the main obligations of TRIPS were mandated to be applied at the beginning of 1996. The deadline for LDCs to conform to the stipulations within the TRIPS Agreement was initially set for January 1, 2006, however, with the Doha Declaration on TRIPS and Public Health, this deadline for pharmaceutical patents was extended to January 1, 2016. The deadline for developing countries and some transition economies to implement patents and data protection of pharmaceuticals in agreement with the TRIPS regulation was January 1, 2000. However, some developing countries had that deadline extended to January 1, 2005 due to a special provision in Article 65.4 of the Agreement. This provision stated that if a developing country did not have a patent protecting a product or technology at the time when TRIPS was officially implemented (in 1995) then that country would have 10 years to do so.

For the transition periods when developing countries and least-developed countries would legislate the implementation of the TRIPS patent rules for pharmaceuticals, the WTO mandated the “mailbox patent system.” Under this system, those wishing to obtain a patent for a pharmaceutical product would put in an application, to be filed and stored. The application will be examined once the transition period is completed.

In March 2005, India amended its 1970 Indian Patents Act in accordance with the 2005 deadline to comply with the TRIPS obligations for pharmaceutical patents. The Indian government made a decisive effort to keep in mind human interests when it chose

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6 A WTO decision on November 30, 2005 extended the deadline in all other areas of the TRIPS Agreement for LDCs to July 1 2015.
7 The transition period for developing countries would be from 1995 to 2000 or 2005 (per Article 65.4).
8 The transition period for LDCs would be from 1995 to 2016.
to allow any generic drug manufacturer that had made a “significant investment” and that was already producing and marketing drugs to continue to do so. The new Act also granted permission to any generic manufacturer that put in an application under a mailbox patent and that ended up getting approval from the Indian government (MSF Article April 21 2005). This was a significant stand since India produces vital medicines to developing nations for keeping diseases and epidemics at bay. In fact, “more than half the medicines now being used for AIDS treatment in developing countries come from India” (Oxfam Press Release February 15, 2007). Another significant amendment was that the “export of medicines produced under compulsory license [would] be possible based on the sole notification by the importing country ... [and] India [would] no longer [require] that a compulsory license be granted in the importing country” (MSF Article April 21 2005). Resistance erupted from pharmaceutical giants like Novartis, Merck and Pfizer which all protested against India’s production and exportation of essential generic medicines to other developing nations.

The crux of the controversy between the Indian government and Big Pharma is India’s use of safeguards that were decided upon in the WTO’s “Waiver Decision” regarding the exporting and importing of essential medicines through the implementation of compulsory licensing. Countries that granted compulsory licenses on AIDS drugs in 2004 include Malaysia, Mozambique, Zambia, and Zimbabwe. The compulsory licences permitted generic manufacturers in India and Africa to produce AIDS drugs without buying the patent rights to do so. These countries have used the provisions of the WTO’s legislation with public health as the top priority, thereby saving millions of lives in the

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9 “India is the world’s biggest producer and exporter of generic medicines to developing countries, particularly in Africa, reaching millions of people.” For instance, “90% of anti-retrovirals used in Zimbabwe’s national treatment program come from India” (Oxfam Press Release February 15, 2007).
process. In a statement prepared for Oxfam in 2006, John le Carré, author of *The Constant Gardener*, states that:

Big Pharma” is dishonouring hard-won international agreements designed to allow lifesaving generic drugs to be produced and marketed in countries where there is urgent and demonstrable need … With unlimited legal resources Novartis is challenging India’s sovereign right under international law to supply cheap, non-patented drugs in situations where the public health is at risk. If the case succeeds, Novartis will have protected the health of its account books at the expense of those who will die because they can’t afford the drugs that could save them (Oxfam Press Release December 12, 2006).

‘TRIPS-plus’ conditions and U.S. Free Trade Agreements

“With developing countries becoming more assertive at the WTO, governments in developed countries have responded by actively encouraging developing countries to sign up to bilateral and regional free trade agreements and investment agreements providing so-called ‘TRIPS plus’ IPR [intellectual property rights] standards in exchange for improved market access” (Dutfield 535). The ‘TRIPS-plus’ protection aims at preventing developing nations from using the safeguards already set in the Agreement to the fullest extent possible. These ‘TRIPS-plus’ conditions include: “extending patents and copyright to new kinds of subject matter; eliminating or narrowing permitted exceptions including those still provided in U.S. and European IPR laws; extending protection terms; introducing new TRIPS-mandated IPR rules earlier than the transition periods allowed by
TRIPS; and ratifying new WIPO [World Intellectual Property Organization] treaties containing TRIPS-plus measures” (Dutfield 535). The United States has successfully negotiated TRIPS-plus conditions into free trade and bilateral agreements with countries such as: Vietnam (2001), Jordan (2001), Singapore (2003), Chile (2003), Australia (2004), Morocco (2004) and DR-CAFTA (Dominican Republic, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua) (2005) (Fink and Reichenmiller 285).

In bilateral agreements with Australia, Jordan, Singapore, and Vietnam, for example, the United States has legislated conditions that “limit the use of compulsory licensing to emergency situations, antitrust remedies [anti-competitive practices], and cases of public noncommercial use [government use]” (Fink and Reichenmiller 286). In the Doha Declaration though, it was clear that WTO Members could implement compulsory licences when necessary for the health of their citizens. The United States further uses the arrangements in these bilateral agreements to discourage the use of compulsory licensing by requiring an “exclusivity of test data.” This means that:

- no competing manufacturer may rely on those data for a period of five years to support a request for approval for its own drug. The compilation of new test data by competing manufacturers may take several years and be prohibitively expensive. For that reason, test-data exclusivity may pose a second obstacle for governments to make effective use of compulsory licensing (Fink and Reichenmiller 287).

Again, the TRIPS Agreements only specified that test data could not be used for “unfair commercial use” (Fink and Reichenmiller 287).
In considering all of these efforts to perpetuate a strong IPR system over pharmaceuticals, there is a wonderful irony when one takes into account the flood of MNCs that are moving their scientific and technical operations to countries like China and India. Since patents will increasingly be awarded to inventors in these developing countries, developed nations like the United States may change their perspective on ‘TRIPS-plus’ conditions and their overall position on IPRs (Dutfield 545).

When the United States experiences marked increases in the proportion of domestic patents being granted to inventors from advanced developing countries like China and India, something which currently seems inevitable, the tide may well turn back to the patent skepticism of yesteryear, especially if in consequence the reliably massive annual trade surplus in royalties and licence fees is converted into a regular deficit (Dutfield 545).

Once the governments of developed countries like the United States look at patents a little differently, they might not align themselves with Big Pharma as closely as they once did. The U.S. government and other developed nations might change their lobbying tactics and actually join in advocating for better access to the very medicines, which they recently tried to block at every opportunity.

“This is OURS”

Big Pharma and its supporters have attempted to appropriate lifesaving knowledge from the Commons for the sake of capital accumulation, and their intention is clear. They are saying: “This is mine.” Fortunately though, there are many unwilling to concede to that.
So long as developed nations (primarily the U.S. government) and multinational pharmaceutical companies (like Novartis, Merck and Pfizer) continue to demand ‘TRIPS-plus’ protection; so long as Big Pharma fails to implement a tiered-pricing policy set according to what people can pay; and so long as R&D funding continues to neglect research into diseases that severely impact poor people in developing countries, NGOs and developing nations will continue the fight to hold Big Pharma to account (Oxfam Press Release November 27, 2007). The fight for access to medicines is by no means over, and therefore, it is important to engage in perspectives and research areas that will further develop and elucidate the questions and issues discussed in this report.

I. Public and Private Partnerships

One area of interest worth investigating further is the many private and public partnerships that have developed from collaborations between the pharmaceutical industry, NGOs, and governments. An early example of such a partnership occurred in 1965 when Wyeth, one of the world’s largest pharmaceutical companies, obtained a patent for its development of the bifurcated needle, which greatly improved the effectiveness of vaccination techniques. Wyeth decided to give the patent to the World Health Organization to assist in smallpox vaccinations forgoing any of the profits from its patent (Foege 387).

A more recent example is the efforts of the William J. Clinton Foundation to negotiate deals with pharmaceutical companies in order to lower the prices of anti-retroviral treatments by thirty to fifty percent. In 2003, The Foundation was able to broker a deal with three Indian pharmaceutical companies (Cipia, Ranbaxy and Matrix) as well as a South African company (Aspen) so that HIV-infected people in thirteen
countries in Sub-Saharan Africa and the Caribbean could get “anti-retroviral drug cocktails for as little as thirty-eight cents per person a day or less than half the price of the most affordable drugs ... available in some of the target countries” (The Economist).

These kinds of partnerships have been beneficial to vaccine production, new drug development, and health delivery programs in developing countries (Foege 390). Writing about the strengths of these partnerships, William H. Foege expresses a desire for this private/public cooperation to branch out even further. One way he suggests might be for corporations to encourage their managers to donate time and expertise to working in the healthcare programs of developing countries. Foege believes this would not only benefit the developing countries but the corporations as well:

If promising managers were expected to spend a year or two working on the improvement of health delivery systems in developing areas, supervising field workers, and developing health training programs, the training component for global health could be strengthened and corporations would have executives with a new understanding of the world” (Foege 391-392).

The rise of these partnerships opens new opportunities for global health governance to recognize how the boundaries between the private and public sectors are being manipulated to provide access to medicines. For the same reason, there are aspects of Big Pharma’s philanthropic involvement that should remain open to scrutiny. For one thing, Big Pharma’s continued emphasis on philanthropic donations to improve access to medicines in developing countries does not amount to the monumental good that would come from larger structural changes within the pharmaceutical industry itself, such as the
implementation of tiered pricing systems. In any case, it is beneficial to research existing private/public collaborations in order to foresee new possibilities for future initiatives as well as to identify areas of concern.

II. Generic Drugs: A Global Powerhouse

A second key research area is the emerging power of the generic drugs industry. The generic industry has a crucial role to play in threatening and combating Big Pharma’s monopoly on patents and the production of pharmaceuticals. To understand the profound impact the generic industry has, we return to India’s pharmaceutical industry. India is known as the “pharmacy of the developing world” because “more than two-thirds of generic medicines exported from India are sold in developing countries at a fraction of the cost of patented brand medicines” (Oxfam, News and Publications, Aug. 6, 2007).

Millions of individuals obtain medicines that they would otherwise not be able to afford under brand-name labels and NGOs have better purchasing power to buy medicines for the healthcare programs that they run because India produces these inexpensive generic medicines. Sandhya Venkateswaran, head of advocacy for CARE International, a humanitarian organization which aims to fight global poverty in India, has said that: “CARE has been able to buy more than twice the amount of anti-retrovirals to treat the HIV and AIDS patients we work with in Peru, thanks to the generic industry in India” (Oxfam, News and Publications, Aug. 6, 2007).

Another example that demonstrates the impact of the generic drug industry is the generic drug company, Apotex, the largest pharmaceutical company in Canada. Apotex has been known to introduce drugs “at-risk” meaning that it introduces drugs on the market before patent litigation has been settled. Apotex released its generic version of
GlaxoSmithKline’s anti-depressant, Paxil in 2003 (Saul). By introducing these drugs “at-risk,” Apotex runs the risk of incurring huge costs if they lose the patent cases brought against them. However, in taking that risk, Apotex partially destabilizes Big Pharma’s monopoly and gets more affordable medicines out to the public faster. A thorough analysis of the relationship and the tensions between the generic drug industry and Big Pharma is crucial to improving our understanding of how the generic market could be manipulated to provide better access to medicines.

III. “Big Pharma” and Global Activism

A third area of future research is the examination of campaigns and initiatives taken by NGOs. This area of activity has been and will continue to be a dynamic catalyst in the fight for access to medicines. Undertaking an in-depth account of the activities of organizations such as Oxfam, MSF and Universities Allied for Essential Medicines, would demonstrate how social activism has made Big Pharma and governments react. From acting as watchdogs of the pharmaceutical industry to lobbying governments with legislative proposals to taking to the streets in protest, the activism of these organizations has proven repeatedly that civil society can take their fight for access to medicines to the front lines and actually cause huge waves of change. Analyzing the different strategies and resulting successes and failures of NGOs and social movements would provide significant research, especially for those organizing future initiatives.

A paradoxical conundrum arises over the question of whether globalization has marked the devolution of power into the hands of the people and away from higher authoritative structures, or whether globalization has facilitated a concentration of power
at higher levels and thus, moved power increasingly out of people’s reach. It would seem that power is in fact moving in both directions.

When looking at the ‘legitimized’ discursive arenas of the global public sphere, such as the WTO, it is important to acknowledge that the dominant discourses and agendas these arenas produce are often the work of a select few, privileged players who get to write global rules for the rest of us. Because multinational corporations and developed countries have accumulated more sway in these institutionalized spaces, they have been able to exercise greater power in bending international laws and norms, and in turn, they govern the economic integration and the communication flows of globalization to suit their interests. However, just as these groups develop ways to harness the new technologies and processes of globalization in their favour, so too do the groups who rise up to challenge the “powers that be.”

The message to take from this is that it is possible. Agendas are set by the dominant discourses of the “powers that be” such as Big Pharma, the United States government, and/or the WTO, but it is possible to challenge those agendas and the rules. What’s more, now more than ever before, it is possible to change those rules, and this presents exciting opportunities for agency in the geopolitical landscape of power. There is a multiplicity of publics in the global public sphere, and the stronger publics are beginning to confront the fact that the subaltern power is a force to reckon with. The counter-discourses constructed by subaltern counterpublics have ensured that the needs of the marginalized weaker publics do not remain neglected. This report has revealed that from the birth of TRIPS to its rebirth in the Doha Declaration on TRIPS and Public Health, subaltern actions have infiltrated dominant agendas, effectively changing them.
When these subaltern counterpublics fight against an intellectual property rights system that operates to inhibit medicines from reaching those in dire need of it, they are reconceptualizing the laws that are supposed to balance private property and the needs of the common good and fighting to reclaim lifesaving knowledge from the global Commons. Stated in even more foundational principles, when fighting for access to essential medicines, this subaltern power fights for the right to health and fundamentally, the right to life. They are saying, “This is OURS and we have the right to claim it.” And, their experience shows that it is possible to do so.
Appendix I: The TRIPS Agreement

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement was agreed upon on January 1, 1994 during the World Trade Organization’s (WTO) Uruguay Round and took effect January 1, 1995. The Agreement provides an international regulatory framework for intellectual property rights which all WTO members are obliged to follow. It includes matters relating to: copyright, trademarks, geographical indications, industrial designs, patents, layout designs of integrated circuits and trade secrets.

As explicitly stated on the WTO’s official website, TRIPS outlines:

- “how basic principles of the trading system and other international intellectual property agreements should be applied”
- “how to give adequate protection to intellectual property rights”
- “how countries should enforce those rights adequately in their own territories”
- “how to settle disputes on intellectual property between members of the WTO”
- “special transitional arrangements during the period when the new system is being introduced.”

TRIPS Agreement and Controversy of Access to Medicines

The WTO’s decision to include pharmaceutical processes and products in the international rules set by the TRIPS Agreement was and still remains a highly disputed topic. Humanitarian organizations like Oxfam and MSF argue that having a rigid international system that standardizes the implementation of pharmaceutical patents can be detrimental to developing nations which should be able to structure their own systems to allow for as much access to essential medicines as possible for their citizens. Big Pharma enthusiasts, on the other hand, argue for a stronger protection of drug patents to ensure that innovation is stimulated and to ensure that more funds can be put towards the research and development of drugs.
Appendix II: Glossary of Relevant TRIPS Terms

*Anti-competitive practices*

A patent owner’s monopoly of a patented product or process might be superseded in cases where the owner is partaking in anti-competitive practices meaning that the intellectual property right is being used in a way that inhibits competition and obstructs trade or technology transfer.

*“Bolar” or “Regulatory” Provision*

This provision employed when governments want to allow generic drug manufacturers to use a patented product before the patent has expired so that they can get marketing approval from the necessary authorities. This enables generic manufacturers to release their generic version of the drug on the market as soon as the patent licence expires.

*Compulsory licensing*

A compulsory licence enables a third party to use a patent without getting permission from the patent owner. A government can use this compulsory licence to give a government agency or a private company the right to produce drugs under a generic label.

*Generic*

The term generic signifies when a patented product is copied by another manufacturer and then is sold under the name of the chemical ingredient or under another brand-name label.
Mailbox Patents System

Under the “mailbox patent system”, those wishing to obtain a patent for a pharmaceutical product must put in an application, which is then filed and stored and does not need to be examined until after the transition period is completed. A pharmaceutical product under a mailbox patent could be granted “exclusive marketing rights ... for five years or until the patent is granted or rejected, whichever is shorter” (Fink 190).

Parallel Importation

Parallel importation means that companies can import the cheapest-priced drug from another country where a patent exists which can effectively drive down the prices of pharmaceuticals. To better illustrate how parallel importation operates, here is an example that the WTO uses on its official website:

“For example, suppose company A has a drug patented in the Republic of Belladonna and the Kingdom of Calamine, which it sells at a lower price in Calamine. If a second company buys the drug in Calamine and imports it into Belladonna at a price that is lower than company A’s price, that would be a parallel or grey import.”

Patents

A patent is the legal means through which a new invention (i.e. a drug) or new piece of information (i.e. the chemical process to create a new drug) is prohibited from being made, used, or sold by any party other than the patent owner. The TRIPS Agreement ensures that patent owners have their product or process protected for 20 years from the date the patent application is filed. There are, however, exceptions to the rights of patent holders which are specified in the TRIPS Agreement. These exceptions include: the research exception, the “Bolar” exception, cases of national emergency; the need to
correct anti-competitive practices; and non-commercial use (government use which
would include the use of compulsory licensing).

*Research exception*

Countries will implement this exception so that researchers can use a patented invention
to understand it better for the purposes of advancing science and technology.

For more information on any of these concepts and terms, please follow this link to the
WTO’s official website where all of the sections of the TRIPS agreement are described in
detail: [www.wto.org](http://www.wto.org)
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About the Author

Karen is in her second year of Ryerson and York Universities’ joint Master’s program in Communications and Culture. Prior to starting this program, she attended the University of Western Ontario and obtained her undergraduate degree in the Media, Information and Technoculture program. Her academic path has cultivated her current research interests in the interplay of political economy, corporate dominance, social movements, and development on the global stage.

Her hope for this report is that in adding to an ever-growing body of knowledge and information, the ideas and issues discussed throughout this report will serve as a launching pad for others to take up further areas of research on this topic. After all, two minds are better than one and three minds are better than two, and so on and so forth.

Please feel free to send any comments to kforhan@ryerson.ca.