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From Trips to ACTA: Establishing the Intent to Uphold Access to Medicine in the Face of Ambiguity

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Introduction

The numbers speak for themselves. Each year, over 9.5 million people die due to infectious diseases for which there exists medication – most live in developing countries.[i] Currently, there are over 33 million people around the world living with HIV/AIDS,[ii] 70 percent of whom are in dire need of anti-retroviral medication but not receiving it.[iii] This has been attributed, in part, to the lack of affordable healthcare in developing countries, along with the high drug prices associated with monopolies provided by pharmaceutical patents.[iv]

Studies demonstrate that there is a significant change in the price of a drug once its patent expires, allowing its generic version to be legally manufactured and introduced into a given market.[v] The introduction of a generic drug often results in the reduction of prices anywhere between 22% and 88%, depending on the type of drug and the number of generic manufacturers producing it.[vi] In some instances, even the *threat* of introducing a generic drug into a market will be enough to significantly lower the price of its patented version.[vii] For this reason, it is in the best financial interest of pharmaceutical companies to acquire and maintain the highest levels of intellectual property rights ("IPR") protection on their patents. In furtherance of that objective, pharmaceutical companies have actively engaged in campaigns, both domestically and around the world, aimed at preventing generic manufacturers from accessing global drug markets.[viii] Unfortunately, this comes at a high cost to patients who are in need of treatment and cannot afford the patented versions of these medicines. This paper will address this concern by explaining how the pursuit of high levels of IPR protection has exacerbated the inaccessibility of medication by keeping more affordable, generic drugs off the market.[ix] This has been largely possible due to a narrow application of the Trade Related Aspects of Intellectual Property Rights Agreement ("TRIPS Agreement"), as well as efforts to establish the highest possible levels of IPR protection, led mainly by industrialized nations.

The first section of this paper will provide an introduction to the TRIPS framework as well as a timeline of international events leading to the Doha Declaration on the TRIPS Agreement and Public Health ("Doha Declaration"). This was a declaration by all members of the TRIPS Agreement reaffirming their obligation to protect public health through the use of provisions referred to as "TRIPS flexibilities." The second section explains that despite the Doha Declaration, certain TRIPS

flexibilities have been undermined through the implementation of bilateral trade agreements with developing countries, and regulations within regional trading blocs providing vigorous protection of IPRs.[x] These trade agreements and regulations contain “TRIPS-Plus” provisions demanding higher levels of IPR protection than those required by the TRIPS Agreement itself.[xi] In essence, they have been seen as attempts to circumvent the obligations agreed to during the Doha Declaration, acknowledging that public health issues take precedent over IPRs. The third section of this paper introduces the Anti-Counterfeiting Trade Agreement (ACTA) recently negotiated by the world's most industrialized nations, and presents the arguments raised in opposition to the accord. Many have argued that due to the special interests behind ACTA's negotiating countries, this agreement will have a detrimental impact on developing countries, as they will be forced to adopt a framework of heightened IP standards to which they did not explicitly assent.[xii] The last section argues that despite the clear threats posed by ACTA, negotiating countries have expressed a clear intent to uphold access to medicine principles as asserted in the Doha Declaration. However, because many of the ACTA negotiations have been held behind closed doors, there is no record that reflects this intent outside of the public statements made by country representatives. The section proposes creating an unofficial drafting history for ACTA based on amendments made to various drafts of the text as well as public statements released by the parties. This drafting history will provide assistance when interpreting any ambiguity within ACTA that may be used to impede access to medicine or undermine any of the obligations made under the Doha Declaration.

I. The implementation of TRIPS and the resulting need for the Doha Declaration on public health

A. The Development of the TRIPS Agreement

During the 1980s, a number of corporate actors mobilized together after realizing that they shared the common goal of increasing the protection of their intellectual property rights.[xiii] This alliance was comprised of trans-national corporations from a variety of sectors, among them agricultural chemical producers, software producers, entertainment providers, and brand-name pharmaceutical providers.[xiv] After successfully lobbying their interests at a domestic level, these actors began seeking a way to further expand the protection of their interests by pursuing higher levels of IPR protection outside the United States.[xv] They did so by creating a strategy to link IP with trade, two areas of law which until then, were vastly unrelated. In addition, this interest group also formed strong political ties within the U.S. and gained considerable support with the U.S. government, particularly the Office of the US Trade Representative.[xvi] Through transnational mobilization and aggressive lobbying of various governments, international organizations and private sectors, this coalition managed to include its newly formulated trade-based IP regime in the agenda for the GATT’s Uruguay Round of Multilateral Trade Negotiations (“Uruguay Round”) held in 1995.[xvii]

During the Uruguay Round, the United States persistently promoted the adoption of a new global intellectual property regime.[xviii] Some scholars have noted that many countries assented to the TRIPS Agreement in hopes that a multi-lateral rule based system would eliminate the US’ coercive economic policy.[xix] As a result, many developing countries were at a disadvantage during TRIPS Agreement negotiations due to the asymmetry in bargaining power vis-à-vis more industrialized countries. Furthermore, developing countries were at an additional disadvantage because their negotiators lacked the necessary training in the area of intellectual property essential to negotiating a new set of IP standards.[xx] Daniel Gervais explains that as a result, industrialized countries made very few concessions during the negotiations while developing countries were “forced to accept a package that they perhaps did not fully understand and yet, contained a set of foreign IP norms which they now had to implement.”[xxi] This Uruguay Round of negotiations resulted in what is known today as the Trade-Related Aspects of Intellectual Property Rights Agreement- adopted and put into force in 1994.[xxii]

The TRIPS Agreement was an effort to implement a global intellectual property rights regime and establish what industrialized countries believed should be the minimum levels of IPR protection required of all countries before acceding as members of the WTO.[xxiii] As a result, the TRIPS Agreement obligated developing nations to enforce levels of IPR protection similar to those adopted by highly industrialized nations, despite the lack of development in their own domestic IP laws.[xxiv] Included as part of the TRIPS Agreement were provisions requiring a 20-year term of protection for patented medication, which pharmaceutical companies argued were necessary to sustain innovation and fund research and development for future pharmaceutical products.[xxv] Along with these higher levels of protection, however, came huge impediments to the accessibility of essential medication in developing nations.

B. Access to Medicine Consequences

The implementation of the TRIPS Agreement provided pharmaceutical companies with a legal and effective monopoly over their products due to the period of protection granted to their products before the introduction of any generic competitors.[xxvi] This meant that name-brand pharmaceutical companies were able to maintain high drug prices so long as they were still under the 20-year patent protecting their products. Within developing countries, however, this additional term of patent protection ultimately resulted in the overall reduction of affordable medicine.

This monopoly over medicines and prices proved to be devastating during the late 1990s when the HIV/AIDS epidemic was reaching its peak.[xxvii] It was at this point that developing countries realized the extent of the serious access to medicine implications that accompanied the adoption of the TRIPS Agreement. Developing countries, particularly South Africa, took initiatives to address the crisis by providing low-cost medication to its citizens and by issuing compulsory licenses for anti-retroviral HIV/AIDS medication.[xxviii] These efforts were met with fierce resistance from pharmaceutical companies and retaliation in the form of a lawsuit by the U.S. government.[xxix] The outcome was a wave of public outrage and widespread protests against the U.S. and pharmaceutical companies, largely led by developing countries, civil activists, and international organizations.[xxx] Due to mounting international pressure, the U.S. government eventually caved, withdrawing the lawsuit against South Africa as well as the trade sanctions previously implemented against it.[xxxi] At this point, it became clear that there was a much-needed reassessment of the objectives and interpretation of the TRIPS Agreement.

C. A Call for the Doha Declaration on the TRIPS Agreement and Public Health

In an effort to address the public health concerns resulting from the implementation of the TRIPS Agreement, the WTO introduced a “development round” in 2001 known as the Doha Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”).[xxxii] During this round, members of the WTO unanimously recognized the need of developing countries to address serious public health issues such as HIV/AIDS, tuberculosis, malaria and other epidemics.[xxxiii] The Doha Declaration thus stands for the assertion that the TRIPS Agreement should not prevent any WTO member from taking measures to protect the health of its citizens. In doing so, the Declaration reaffirmed each member’s right to use the safeguards within the TRIPS Agreement without risking retaliation from other WTO members.[xxxiv] Specifically, the Doha Declaration reaffirmed a member’s right to parallel import medication under Article 6 of the TRIPS Agreement, and issue compulsory licenses under Article 31.[xxxv]

Parallel Imports

Article 6 of the TRIPS Agreement provides WTO members with the right to import patented drugs after they have been sold in other markets.[xxxvi] This provision essentially allows WTO members to

import brand-name drugs from other countries where it is being sold at a lower retail price.[xxxvii] This means that once a brand-name drug is legally sold in one country, the patent holder "exhausts" his rights over the product, at which point the drug may be re-sold and exported to other countries.[xxxviii] This TRIPS flexibility thus provides developing countries the option to purchase medicine from foreign markets where it is being sold at a lower price than within its own domestic market. By taking advantage of this flexibility, developing countries with limited healthcare resources are able to import cheaper medicine, thereby increasing its affordability and overall access to its citizens.

Compulsory Licensing

Another safeguard reaffirmed during the Doha Declaration is a country's right to issue compulsory licenses in cases of national emergencies, granted through Article 31 of the TRIPS Agreement.[xxxix] Article 31 allows a country to license the manufacturing of a generic drug while its brand-name version is still under patent without the express consent of the patent holder.[xl] Compulsory licenses have proven to be one of the most effective tools for providing life-saving drugs, such as anti-retroviral medication, to patients in developing countries, particularly within Africa.[xli] They have led to greater competition in the drug market by allowing generic drugs to compete with patented pharmaceutical products, driving down its overall cost.[xlii] This leads to more affordable prices for both citizens *and* governments providing healthcare services in the country where it is issued. The issuance of compulsory licenses have proved so effective in reducing drugs costs that even the mere *threat* of issuing one will often compel pharmaceutical companies to drastically reduce their prices in an effort to keep generic manufacturers off the market.[xliii]

The use of TRIPS flexibilities such as the two discussed above have been praised and strongly encouraged by non-profit organizations and civil society groups working to promote access to medicine in developing countries.[xliv] Despite the progress made, however, there is growing concern that these efforts have been undermined through pressure from bilateral and regional trade agreements, domestic legislation, and new forms of multilateral agreements such as ACTA.

II. Circumventing the Doha Declaration Through TRIPS-Plus Agendas

The TRIPS Agreement succeeded in implementing a new global regime of heightened standards of intellectual property right protection. However, it also left room for countries to implement measures to protect the public health of its citizens through provisions known as "TRIPS flexibilities."[xlv] Through TRIPS flexibilities, governments are free to address issues arising from the lack of innovation for diseases affecting their populations, coupled with high pharmaceutical prices and restrictions on availability.[xlvi] Despite these flexibilities though, recent free trade agreements (FTA) between developed and developing countries, particularly those with the US, have been criticized for restricting the adoption of these TRIPS flexibilities.[xlvii] By including "TRIPS-Plus" provisions into their FTAs, developed nations have narrowed the application of TRIPS flexibilities, thereby posing dangers to the production and availability of medicines in developing countries. More recently, regional trading blocs, such as the EU, have similarly begun to draw criticism due to the inclusion and strict enforcement of TRIPS-Plus measures within its borders.

A. TRIPS-Plus Obligations in Free Trade Agreements

Since the Doha Declaration and the reinforcement of TRIPS flexibilities, several industrialized countries have continued to vigorously represent the commercial interest of pharmaceutical companies in trade negotiations with developing countries.[xlviii] By using access to their markets as a form of inducement, developed countries have been able to secure higher levels of IPR protection, known also as "TRIPS-Plus" measures, through trade agreements.[xlix] As reported by Oxfam

International, some FTAs have contained TRIPS-Plus provisions providing for the following increased protection:

- Expanded scope over pharmaceutical patents (covering new therapeutic uses of *existing* medicines and formulations);
- Limitations on the grounds for issuing compulsory licenses to highly restrictive emergencies, government non-commercial use, and competition cases;
- Barring parallel imports of patented medicines sold more cheaply elsewhere;
- Extending patent monopolies for administrative delays by patent offices and drug regulatory authorities.[l]

In a report prepared for House Representative Henry Waxman in 2005, the Committee on Government Reform declared that "[C]ontrary to the Doha Declaration, U.S. trade negotiators have repeatedly used trade agreements to restrict the ability of developing nations to acquire medicines at affordable prices."[li] Although Congress requires that the U.S. Trade Representative ("USTR") comply with the Doha Declaration on Public Health, nearly every free trade agreement negotiated in the past decade by USTR has included TRIPS-Plus provisions significantly restricting the manufacturing of generic drugs.[lii] In addition, the USTR has previously announced its TRIPS-Plus agenda as well as a commitment to pursue levels of IPR protection in accordance with those of the pharmaceutical industry.[liii] Oxfam International asserts that this commitment to higher standards of IPR protection can be explained by the close relationship between the USTR and the pharmaceutical industry within the U.S.[liv]

Special 301 Watch List

One effective tool that the U.S. has used to enforce the TRIP-Plus provisions within its FTAs is the Special 301 Watch List ("Special 301").[lv] The Special 301 is a report mandated by the U.S. Trade Act of 1974 through which the USTR assesses whether countries are complying with IPR standards contained in bilateral or multi-lateral agreements with the U.S.[lvi] If the USTR finds that a country is not in compliance with such standards, it sends a "warning" through the Special 301 Report threatening to impose trade sanctions pursuant to the U.S. Trade Act.[lvii] Oxfam International argues that the U.S. has used the Special 301 process to pressure countries into unilaterally implementing TRIPS-Plus provisions.[lviii] In addition, the Government Accountability Office has noted that while the overall number of countries listed on the Special 301 has decreased, the number of countries cited for pharmaceutical-related issues has increased.[lix] One example of this, sparking controversy among various members of Congress, was the placement of Thailand on the Special 301 Watch List for having issued a compulsory license for HIV/AIDS medication in 2006.[lx]

After this incident sparked international attention, however, Congress took it upon itself to adjust the USTR's attitude on how it proceeded to negotiate bilateral trade agreements.[lxi] Since then, the USTR has made significant concessions by providing greater flexibility to provisions that at one point may have impeded access to medicine in developing countries.[lxii] These efforts have been reflected in amendments made to the US-Colombia and US-South Korea FTAs, making them more amenable to the adoption of TRIPS flexibilities.[lxiii]

B. TRIPS-Plus Obligations in Regional Agreements: The Case of EU Council

Regulation 1383/2003

In addition to TRIPS-Plus obligations contained in FTAs, some industrialized nations have enacted far-reaching TRIPS-Plus measures as part of their domestic legislation. As noted by the International Centre for Trade and Sustainable Development (ICTSD), the European Union (EU) has been particularly active in vigorously enforcing "maximalistic" standards of IPRs within its own region.[lxiv] To illustrate, the EU implemented Council Regulation 1383/2003, which involves the searches, seizures, and destruction of goods suspected of infringing intellectual property rights by customs officials throughout its borders.[lxv] This regulation explicitly grants IP right holders the ability to prohibit the import or export of goods suspected of infringing patents, copyrights, and trademarks to and from the EU.[lxvi] Because this regulation is directed at all imports and exports, it has been greatly criticized by advocacy groups concerned with access to medicine due to its obstruction to the transit of pharmaceutical goods passing through EU territory.[lxvii] In doing so, EC 1383/2003 comes into conflict with Article V of the GATT, which establishes the principle of freedom of transit through the territory of each contracting party.[lxviii] The regulation also conflicts with the obligations to public health undertaken by all WTO members under the Doha Declaration.

In particular, the implementation of EC 1383/2003 has resulted in several detentions of shipments of generic medication that did not meet the heightened IP standards within the EU, but were otherwise legal in their importing and exporting countries.[lxix] This incident sparked widespread controversy as most of the shipments were traveling from India and destined to developing countries – such as Mexico, Brazil, Nigeria, Peru, Colombia and Ecuador – and only briefly traveling through the EU.[lxx] While most of the shipments were only temporarily seized, some of them were in fact destroyed for not complying with IPR standards within the EU, pursuant to EC 1383/2003.[lxxi] The EU defended its actions as an unfortunate result of the MEDI-FAKE initiative, which targets illegal counterfeit medicines entering the EU.[lxxii] Still, critics argue that these detentions, all involving generic medication, were neither incidental nor accidental, but were rather opportunistic acts of IPR holders in an effort to obstruct generic competition through false counterfeiting allegations.[lxxiii] Whichever may be the case, these incidents demonstrate EU officials generalized the use of the term “counterfeit,” thereby implicating other forms of IP infringements having nothing to do with counterfeiting (such as patent violations). The EU seizures have resulted in a great deal of debate over the consequences that EC 1383/2003 (and similar policy) has on freedom of transit principles and on the overall impeding effect it can have on access to medicine. This brings us to ACTA.

III. The Anti-Counterfeiting Trade Agreement

The Anti-Counterfeiting Trade Agreement ("ACTA") is a multilateral agreement currently being negotiated between the world's most industrialized nations,[lxxiv] and aimed at combating counterfeit goods.[lxxv] It represents one of the most important attempts to negotiate a “North to North” agreement on issues of intellectual property rights protection after the TRIPS Agreement. For this reason, ACTA is seen by critics as an attempt to create a new template of TRIPS-plus protection outside any interference from developing countries, multilateral organizations, or civil society in general. Parties to these negotiations assert, however, that the objectives behind the implementation of ACTA are to "establish an international framework for participating governments to more effectively combat the proliferation of counterfeiting and piracy" and to "define effective procedures for enforcing *existing* intellectual property rights."[lxxvi]

To many of its critics though, ACTA reflects a fairly clear intent to expand TRIPS standards and even remove some of its flexibilities.[lxxvii] In particular, ACTA has been criticized by civil society groups and developing countries for threatening the freedom of transit of generic medicines. India and China are some of ACTA's most vocal opponents; they argue that such measures do not take

into consideration the interests of developing countries or their commitments to the Doha Declaration on Public Health.[lxxviii] These countries also warn that ACTA would create trade restrictions for WTO members who are not negotiating parties of ACTA, yet who are still subjected to obligations beyond those required by the TRIPS Agreement.[lxxix]

The criticism over ACTA has not stopped there. Other institutions that have taken issue with ACTA have included the World Trade Organization and the World Intellectual Property Organization. These organizations argue that ACTA goes far beyond what was needed to combat counterfeiting and piracy, and in the process, is creating a new regime of IPR protection that will undermine multilateral institutions such as themselves by weakening their authority.[lxxx]

A. *Access to Medicine Threats Posed by ACTA*

The most serious concern raised by access to medicine advocates is that like EC 1382/2003, ACTA will jeopardize shipments of affordable medicines in transit between developing countries, having a chilling effect on the trade of generic pharmaceuticals and on the TRIPS Agreement flexibilities.[lxxxi] This problem has been mostly raised with regard to proposed border measures granting customs officials the ability to restrict shipments being imported or exported from ACTA member countries. This measure has been highly criticized for essentially requiring customs officials to make highly specialized and technical determinations as to what amounts to patent infringements.[lxxxii] These complex adjudications, critics say, should follow after the presentation of highly specific facts related to patents, which may only be resolved by an appropriate panel or tribunal post hoc, not while the goods are in transit.[lxxxiii]

Under existing TRIPS provisions, border measures are to be taken only against suspected counterfeit, trademark, and copyright violations.[lxxxiv] Customs officials are allowed to take ex officio action against alleged infringers *only after* they have acquired prima facie evidence showing that an IP right has been infringed.[lxxxv] In addition, TRIPS requires those who requested the ex officio action to pay for any injury caused to suspected infringers as a result of a wrongful detention of goods.[lxxxvi] ACTA, on the other hand, permits such actions to be taken on the mere *suspicion* that the goods are infringing not only copyright and trademark, but also patent rights. Furthermore, ACTA indemnifies authorities from any injury caused by the wrongful detention of goods, which may last for up to a year under this new agreement.[lxxxvii] This creates incentives for right holders to abuse ACTA procedures and to initiate border investigations and seizures without having to prove, within any reasonable period of time, that the goods are in fact infringing. This leaves serious implications relating to the transit of shipments carrying generic medication.

In addition, provisions addressing penalties for ACTA violations vis-à-vis the penalties enforced under the TRIPS Agreement have similarly raised serious concerns.[lxxxviii] Under the TRIPS Agreement, any willful, commercial-scale counterfeiting is a criminal act sanctioned by national law enforcement.[lxxxix] In contrast, civil IP infringements under TRIPS, including violations of patent rights, consist of commercial disputes between legitimate entities and are compensable only through legal remedies.[xc] The reason for this distinction is that unlike counterfeiting, civil infringements of IPRs are not seen as attempts to defraud the public and are therefore not subject to the same criminal sanctions.[xci] While TRIPS has made it clear what types of infringements will result in criminal and civil liability, ACTA does not distinguish between the two.[xcii] This leaves the inference that because ACTA explicitly targets counterfeits, all infringements will be punishable as criminal violations.

Furthermore, various ACTA drafts have included provisions extending injunctions against third parties who have provided "intermediary services" that have facilitated the infringement involved.[xciii] While ACTA fails to define what an "intermediary party" is, those who would likely be affected under this

provision include generic drug manufacturers, international shippers, and other key players involved in the international trade of medicines.[xciv] In turn, such injunctions could potentially "inhibit the supply and distribution systems and thereby deter generic entry, robust generic competition, and legitimate international trade of generic medicines of assured quality."[xcv] Due to its failure to define "intermediary," this provision may similarly jeopardize non-government organizations such as Medicins Sans Frontieres and UNITAID, who assist in funding the purchase of generic drugs destined for developing countries.[xcvi]

The unfortunate result of these ACTA provisions is that they have a potentially chilling effect on the production, trade, and ultimate distribution of generic drugs. Due to the risk of incurring not only civil, but *criminal* liability, many generic drug manufacturers and third-party carriers will potentially be deterred from producing and transporting medication because of the blurred distinctions between counterfeit and simple patent infringements.

B. New IP Law-Making in the Process?

A number of scholars have argued that ACTA is an effort to seek an alternative forum that is more responsive to higher levels of IP protection.[xcvii] As part of this forum-shifting argument, Susan Sell notes that protectionists have previously shifted their agenda from the World Intellectual Property Organization ("WIPO") to the World Trade Organization (through the TRIPS Agreement), to bilateral and regional trade agreements (such as those discussed above), and now to ACTA.[xcviii] Each time the chosen forum becomes more receptive to exceptions, likely due to pressure from civil society groups, the forum once again changes. Thus, ACTA is seen as the creation of an entirely new international institution for IP enforcement, establishing its own set of rules, standards, and methods of enforcement, notwithstanding those outlined in prior multilateral negotiations such as the TRIPS Agreement.

However, other scholars argue that ACTA is more than a mere effort aimed at shifting the forum of protection. Instead, they assert that such attempts reflect a broader notion of international IP law-making in the process.[xcix] This argument is based on the impact which bilateral trade agreements tend to have on a country's position on IP standards during subsequent multilateral negotiations. These scholars argue that this is all part of a strategy to create an endless upward spiral of international IP obligations.[c] This movement, often referred to as the "global IP ratchet," is only the first stage of a conscious effort on the part of IP interest groups to use bilateral agreements as vehicles to incorporate heightened IP standards into subsequent multilateral treaties, such as ACTA.[ci] Targeting countries on a one-on-one basis through bilateral agreements ensures that they are on-board with future stated agendas. Scholars argue that in the end, if enough of these bilateral agreements are negotiated, these higher IP standards will become the minimum standards from which future trade negotiations will proceed.[cii] As cited by Kimberlee Weatherall:

"Once a substantial portion of trading partners have agreed to observe the same standards as those enshrined in present U.S./EU legislation, there is no way back to a meaningful lessening of what appear as widely accepted rules, creating a spiral endlessly moving upwards." [ciii]

That is to say, that all of this is not merely about shifting the forum away from the WTO, but rather, a part of an overall scheme to slowly, but certainly, increase global levels of protection for IP right holders. Weatherall suggests that bilateral agreements have ultimately served as the "stepping stones" for ACTA by setting minimum standards of IP protection among the parties involved, while creating leverage for certain countries at the negotiating table.[civ] As reflected by the leaked ACTA drafts, these higher levels of IP protection were, without a doubt, introduced during the various rounds of negotiation.[cv]

Along these lines, ACTA is seen as part of a larger "enforcement agenda" being pushed by special interest groups within highly industrialized nations. This enforcement agenda has been described as, "[A] continuous, wide-ranging effort by special-interest groups and lobbyists to secure favorable legislation and institutionalize practices that support their current business models, all under the claim of enforcing intellectual property rights."[cvi] Ultimately, what emerges is "[A] web of numerous forums, regional, and bilateral agreements and unilateral institutions, all being captured to pursue a global TRIPS-plus agenda."[cvii] The unfortunate consequence of this agenda is that because it caters to special interest groups, it fails to consider the disproportionate impact that these higher standards carry for developing countries lacking the resources and infrastructure to implement them. Nonetheless, many fear that such standards will soon become the norm as more and more countries continue to adopt them through efforts such as ACTA.[cviii]

IV. ACTA's Unofficial Drafting History: Establishing An Intent to Promote Access to Medicine

Despite the concerns stated above, recent leaked drafts of the text have indicated that ACTA has amended some of the measures that have been stirring controversy with access to medicine advocates.[cix] The two most significant of these are provisions on border measures and intermediary liability.[cx] According to the new draft, ACTA no longer requires countries to provide preemptive border measures for patents, meaning that if adopted, generic medicines will no longer be subject to border detentions for alleged patent violations.[cxi] In addition to this, ACTA parties have dropped the provision requiring intermediary liability for carriers of shipments of generic medication. The new draft reflects that the parties have made significant concessions in response to public health concerns, resulting in what some have referred to as “ACTA-Lite,” a watered down version of what ACTA was intended to be.[cxii]

Aside from demonstrating the tremendous impact that civil society groups can bring to the negotiating table, this move indicates that there is at least some commitment to preserve the safeguards and flexibilities established by the TRIPS Agreement. To demonstrate this commitment, many governments have released public statements ensuring that the passage of ACTA will not affect a country's right to provide for the public health of its citizens.[cxiii] In a joint statement issued by the participating governments with respect to the potential obstruction to access to medication, the parties stated that, "ACTA will not hinder the cross-border transit of legitimate generic medicines," while reaffirming that “patents will not be covered in the section on Border Measures."[cxiv]

USTR officials released similar statements after certain members of Congress voiced concern over the ways in which ACTA would affect the availability of generic medicine. In a letter from Senator Ron Wyden to the USTR regarding ACTA’s impact, one of his main questions involved the ways in which ACTA would preserve the public health flexibilities under the TRIPS Agreement and the Doha Declaration.[cxv] In its response, the USTR stated that “ACTA is not intended to interfere with a signatory’s ability to respect its citizens’ fundamental rights and civil liberties, *and will be consistent with the WTO TRIPS Agreement and will respect the Declaration on TRIPS and Public Health*. (emphasis added).”[cxvi] From these comments, it would therefore appear that the overall purpose of ACTA is not to limit the transit, sale, or distribution of generic medicine. Nonetheless, while this intent has been reflected through a number of press releases, likely aimed at bolstering public support, there is no record of negotiation binding the parties to this intent.

The importance of legislative history within the context of multilateral negotiations is that it establishes the parties’ intent at the time of negotiation, giving the text meaning in light of potential ambiguity. However, in the case of ACTA, there is no such record of negotiations as these have been highly secretive and mostly held behind closed doors.[cxvii] As a result, the only evidence of the parties'

actual negotiating intent comes from inferences that have been drawn from the modifications made to several leaked versions of the agreement.[cxviii] This paper suggests that based on these modifications, there be an unofficial "drafting history" established, reflecting a principle of intent aimed at upholding access to medicine. This legislative history would be a compilation of the parties' stated objectives to the press, civil society, members of Congress and Parliament, and other government officials regarding the purpose of ACTA. These statements should be analyzed with respect to the various proposals for modification made by each respective party, as reflected by the leaked versions of the agreement. Furthermore, such a drafting history will require close scrutiny of prior versions of the text in comparison with its final version (to be released in the following weeks) in order to determine whether the parties did in fact bind themselves to their publicly stated objectives. Such an analysis will also allow scholars to draw inferences from the various amendments proposed and those that were actually adopted, such as the changes to border measures discussed above. Functionally, this drafting history will serve to provide guidance to officials whenever there may be ambiguity in the text, by establishing a principle that such ambiguity shall be read in light of the parties' intent to provide for the unrestricted transit of generic medication.

V. CONCLUSION

Due to legitimate concerns that ACTA may be creating a new institutional framework of IP standards, it is vital that parties clearly define the limits of this new agreement. As we have seen with the cases of EU detentions, there is a genuine fear that heightened IP standards may have serious restrictions on the transit and ultimate distribution of generic medication within developing countries. For this reason, there is a need to clearly and effectively communicate that parties do not intend for this to be the case with the implementation of ACTA. Through publicly released statements, leaked drafts, and new amendments made to the agreement, it appears that the parties to ACTA have made active efforts to communicate that they do not intend to impede the flow of generic medication. However, there is still a need to bind parties to this principle through a more formal manifestation of this commitment.

i *Global Health Council,* Impact of Infectious Diseases. Available from: http://www.globalhealth.org/infectious_diseases (citing World Health Organization, *WHO Global Burden of Disease: 2004 Update*).

ii World Health Organization, *Global Summary of Aids Epidemic: 2009*. Available from: http://www.who.int/hiv/data/2009_global_summary.png.

iii Medicines Sans Frontiers, *Running In Place: Too Many Patients Still in Urgent Need of HIV/AIDS Treatment*, Briefing Document on HIV/AIDS. Available from: http://www.msfaccess.org/main/hiv-aids/introduction-to-hivaids/msf-and-hivaids.

iv *See Generally,* Bryan C. Mercurio, *TRIPS, Patents, and Access to Life-Saving Drugs in the Developing World*, Marquette Intellectual Property Law Review 211 (Summer 2004).

v *Id*.

vi *Id*.

vii *Id*.

viii *Id*.

ix Oxfam Briefing Paper, *Patents versus Patients: Five Years after the Doha Declaration*, Oxfam International (November 2006).

x *Id*.

xi *Id*.

xii See Generally, Andrew Rens, *Collateral Damage: The Impact of ACTA and the Enforcement Agenda on the World's Poorest People.* PIJIP Research Paper No. 2010-08, Program on Information Justice and Intellectual Property (2010).

xiii Susan Sell, *Trips and the Access to Medicine Campaign*, Wisconsin International Law Journal 481, 484 (2001-2002).

xiv *Id*.

xv *Id*.

xvi *Id*. at 485.

xvii *Id*. at 487, 488.

xviii *Id*. at 489.

xix *Id*. (noting that the US often used access to its large domestic market as a means to force other countries to adopt and enforce stricter intellectual property policies).

xx Daniel Gervais, *Intellectual Property, Trade & Development: The State of Play*, Fordham Law Review 505, 507 (2005).

xxi *Id*. at 509.

xxii Trade Related Aspects of Intellectual Property Rights Agreement (1994), *available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm*.

xxiii Bryan C. Mercurio, *supra* note 4, at 218.

xxiv Oxfam Briefing Paper, *supra* at note 9, at 5.

xxv *Id*.

xxvi *Id*.

xxvii *Id*.

xxviii *Id*. A compulsory license is a type of flexibility provided by the TRIPS Agreement, stating that countries may grant drug manufacturers the authorization to produce the generic version of a patented drug without the consent of the right holder in order to meet a public health emergency.

xxix *Id*.

xxx Bryan C. Mercurio, *supra* note 4, at 224.

xxxi *Id*.

xxxii Doha Declaration on the TRIPS Agreement and Public Health (2001), *available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm*.

xxxiii *Id*.

xxxiv Rahul Rajkumar, *The Central American Free Trade Agreement: An End Run Around the Doha Declaration on TRIPS and Public Health*, Albany Law Journal of Science and Technology 433, 441 (2005) (citing Doha Declaration).

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xxxvi Agreement on the Trade Related Aspects of Intellectual Property Rights (1995).

xxxvii Rahul Rajkumar, *supra* note 35, at 444.

xxxviii *Id*.

xxxix Agreement on the Trade Related Aspects of Intellectual Property Rights (1995).

xl Oxfam Briefing Paper, *supra* note 9, at 9.

xli *Id*.

xlii *Id*. at 10.

xliii *Id*. (explaining the case in Brazil in 2005 after it threatened to issue a compulsory license, causing a 46% discount in the price of Kaletra, an anti-retroviral AIDS drug).

xliv *See e.g.*, Medicine Sans Frontieres, *available at http://www.msf.org*.

xlv *See Generally* Bryan C. Mercurio, *supra* note 4.

xlvi Sisule F. Musungu et al., *The Use of Flexibilities in TRIPS by Developing Countries : Can They Promote Access to Medicine?* Study #C, Commission on Intellectual Property Rights, Innovation and Public Health (August 2005).

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xlviii Oxfam Briefing Paper, *supra* note 9, at 13.

xlix *Id*. (citing as an example, the US-Jordan free trade agreement).

l *Id*. at 15.

li Report of Committee on Government Reform, *Trade Agreements and Access toMedicine Under the Bush Administration* (June 2005).

lii Jorn Sonderholm, *Intellectual Property Rights and the TRIPS Agreement: An Overview of Ethical Problems and Some Proposed Solutions*, Policy Research Working Paper No. 5228, World Bank Development Research Group (March 2010).

liii Oxfam Briefing Paper, *supra* note 9, at 13. (USTR declaring an internal reorganization plan to "better support vital US innovation, including those of the pharmaceutical industry").

liv *Id*. (noting that there are currently 20 pharmaceutical-industry representatives on USTR advisory committees).

lv 19 U.S.C. § 2411 (1974).

lvi *Id*.

lvii Oxfam Briefing Paper, *supra* note 9, 1t 14. (noting that this applies despite the fact that countries may be in compliance with minimum IPR standards required by the TRIPS Agreement).

lviii *Id*. at 17.

lix Government Accountability Office Report, *supra* note 60.

lx *Id*.

lxi *Id*.

lxii *Id*. at 41. (noting that several pending free trade agreements have been amended and made more responsive to provisions outlining TRIPS flexibilities).

lxiii *Id*.

lxiv Xavier Seuba, *Free Trade of Pharmaceutical Products: The Limits of Intellectual Property Enforcement at the Border*, International Centre for Trade and Sustainable Development, Issue Paper No. 27, 9 (2010).

lxv Council of Regulation (EC) No. 1383/2003 of 22 July 2003.

lxvi *Id*.

lxvii Xavier Seuba, *supra* note 65.

lxviii General Agreement on Tariffs and Trade (1947).

lxix Xavier Seuba, *supra* note 65, at 2.

lxx *Id*. at 5.

lxxi *Id*.

lxxii *Id*.

lxxiii *Id*.

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lxxvi *Id*.

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lxxviii *Id*.

lxxix ICTSD, *ACTA Faces Criticism at WTO and in the United States*, Bridges Weekly Trade News Digest, at 8, Vol. 14:38 (Nov. 3, 2010).

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lxxxi Peter Mayberduk, *ACTA and Public Health*, PIJIP Research Paper No. 2010-09, Program on Information Justice and Intellectual Property (2010).

lxxxii *Id*. at 2.

lxxxiii *Id*.

lxxxiv *Id*. (citing Trade Related Aspects of Intellectual Property Rights Agreement (1994)).

lxxxv *Id*. (citing TRIPS Article 48).

lxxxvi *Id*.

lxxxvii Peter Mayberduk, *supra* note 82, at 3.

lxxxviii *Id*. at 5.

lxxxix *Id*.

xc *Id*. (These remedies include monetary damages, injunctions, and declaratory relief).

xci *Id*.

xcii *Id*.

xciii Anti-Counterfeiting Trade Agreement (August 2010).

xciv Brook K. Baker, *ACTA: Risks of Intermediary Liability for Access to Medicine*, Program on Information Justice and Intellectual Property, PIJIP Research Paper No. 2010-01.

xcv *Id*.

xcvi *Id*.

xcvii *See Generally*, Peter K. Yu, Six Secret *(and Now Open) Fears of ACTA* (June 14, 2010). SMU Law Review, Vol. 64, 2011.

xcviii Susan K. Sell, *The Global IP Upward Ratched, Anti-Counterfeiting and Piracy Enforcement Efforts: The State of Play*, *IQsensato Occasional Papers No. 1 (June 2008) (stating that, "As soon as one venue becomes less responsive to a high protectionist agenda, IP protectionists shift to another In search of a more hospitable venue.").*

xcix Kimberlee Weatherall, *ACTA as a New Knd of International IP Law-Making*, PIJIP Paper No. 2010-12, Program on Information Justice and Intellectual Property (2010).

c *Id*.

ci *Id*. at 6. (noting that several of the countries participating in ACTA negotiations are parties to a U.S. free trade agreement (either active or pending Congressional approval) and that the negotiating position of these countries has been influenced by their respective FTA with the US).

cii *Id*.

ciii *Id*. at 9.

civ *Id*. at 6.

cv Anti-Counterfeiting Trade Agreement (August 2010).

cvi Peter Mayberduk, *supra* note 82 (arguing that the key players behind this agenda are multinational tobacco, pharmaceutical, film and record companies, noting that these are the primary lobbying bodies behind the advancement of ACTA).

cvii Andrew Rens, *supra* note 12.

cviii *Id*.

cix ICTSD, *Watered-down ACTA Approaching Conclusion*, Bridges Weekly Trade News Digest, Vol. 14:30 (September 8, 2010)

cx Anti-Counterfeiting Trade Agreement (October 2010).

cxi *Id*.

cxii ICTSD, Watered-down ACTA Approaching Conclusion, *supra* note 110.

cxiii ICTSD, *Officials Seek to Ease Fears of Privacy Violations under ACTA*, Bridges Weekly Trade News Digest, Vol. 14: 25 (July 7th 2010).

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cxv Letter from Ron Wyden to USTR, January 6, 2010, *available at http://www.ustr.gov/webfm_send/1701*.

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cxvii *See generally*, Over 75 Law Profs Call for Halt of ACTA, *available at http://www.wcl.american.edu/pijip/go/blog-post/academic-sign-on-letter-to-obama-on-acta* (accessed November 22, 2010).

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