# 1AC-Bioterrorism

## Advantage is Bioterrorism

#### The US handled COVID terribly – it put the whole world at risk for potential attacks, due to their poor reaction time to solving the pandemic.

#### Lewis 21

Tanya Lewis, 3-11-2021, "How the U.S. Pandemic Response Went Wrong—and What Went Right—during a Year of COVID," Scientific American, <https://www.scientificamerican.com/article/how-the-u-s-pandemic-response-went-wrong-and-what-went-right-during-a-year-of-covid/>

When the World Health Organization first called COVID-19 a pandemic on March 11, 2020, few people had any idea what the world was in for. The progression was swift: borders clamped shut, authorities issued stay-at-home orders, and public life ground to a near halt. Most of the world had no experience dealing with an infectious disease outbreak of this scale. The previously unknown virus, now called SARS-CoV-2, could spread through the air, often before (or, in some cases, possibly without ever) causing any symptoms. COVID—though mild for many people—struck down elderly and more vulnerable individuals (and occasionally very healthy ones) with a vengeance, launching a wave of fear, suffering and death unlike any in recent memory. “In the beginning, when this started a year ago, we knew that it was spreading. And we knew that it also was lethal in some percentage of people,” says Stanley Perlman, a virologist at the University of Iowa, who is an expert on coronaviruses, a group that includes SARS-CoV-2. “But I don't think we had a full appreciation about how bad it was.” Among the biggest shocks was that the U.S. fared worse than most other countries, with more than 29 million cases and nearly 530,000 deaths as of this writing. “We absolutely can’t say that we had the most robust response to the pandemic, up till this point, because we have had a higher death rate per capita than so many other places,” says Monica Gandhi, a professor of medicine at the University of California, San Francisco. As the country raced to react to this new and terrifying scourge, mistakes were made that together cost hundreds of thousands of lives. Yet the tireless efforts of health care workers, along with an unprecedented vaccine push, have saved countless others. *Scientific American* interviewed scientists and public health experts about the biggest mistakes in the U.S.’s response, some of the key successes and the lingering questions that still need to be answered. **Downplaying the danger and sidelining experts.** During the pandemic’s crucial early days and weeks, then president Donald Trump and other authority figures actively minimized the virus’s threat. Trump dismissed it as [no worse than the flu](https://www.scientificamerican.com/article/eight-persistent-covid-19-myths-and-why-people-believe-them/) and said the pandemic would be over by Easter. “One thing that shouldn’t have been done is people downplaying the infection,” Perlman says. “That was a real big problem, because if you let the pandemic get out of control and don’t take it seriously, it gets worse.” The U.S. Centers for Disease Control and Prevention initially told the media that the threat to the American public was low. When a CDC spokesperson acknowledged in late February that disruptions to daily life could be “severe,” the agency was quickly sidelined—and Trump himself became the government’s main conduit for COVID updates through his daily briefings. “The Trump administration really tightly controlled what [the CDC] could put out,” says Angela Rasmussen, a virologist at the Georgetown University Center for Global Health Science and Security. This muzzling of the CDC and top government health experts made it hard for them to communicate accurate and lifesaving scientific information to the public. Under President Joe Biden’s administration, government science agencies and health officials have been given renewed respect and independence. But rebuilding public trust in these authorities will still take time. **Slow and flawed testing.** The CDC developed its own test for the virus rather than employing [a German-developed one used by the World Health Organization](https://www.who.int/docs/default-source/coronaviruse/wuhan-virus-assay-v1991527e5122341d99287a1b17c111902.pdf?sfvrsn=d381fc88_2). But the CDC test was flawed, causing a deadly delay while scientists worked out the problem. The agency was not designed to produce tests at the scale needed to spot the infections as they silently spread through the population. Meanwhile the Food and Drug Administration [was slow to approve tests](https://www.politifact.com/factchecks/2020/mar/23/dan-crenshaw/did-fda-regulations-slow-testing-coronavirus/) made by private companies, says Caitlin Rivers, an epidemiologist at the Johns Hopkins Center for Health Security. She also says the earliest criteria for getting a test were too stringent—one often had to have been hospitalized with severe symptoms and have recently traveled to a “high-risk” area. As a result of these hurdles, the virus spread undetected for weeks. By the time testing became somewhat more available, community spread was already rampant in many places, making it difficult or impossible to do contact tracing and isolate people before they infected others. “In this pandemic, things moved so quickly that when you screwed up for two or three weeks, it made a difference,” Perlman says. Testing availability has improved but remains uneven. Some experts have argued for the use of widespread rapid antigen testing, a type that is cheap, does not require sophisticated laboratory processing and could be done at homes, schools or offices. But some scientists still have concerns about the accuracy of these tests, and the FDA has been [slow to approve them](https://www.axios.com/rapid-coronavirus-tests-fda-approval-1cc1928a-68d4-485d-aafe-0c1a69b31384.html).

**Covid means the US is extremely vulnerable to a potential bioterror attack – threat has only gotten worse.**

Marx 20, Willem Marx, 4-22-2020, "COVID-19 has shown U.S., U.K. are vulnerable to biological terrorism, experts say," NBC News, https://www.nbcnews.com/politics/national-security/experts-covid-19-has-shown-u-s-u-k-are-n1207776

Former officials in the U.S. and the U.K. warn that the devastating impact of the coronavirus on health care infrastructures and economies may act as a "neon light" for terrorist groups looking to unleash pathogens on Western nations. The pandemic has shown that the West has trouble testing, tracking and treating a pandemic or sustaining a supply of protective equipment for health care workers. It has also raised questions about the security of pathogen research labs worldwide. "Many of the very worst-case characteristics of an intentional event are also being seen in this naturally occurring pandemic," said Dr. Robert Kadlec, the assistant secretary for preparedness and response at the U.S. Department of Health and Human Services. Kadlec, a retired Air Force colonel and surgeon who has spent much of the past two decades focused on biodefense policy and legislation inside the White House, the Defense Department and the Senate, helped the FBI with its investigation into the 2001 "Amerithrax" attacks. The perpetrator in the attacks, which killed five people and infected 17 others, used anthrax from a government lab. "We've come a long way in 20 years, and yet there is so much more that needs to be done," he said. The Trump administration's repeated assertion that the virus may have escaped from a Chinese laboratory has placed the security measures at such facilities worldwide under a microscope. Over the past century, only a couple of dozen countries have developed biological weapons programs. But security experts expressed concern about "dual use" laboratories — where scientists examine pathogens for research purposes and to develop vaccines. Full coverage of the coronavirus outbreak Legislation signed by President Barack Obama obliged the incoming Trump administration to develop a national biodefense strategy, which was published in September 2018. It sought to centralize a federal response team to handle naturally occurring, accidental and deliberate biological threats and to build on previous experiences, including the 2001 anthrax attacks, a 2009 influenza pandemic, the 2014 Ebola epidemic and the more recent fallout from the Zika virus. But it also highlighted the dangers of storing lethal pathogens in laboratories that might lack "appropriate biosecurity measures," which would mean that "actors who wish to do harm" could divert them. The number of these "biosafety level 4" labs, where scientists research easily transmitted pathogens, has multiplied rapidly in recent years. And to many security experts, the locations of some facilities and their insufficient safeguards represent a substantial threat. "You've got to start thinking about the mind of the terrorist or the criminal," said Chris Phillips, the former head of the British government's National Counter Terrorism Security Office, a police unit housed inside the country's domestic intelligence agency, MI5, with responsibility for safeguarding the facilities in the U.K.

#### Big companies investment in barriers to compulsory licensing invites circumvention.

#### **Avedissian 02**

Avedissian, Grace K (J.D. Candidate, May 2003, American University, Washington College of Law; B.A., Political Science, 1997, Rutgers College). "Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of "Super-Terrorism"." American University International Law Review 18, no. 1 (2002): 237-294.

Compulsory licensing is an essential legal and legislative tool in the fight against global super-terrorism. 24 ° The U.S. opposition to compulsory licensing permits pharmaceutical companies to profit from bioterrorism, 24I and poses an unacceptable health risk to populations exposed to biological or chemical agents.242 In light of the effects of globalization, the United States and other developed countries cannot afford to ignore global health concerns. 243 A large- scale super-terrorist attack on any country would result in devastating human loss and would create regional or global panic, with rippling effects on the global economy.244 Accordingly, the WTO must add breadth to the compulsory licensing provisions of the TRIPS Agreement. 245 Also, the U.S. government must facilitate the use of compulsory licensing by addressing concerns regarding remuneration to patent holders and the effects of compulsory licensing on research and development. 246 This policy shift would recognize the need to assist the developing world during health emergencies, particularly those arising from the acts of super- terrorism. 2 47 A. THE WTO MUST RECOGNIZE ITS MEMBERS' RIGHT TO OBTAIN COMPULSORY LICENSED PRODUCTS FROM FOREIGN MARKETS In the event of a biological or chemical disaster, developing countries that lack the capacity to manufacture essential drugs must be able to exercise their legitimate right to use compulsory licensing without the fear of economic or legal reprisal from developed countries.2 48 The WTO must acknowledge this right by adopting an interpretation of the TRIPS Agreement that protects public health.2 In the Doha Declaration, the WTO Ministers instructed the TRIPS Council to find a solution to the problem arising from the inadequate manufacturing capacity of some developing nations.25 ° As an integral part of the solution, the Council must allow countries to either (1) grant a compulsory license to a generic drug manufacturer in a foreign market under Article 31 (f) of the TRIPS Agreement,25 ' or (2) import medicines that are the product of a compulsory license issued by the exporting country-as permitted under House Bill 3235.252 A contrary interpretation would simply defeat the fundamental purpose and premise of compulsory licensing under the TRIPS Agreement, that is, increasing global access to life-saving drugs.253 Without a proper implementation mechanism for compulsory licensing, the TRIPS Agreement offers empty benefits to poor countries in dire need of affordable drugs.254 Although the WTO could permit Members to issue compulsory licenses under either Article 30 or Article 31(f) of the TRIPS Agreement, it is more feasible to employ Article 3 1(0.255 Since Article 31 is the technical provision that authorizes compulsory licensing, it contains various terms and conditions that grant some protection to patent holders. 256 For instance, under Article 31, a compulsory license expires when the circumstances requiring it cease to exist, and the licensee must pay the patent holder "adequate remuneration" for the license.257 On the other hand, Article 30 does not offer such specific protections to patentees.258 Consequently, developed countries are more likely to oppose the use of this provision as the basis for permitting compulsory licensing for exports. 259 These countries, however, may be more receptive to a broad interpretation of Article 31(f), whereby a WTO Member can export medicines under a compulsory license to a Member that lacks or has an insufficient manufacturing capacity for pharmaceuticals.26 ° The enactment of House Bill 3235 would be significant for the development of a WTO resolution regarding the scope of compulsory licensing under the TRIPS Agreement. 6 In the past, the U.S. government acted strategically to prevent the WTO from adopting a flexible interpretation of the TRIPS Agreement by exerting economic and political pressure on developing countries.262

#### COVID has proven how to solve for a bioterrorism attack – vaccination is the most important thing and making sure everyone can get access to it.

#### Lyon 21

Regan F Lyon, 7-1-2021, "COVID-19 Response Has Uncovered and Increased Our Vulnerability to Biological Warfare," OUP Academic, https://academic.oup.com/milmed/article/186/7-8/193/6135020 - Harker PG

The 2018 National Biodefense Strategy (NBS) articulated a collaborative plan to prevent, detect, and respond to biological threats to the USA.1 The NBS highlights recent, isolated outbreaks of Systemic Acute Respiratory Syndrome (SARS), Ebola, and Zika viruses as warnings to nation states and justification for enhanced biological threat responses. Although these events are not considered deliberate threats, clandestine bioweapon programs and terrorist groups seeking such programs are known to exist and capitalize on such natural outbreaks.1 The NBS’s emphasis on prevention and response drives the requirement to enhance biological weapon deterrence and defense strategies to avert the employment of biological weapons on U.S. civilians or military personnel.1 The public health crisis that ensued with SARS-associated coronavirus-2 (SARS-CoV-2) has highlighted our nation’s bioweapon vulnerabilities on the international stage and has the potential for disastrous effects on national security. Previous questions regarding how the USA would respond to a large biological outbreak (or biological weapon) have now been answered for potential adversaries across the world. The ambiguity of both our capabilities and weaknesses, which provided deterrence to adversarial employment of biological weapons before the pandemic, no longer exists. This article will provide an overview on biological weapons and the concepts of deterrence and defense in the context of bioterrorism. Then, it will analyze how the national personal protective equipment (PPE) shortage, public resistance to public health measures, the anti-vaccination movement, and USNS (United States Navy Ship) Comfort deployment to New York City have increased our vulnerability to bioterror attack by impacting our deterrence and defense measures. Finally, it will offer recommendations to restore our bioterrorism security after the detrimental effects from the events unfolding in the USA. BIOLOGICAL WEAPONS REGULATIONS, DETERRENCE, AND DEFENSE Even though biological warfare is considered a “weapon of mass destruction” and is prohibited by a treaty drafted by the 1972 United Nations Biological Weapons Convention (BWC), not all adversaries adhere to these standards. Terrorist groups and covert operations have utilized biological weapons for small operations because the actors, by nature, are either non-eligible to ratify the treaty or would not do so if they could. Although there have been no intentional large-scale attacks, especially by adversarial nation states, this is not guaranteed to be the case in the future.2 The BWC does not prohibit ratified nations from having pathogens or toxins for peaceful purposes, such as the development of vaccines. After the natural outbreak of smallpox and its subsequent eradication accomplished by the World Health Organization in 1980, less virulent poxviruses have continued to be used in a variety of laboratories for research and development of vaccines for a variety of diseases.3 The original, more deadly strain of smallpox has been retained at two facilities in Russia and Atlanta.4 Because smallpox’s virology makes it an ideal biological weapon, the samples in Atlanta and Russia offer defense through researching countermeasures should an attack occur and simultaneously provide a repository from which a biological weapon can be acquired. “Deterrence” and “defense” are two concepts which are typically described in terms of nuclear warfare, but they can also be applied to national security from a biological attack.5 Deterrence is the ability to prevent an adversary from taking some action during peacetime.5 For biological warfare deterrence, vaccines and preventative medicine measures prevent susceptibility to a microbe. For a largely vaccinated and/or health-conscious population, the costs of production, storage, and dissemination of a bioweapon greatly outweighs the rare chance of the target contracting the disease. New Zealand’s robust public health measures, citizen compliance, and continued efforts to sustain a caseload under 20 since April is a strong deterrent for biological attack.6 Defense mechanisms decrease the effectiveness of the attack, putting a high cost-to-benefit burden on the adversary.5 A defense measure for bioterrorism would be an adequate medical treatment response to casualties of the bioweapon, decreasing mortality and the overall effectiveness of the weapon. COVID-19 PANDEMIC ANALYSIS The novel SARS-CoV-2 has several characteristics of an ideal biological weapon, including high transmission rate, long incubation period, airborne transmission, and significant morbidity/mortality.7 In fact, early in the pandemic, suspicion was cast that the virus was being developed as a biological weapon by a laboratory in Wuhan, China.8 Although these allegations have been deemed conspiracy theories as a result of misinformation operations, the resulting pandemic and the panicked public share similarities to a bioterror attack. The events occurring within the USA during the coronavirus disease 2019 (COVID-19) pandemic create a global narrative on how we respond to a biological crisis. The 2018 NBS emphasized the continued threat of biological weapons to national security and identified the need to deter and defend against bioterrorism acts.1 This section will analyze events in the USA during the pandemic, how they bolstered or negated our current bioterrorism deterrence or defense strategies, and offer areas for improvement to restore our bioterror security.

#### Companies reducing IP protections are key for everyone to get access to drugs and vaccines – especially in low income countries.

#### **Baird, 13**

[Sean, Magic and Hope: Relaxing Trips-Plus Provisions to Promote Access to Affordable Pharmaceuticals. Boston College Journal of Law & Social Justice, 33(1), 107-145, 2013, <http://lawdigitalcommons.bc.edu/jlsj/vol33/iss1/4>, accessed 7-31-21 Boston College of Law]

TRIPS-Plus provisions in U.S. FTAs impede access to pharmaceuticals for indigent populations.42 The similarities between U.S. patent law and the TRIPS Agreement demonstrate the United States's influence in establishing global intellectual property standards.43 Despite the suc- cess of the United States in shaping global intellectual property stan- dards, the TRIPS Agreement maintains several flexibilities, namely data exclusivity and compulsory licensing, which were affirmed by the Doha Declaration.44 The United States's dissatisfaction with the level of intellectual property protection afforded by the TRIPS Agreement prompted the proliferation of TRIPS-Plus provisions in U.S. FTAs.45

A. Values and Ideals in U.S. Patent Law

The preeminence of patents in the United States is evidenced by the fact that patents are constitutionally protected to promote innova- tion and discovery.46 A patent is a grant of property issued by a gov- ernment that provides limited rights to the patent owner.47 A patent owner in the United States is granted monopolistic control over his or her invention for twenty years, during which time no one may make, sell, or use the patented product, absent permission from the patent holder.48 This exclusive right promotes innovation by enabling the pat- ent owner to avoid pricing competition when selling the patented product.49 In return for monopolistic power to exclude, a patent owner must disclose the technological processes and data behind the prod- uct.50 Other producers use this information, saving on the cost of re- search and development while also expediting the regulatory process, in order to offer competitive pricing when the patent terminates.51

Patents are particularly valuable to the drug industry given the plethora of research and development required to produce pharma- ceuticals.52 When a drug is no longer under patent, pharmaceutical companies must compete with generic producers who provide medi- cines at much lower prices.53 Pharmaceutical companies assert that re- search and development challenges require a rigid patent system to recover investment, turn profit, and promote continued innovation.54

In the context of international trade, pharmaceutical companies have much at stake as LMICs produce generic versions of patented drugs and sell these medications around the world, undercutting brand- name profitability.55 Although the pharmaceutical industry ranks as one of the most profitable industries in the United States, these patent con- cerns have led to the development of powerful special interest groups that the United States relies on when considering trade agreements, in- cluding the TRIPS Agreement.56

B. Global Expansion of U.S. Patent Ideals Through the TRIPS Agreement

The combination of special interests and traditional value placed on patent protection has encouraged the United States to enforce its patent ideals globally by linking patent protection and international trade through the TRIPS Agreement.57 Touted as "unquestionably the most important development in international intellectual property law [in a century]," the TRIPS Agreement "attempts to strike a balance be- tween the long term social objective of providing incentives for future inventions and creation, and the short term objective of allowing peo- ple to use existing inventions and creations."58 To accomplish this, the agreement requires all WTO signatories to implement minimum stan- dards of intellectual property law.59

The United States's influence is acutely evident throughout the TRIPS Agreement's patent provisions, which practically mirror U.S. patent law.60 For example, like U.S. patent law, the TRIPS Agreement grants patent owners exclusive rights to prevent others from making, using, selling, or importing the patented product for twenty years.61 Moreover, neither the TRIPS Agreement nor U.S. patent law permits exceptions for patenting pharmaceuticals or pharmaceutical proc- esses.62 Both the United States and the TRIPS Agreement prohibit the use of compulsory licensing for products not developed locally.63 Lastly, both the United States and the TRIPS Agreement stipulate that in ex- change for a period of monopolistic control, the patent owner must disclose the invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art . . . ."64

Although the United States was largely successful in expanding its patent ideals through the TRIPS Agreement, LMICs maintained considerable flexibility to promote access to drugs.65 This success is highlighted by the TRIPS Agreement's treatment of data exclusivity and compulsory licensing.66

1. Data Exclusivity

The TRIPS Agreement requires patent holders to disclose relevant information regarding the development of the patented product, in- cluding clinical data.67 Pharmaceutical companies invest a significant amount of time and money to develop the clinical data required to patent new drugs.68 Generic drug companies rely on the clinical data collected by brand-name drug companies in order to demonstrate that the generic drug is pharmacologically equivalent to the brand-name pharmaceutical.69 In doing so, generic producers avoid the inordinate time and expense required to generate this data, enabling expeditious regulatory approval and delivery of affordable medicines upon the ex- piration of brand-name patents.70 The TRIPS Agreement requires pro- tection of such data but affords signatories broad discretion to utilize clinical data to protect the public and promote public health, as long as steps are taken to prevent unfair commercial use.71 Moreover, scholars contend that in light of the TRIPS Agreement's purpose and objectives, the agreement does not require a period of data exclusivity, contrary to U.S. patent law.72

2. Compulsory Licensing

A compulsory license is a government authorized license to a third party for the purpose of manufacturing and producing a patented in- novation without consent from the patent owner.73 Article 31 governs compulsory licenses under the TRIPS Agreement, granting a govern- ment broad discretion in issuing these licenses.74 The following re- quirements must be met in order to obtain a compulsory license: (1) the country must ensure that the third party seeking the license at- tempts to obtain authorization from the patent holder on reasonable commercial grounds; (2) the scope and duration of the compulsory license must be limited to the purpose for which the license was author- ized; (3) the compulsory license must be predominately used "for the supply of the domestic market of the Member authorizing such use;" and finally (4) the country must provide the patent holder with "ade- quate remuneration . . . taking into account the economic value of the authorization."75 Article 31 may be waived in cases of extreme urgency, national emergency, or public non-commercial use.76

Although HICs and LMICs reached a compromise on compulsory licensing, the issue became increasingly contentious upon implementa- tion.77 HICs were dismayed with the lack of clarity surrounding terms like "adequate remuneration" and "national emergency."78 LMICs were frustrated with Article 31(f) which stipulates that compulsory licenses must be predominately used for distribution within the domestic mar- ket.79 Because many low-income countries lack manufacturing capacity, compulsory licensing under Article 31 does not provide a viable method of obtaining pharmaceuticals at a competitive price.80 At the same time, alarm over HIV/AIDS, malaria, and tuberculosis grew as developing countries struggled to contain and treat infectious disease epidemics.81 These concerns led to the signing of the Doha Declaration at the WTO Ministerial Conference in 2001.82

C. A Blow to U.S. Interests: The Doha Declaration and Article 31bis

As WTO signatories began implementing the TRIPS Agreement, the scourge of HIV/AIDS proliferated and infections increased by ten percent from 2000 to 2001.83 At that time, the World Health Organization estimated that less than four percent of those in need of HAART had access.84 It is in this context that the Doha Declaration "recog- nize[d] the gravity of the public health problems afflicting many [LMICs], especially those resulting from HIV/AIDS, tuberculosis, ma- laria and other epidemics."85 WTO delegates agreed that signatories should interpret and implement the TRIPS Agreement in a way that promotes public health and access to medicines for all.86

Intellectual property flexibilities promoted by the TRIPS Agree- ment were reaffirmed in the Doha Declaration.87 Specifically, the Doha Declaration implicitly affirmed the TRIPS Agreement's deferential data exclusivity provisions and explicitly confirmed the use of compulsory licenses.88 The Doha Declaration granted broad discretion with regard to compulsory licensing, asserting that WTO signatories have "the right to grant compulsory licences [sic] and the freedom to determine the grounds upon which such licences [sic] can be granted."89 Perhaps most importantly, the Doha Declaration recognized the ineffectiveness of compulsory licensing for countries with limited or no manufacturing capacity.90 To address this weakness, WTO signatories amended the TRIPS Agreement with Article 31bis, which enables countries with lim- ited or no manufacturing capacity to import generic drugs from other countries, thereby promoting access to more affordable medicines.91

Despite the Doha Declaration's affirmance of deferential data exclusivity and compulsory licensing as valuable mechanisms to promote access to medicine, the United States dominated the TRIPS Agreement negotiations.92 A World Bank study concluded that low-income countries stand to lose twenty billion dollars from transfers of technology, including pharmaceuticals, if the TRIPS Agreement is fully imple- mented.93 Still, the United States had to accept compromises during the negotiations and has remained discontent with the level of protection afforded to pharmaceutical patents by the TRIPS Agreement.94 This dissatisfaction spurred the proliferation of TRIPS-Plus provisions in bilateral U.S. FTAs.95

D. The Proliferation of TRIPS-Plus Provisions in U.S. FTAs

The TRIPS Agreement creates a regulatory "floor," consisting of minimum levels of protection that must be afforded to intellectual property by all WTO signatories.96 Countries are therefore permitted to seek higher levels of protection in FTAs, and the United States has done so in negotiating bilateral FTAs with numerous countries.97 These trade agreements are commonly called TRIPS-Plus U.S. FTAs because they incorporate more stringent intellectual property protection provisions than the TRIPS Agreement, while also limiting the freedoms and flexibilities provided by the TRIPS Agreement.98

Beginning with the Bush administration and continuing through the Obama administration, the U.S. has sought to "ensur[e] that the provisions of any multilateral or bilateral trade agreement governing intellectual property rights that is entered into by the United States re- flect a standard of protection similar to that found in United States law."99 Pressure from the pharmaceutical industry led to the implementation of several TRIPS-Plus provisions, including rigid data exclusivity policies and limitations on compulsory licensing, thereby impeding access to affordable medicines for indigent populations in desperate need.100

1. TRIPS-Plus Impact on Data Exclusivity Provisions

TRIPS-Plus data exclusivity provisions in U.S. FTAs constrict the flexibilities afforded by the TRIPS Agreement.101 Whereas the TRIPS Agreement applies a deferential approach towards data exclusivity, U.S. FTAs apply the same level of protection afforded under U.S. patent law.102 In U.S. FTAs, competing manufacturers are prohibited from relying on clinical data for five to fifteen years after the date of a pharmaceutical's initial regulatory approval.103 Brand-name pharmaceutical companies favor data exclusivity provisions because they enable drug companies to exploit profits by suspending competition.104

Clinical data is costly and time consuming, and data exclusivity provisions may prohibit generic producers from introducing more affordable medication immediately following a patent's expiration by prohibiting access to data previously gathered by the patent holder.105 To compete, generic producers may be forced to conduct their own costly research and development, negating their ability to provide affordable drugs.106 Alternatively, generic companies would have to delay regulatory approval and production of generic drugs.107 Thus, TRIPS- Plus data exclusivity provisions in U.S. FTAs effectively empower patent holders to extend monopolistic control of pharmaceuticals by obstructing generic competition, consequently diminishing access to medicines for indigent populations.108

2. TRIPS-Plus Impact on Compulsory Licensing

Although to the TRIPS Agreement enables WTO signatories to es- tablish their own national compulsory licensing scheme, TRIPS-Plus provisions in U.S. FTAs significantly limit compulsory licensing.109 Under U.S. FTAs, parties may typically only grant compulsory licenses in emergency situations, as an anti-trust remedy, or for public non- commercial use.110 Notably, U.S. FTAs do not define "emergency situa- tions" or "public non-commercial use."111 Some TRIPS-Plus provisions require "reasonable and entire" remuneration for patent owners as op- posed to "adequate remuneration" required by the TRIPS Agree- ment.112 Finally, U.S. FTAs permit challenges to compulsory licenses on the grounds that a license was not warranted under the specific circum- stances.113 By confining a government's ability to issue compulsory licenses and providing an opportunity for the patent holder to challenge the issuance of compulsory licenses, TRIPS-Plus compulsory licensing provisions diminish a generic producer's ability to compete and enable the patent holder to manipulate drug pricing.114 The net result is diminished access to medicines for Hope Tukahirwa and millions like her.115

II. Why TRIPS-Plus Provisions are Problematic: Rigid Data Exclusivity Provisions and Compulsory Licensing Provisions Obstruct Access to Medicine

TRIPS-Plus provisions promote unyielding data exclusivity and limit compulsory licensing to the detriment of indigent populations lacking access to affordable pharmaceuticals.116 Data exclusivity provisions in U.S. FTAs with Guatemala and Vietnam, two countries struggling with staggering poverty, have led to increased pharmaceutical prices by delaying generic competition.117 Moreover, the exclusion of compulsory licensing from FTAs or proposed FTAs with the Dominican Republic, Thailand, and the Southern African Customs Union (SACU) could lead to overwhelming public health challenges as generic competition is strangled from the market while patent holders maintain monopolistic control over pharmaceutical prices.118

A. Examples of How Rigid TRIPS-Plus Data Exclusivity Provisions Have Had a Deleterious Effect on Public Health

U.S. FTAs include rigid data exclusivity provisions that ultimately obstruct generic drug competition, resulting in disastrous public health consequences for destitute populations.119 Trade agreements with Gua- temala and Vietnam illustrate the injurious effect that data exclusivity provisions have on access to affordable drugs.120

1. Guatemala

The number of people living with HIV/AIDS in Guatemala has doubled since 2001; an estimated 62,000 people are living with the dis- ease and less than 11,000 are receiving antiretroviral therapy.121 Fur- thermore, approximately twenty percent of Guatemala's largely rural population lacks regular access to health facilities and services.122 TRIPS-Plus data exclusivity provisions exacerbate these public health concerns by restricting access to affordable pharmaceuticals in Guate- mala where over fifty percent of the population lives below the national poverty line.123

The U.S.-Dominican Republic-Central American Free Trade Agreement (DR-CAFTA) came into effect in Guatemala in 2006.124 The DR-CAFTA is an agreement between the United States and six Central American countries, namely Costa Rica, El Salvador, Guatemala, Hon- duras, Nicaragua, and the Dominican Republic.125 Rigid data exclusiv- ity provisions in the DR-CAFTA have prohibited a number of generic drugs from entering the Guatemalan pharmaceutical market, despite the fact that many of these drugs may successfully treat major causes of morbidity and mortality.126 For example, Pfizer's Vfend, which is used to treat invasive fungal infections generally found in patients with com- promised immune systems (like those suffering from HIV/AIDS), costs 810% more than the generic version.127 Vfend, however, is subject to fifteen years of data exclusivity, thus barring generic producers' access to clinical information, quashing competition, and granting Pfizer mo- nopolistic pricing control.128

Similarly, data exclusivity provisions have restricted access to af- fordable antiretrovirals.129 For example, the Guatemalan government provides a list of drugs that public organizations may procure at subsi- dized costs.130 A generic antiretroviral was registered in 2004, yet when Abbott Laboratories' patented version of the same drug, Kaletra, which costs 166% more than the generic pharmacological equivalent, was reg- istered a year later, it was granted retroactive data exclusivity through 2000-the patent expires in 2015.131 Accordingly, only Kaletra, and not the generic version, has been listed by the Guatemalan government as available through subsidized costs.132 Public organizations seeking the more affordable generic drug are required to procure the drug else- where.133 Thus, rigid TRIPS-Plus data exclusivity provisions in the DR- CAFTA have reduced or eliminated generic pharmaceutical competi- tion, resulting in an inordinate pricing structure making critical drugs unavailable to much of Guatemala's indigent population.134

2. Vietnam

The United States signed a trade agreement with Vietnam in 2000.135 When Vietnam adopted data exclusivity provisions as part of the agreement, the United States praised the country for its alignment with U.S. data exclusivity standards.136 From 2000 through 2005, the Vietnamese government saw a threefold increase in health spending, much of which was attributed to rising pharmaceutical costs.137 This is particularly evident in the pricing of antiretrovirals produced in Viet- nam, which cost five to seven times more than the lowest international prices for the same pharmaceuticals.138

The precipitous increase in the cost of antiretrovirals occurred as HIV/AIDS became increasingly problematic in Vietnam.139 In 2009, an estimated 280,000 people were living with HIV/AIDS, a figure that has doubled since 2001, shortly after the U.S.-Vietnam Trade Agreement was reached.140 Nearly seven percent of all people living with HIV/AIDS in Southeast Asia live in Vietnam.141 In 2009, over fourteen thousand Vietnamese died from AIDS related causes.142 Additionally, only half of those in need of HAART currently receive antiretroviral therapy.143 Un- der these conditions, stringent data exclusivity provisions limit access to medicines in Vietnam, exacerbating an already dire public health situa- tion in a country where fifteen percent of the population lives below the national poverty line.144

For example, like many LMICs, Vietnam requires greater access to second-line antiretroviral treatment.145 As HIV/AIDS evolves, it may grow resistant to first-line treatment, requiring second-line drugs, many of which are patented by multinational pharmaceutical companies.146 One of these second-line pharmaceuticals is Kaletra from Abbott Labo- ratories.147 It was recently reported that Abbott Laboratories has a pat- ent pending for Kaletra in Vietnam, and it intends to use that patent to prevent the procurement of generic alternatives.148 Unyielding TRIPS- Plus data exclusivity provisions prohibit the use of clinical data for at least five years (and upwards of fifteen years, as seen in Guatemala), thereby eliminating generic competition for a pharmacological equiva- lent to Kaletra.149 Thus, Abbott Laboratories will be able to charge in- ordinate prices, rendering access to affordable pharmaceuticals unat- tainable for low-income populations gravely in need of second-line antiretroviral therapy.150

B. U.S. Policy Towards Compulsory Licensing Severely Harms Public Health in Middle and Low-Income Countries

TRIPS-Plus provisions in U.S. FTAs discourage the use of compulsory licensing thereby restricting generic competition and furthering a patent holder's monopolistic control of pricing, which results in restricted access to affordable drugs.151 These potentially negative effects of U.S. policy towards compulsory licensing are illustrated in two proposed, but stalled, FTAs with Thailand and the Southern African Customs Union.152

1. Dominican Republic

The island of Hispaniola, comprised of the Dominican Republic and Haiti, contains approximately eighty-five percent of all HIV/AIDS cases in the Caribbean, the region with the second highest per capita prevalence of HIV/AIDS after sub-Saharan Africa.153 In 2009, an esti- mated 57,000 people living with HIV/AIDS were domiciled in the Do- minican Republic, with 3,200 new infections that year.154 Also in 2009, an estimated 2,300 people died from AIDS-related causes.155 TRIPS- Plus compulsory licensing provisions further exacerbate the Dominican Republic's public health landscape by contributing to rising pharma- ceutical costs and discouraging generic competition, thereby limiting access to affordable drugs in a country where fifty percent of the popu- lation lives below the national poverty line.156

Although it has never issued a compulsory license, the Dominican Republic maintains liberal compulsory licensing provisions in its na- tional intellectual property law.157 Moreover, the Dominican Republic's commitment to compulsory licensing as a vital mechanism for securing access to medicines is evidenced by the fact that the Dominican Repub- lic was a sponsor of both the Doha Declaration and the Article 31bis Amendment, which sought to ease the process for issuing compulsory licenses.158 The Dominican Republic also maintains a strong generic pharmaceutical industry with generic firms controlling approximately fifty percent of the domestic pharmaceutical market.159 In fact, the in- troduction of generic antiretrovirals in the Dominican Republic led to a ninety-nine percent decrease in their cost.160

The Dominican Republic ratified the DR-CAFTA on March 1, 2007.161 TRIPS-Plus provisions in the DR-CAFTA have been character- ized as the most "onerous" protections among all U.S. FTAs with LMICs.162 Researchers assert that by 2027, the Dominican Republic will experience a nine to fifteen percent increase in pharmaceutical prices as a result of the DR-CAFTA.163 Evidence of TRIPS-Plus compulsory licensing provisions on price increases and diminished access to phar- maceuticals, however, is already prevalent as illustrated by the second- line antiretroviral Efavirenz, which costs three times more than its ge- neric pharmacological equivalent.164

TRIPS-Plus patent provisions in the DR-CAFTA effectively bar com- pulsory licensing by linking marketing approval of generic pharmaceu- ticals to the consent of patent holders.165 Thus, if a generic drug com- pany developed the pharmacological equivalent to Efavirenz under a compulsory license issued by the Dominican Republic, the generic pro- ducer would still be required to obtain consent from the patent holder to sell the generic version of the drug, which is highly unlikely.166 Be- cause debilitating poverty prohibits procurement of brand name Efavirenz and compulsory licensing provisions constrict generic compe- tition, Dominicans are forced to use a similar but slightly more harmful drug, Nevirapine.167 Nevirapine may weaken a patient's immune system if provided too early in the progression of HIV/AIDS, thereby further compromising the patient's health.168 By delaying treatment, however, individuals diagnosed with HIV/AIDS face the same risk of a weakened immune system.169

Given rampant poverty and rising pharmaceutical costs, one healthcare provider suggested that Dominicans have the bleak choice of, "[buying] medication [or] buying lunch."170 TRIPS-Plus compulsory licensing standards included in the DR-CAFTA have paralyzed the Do- minican Republic from utilizing this TRIPS-compliant method of pro- viding affordable access to antiretrovirals and other drugs.171

2. Thailand

In 2002, an estimated 670,000 people were living with HIV/AIDS in Thailand.172 The Thai government recognized the threat posed by the pandemic and initiated a national HIV/AIDS program aiming to provide its citizens with universal access to HAART.173 The program has been widely successful; the number of people receiving treatment rose from 3,000 in 2002 to 52,000 by 2005.174 The annual number of HIV/AIDS related deaths prior to the universal access program was ap- proximately 52,000, but in 2009, after several years of universal access, that number decreased by nearly fifty percent.175 By 2010, nearly sev- enty percent of those in need of antiretroviral therapy received treat- ment.176 Thailand's commitment to universal access to antiretroviral therapy has been praised by the World Health Organization and non- governmental organizations from around the world.177 The most criti- cal aspect to the success of the universal access program has been the Thai government's ability to promote the availability of inexpensive generic antiretrovirals.178

To ensure the success of the HIV/AIDS program, however, Thai- land required access to patented second-line pharmaceuticals.179 These patented medications are significantly more expensive than the generic alternatives.180 For example, Abbott's Kaletra cost well over two thou- sand dollars per patient per year, limiting the Thai government's provi- sion of the medication to six hundred patients out of eight thousand in need.181 The World Bank reported that by issuing compulsory licenses, Thailand could reduce the cost of second-line antiretroviral treatments by ninety percent.182 Thailand attempted to negotiate reduced prices for several pharmaceuticals, including Kaletra, but failed to reach an agreement.183 Thus, in late 2006 and early 2007, the Thai government issued compulsory licenses for two antiretrovirals, including Kaletra, and a third compulsory license for Plavix, a pharmaceutical used to treat cardiovascular disease.184

The United States and Thailand began negotiating a trade agree- ment in 2004, but suspended negotiations in 2006 following a military coup in Thailand.185 The World Bank concluded that TRIPS-Plus provi- sions in the proposed U.S.-Thailand FTA would have crippled Thai- land's ability to issue compulsory licenses, resulting in costs exceeding 3.2 billion dollars over twenty years.186

U.S. FTAs permit challenges to compulsory licenses on the grounds that the license was not warranted under the specific circumstances.187 Given that Abbott Laboratories and Thailand were unable to reach an agreement about the price of Kaletra, it is likely that Abbott Laborato- ries challenged the Thai government's decision to issue a compulsory license.188 In fact, Abbott was so furious with Thailand's issuance of a compulsory license for Kaletra, that it withdrew several pending phar- maceutical patents from Thailand-an unprecedented move in which a U.S. drug company retaliated against a foreign government by cutting off the supply of certain pharmaceuticals.189 If Abbott Laboratories were to prevail in such a challenge, Thailand may have been subject to U.S. sanctions and may have been required to discontinue the license.190 Thus, rigid TRIPS-Plus compulsory licensing provisions in the proposed U.S.-Thailand FTA may have curbed Thailand's use of this critical mechanism for improving access to affordable antiretrovirals necessary for Thailand's remarkably successful HIV/AIDS program.191

3. The Southern African Customs Union

Perhaps nowhere on Earth has the scourge of HIV/AIDS afflicted more people than the members of the Southern African Customs Un- ion (SACU), which is comprised of Botswana, Lesotho, Namibia, South Africa, and Swaziland.192 The SACU is burdened by over twenty percent of the global HIV/AIDS epidemic, as approximately seven million peo- ple living with HIV/AIDS inhabit SACU member countries.193 The SACU member countries are rife with poverty as nearly one-quarter of the population in each country live below the national poverty line.194 This rampant poverty has quashed access to antiretrovirals, with less than sixty percent of those in need of treatment currently receiving therapy.195 Despite extreme poverty, the SACU forms a formidable trad- ing block and has agreed to treaties with several European countries, South American countries, and is in the midst of negotiating a trade agreement with India.196

In fact, in 2003, the United States and the SACU entered negotia- tions to establish a U.S.-SACU FTA.197 The United States insisted on sev- eral TRIPS-Plus provisions, many of which are similar to those included in current U.S. FTAs.198 The SACU nations expressed particular con- cern over the proposed compulsory licensing provisions.199 The United States sought to impose a ban on exportation of pharmaceuticals devel- oped by compulsory licenses, which would have prohibited South Af- rica's generic pharmaceutical industry from supplying SACU nations with affordable drugs, including antiretrovirals.200 Thus, rigid TRIPS- Plus compulsory licensing provisions in the proposed U.S.-SACU FTA would have compromised access to generic drugs that SACU nations rely on to handle the scourge of HIV/AIDS in sub-Saharan Africa.201

The SACU refused the TRIPS-Plus provisions that the United States obstinately sought, recognizing that such compulsory license provisions would limit the delivery of affordable medicines, and as a result, nego- tiations stalled in 2006.202 Nevertheless, in 2008, the United States and the SACU signed a Trade, Investment, and Development Cooperative Agreement that "establishes a forum for consultative discussions, coop- erative work, and possible agreements on a wide range of trade issues" which would "[i]deally . . . put in place the 'building blocks' for a future FTA. . . ."203 Given the tremendous burden of HIV/AIDS on SACU na- tions, standard U.S. TRIPS-Plus compulsory licensing provisions could provoke devastating consequences.204

III. Promoting Access to Medicine Through Amendment of U.S. FTAs

TRIPS-Plus provisions in U.S. FTAs have come under fire and have even been criticized by Congress.205 The congressional response to TRIPS-Plus provisions in the Bipartisan Agreement on Trade Policy has fallen short of addressing the burdensome data exclusivity and compulsory licensing provisions in U.S. FTAs.206 To remedy these shortcom- ings, the United States should amend all U.S. FTAs to incorporate a balancing test that would provide review panels an opportunity to weigh the benefits and detriments associated with relaxing data exclu- sivity and compulsory licensing provisions for various drugs.207

#### Bioterror is possible and an existential risk – outweighs nuke war

#### **Von Hippel 17**

Frank Von Hippel, Professor of Public and International Affairs at the Woodrow Wilson School of Public and International Affairs, former assistant director for national security in the White House Office of Science and Technology, Ph.D. in Physics from Oxford University (“Bioweapons Then and Now,” Nuclear Futures Lab @ Princeton University, February 19th, https://nuclearfutures.princeton.edu/wws353-2017-blog-week03-1/)

“Bioterrorism could kill more than nuclear war – but no one is ready to deal with it,” says Bill Gates at the recent Munich Security Conference (Washington Post, 2017). His remarks focused on the world’s governments’ relative lack of preparation to respond to any pandemic, manmade or not. Although the probabilities of either large-scale war event are low, the potential threat of a deadly biological weapon on major civilian areas is high. Even developed countries’ public health regulations and precautions could provide little defense towards a virulent, engineered microbe.

Bioweapons were originally considered in the same league as chemical weapons until germ theory and epidemiology were well understood. After use in World War I, chemical weapons faced opposition by the public and many governments around the world for its inhumane killing mechanism. The Geneva Protocol, signed 1925, prohibited chemical weapon use primarily – bioweapon use was included on the virtue of similar unconventionality. While bioweapons were ineffective for the short battlefield timescales, some saw the wartime advantages of using them to cripple enemy cities, economies, and supplies. The Protocol did not have binding restrictions nor enforcement, and states such as France and the Soviet Union pursued bioweapon research and development under intense secrecy. According to the Guillemin chapter, a few visionary scientists were responsible for advocating for and heading the state-sponsored programs in the face of adverse international treaties and public opinion. This stands in contrast with scientists’ attitudes towards nuclear weapons, who were more reluctant to aid in development after recognizing its destructive power. As a few countries developed bioweapons under secrecy, the threat of the unknown spurred other countries to adopt defensive programs to understand bioweapons. These programs gradually expanded into offensive capabilities. For example, the U.S. tested how sprayed microbials might spread in a metropolitan area by releasing a benign bacteria over San Francisco in 1950 (PBS, 2017). Fortunately, these weapons were never used and President Richard Nixon denounced them completely in 1969. Not much later, 151 parties signed the Biological Weapons Convention of 1972 which formally banned development, production, and possession of bioweapons.

Today, bioterrorism is a more likely source of biological attacks. It requires malicious intent, process know-how, and the right supplies – all of which are available. While crude nuclear devices can also be fashioned with general ease, domestic and international nuclear activity is much more closely monitored than biological research is. It would be rather difficult to regulate and restrict activities that could be precursors to bioweapons. Rather, governments may only have responsive measures to counter this form of terrorism, of which Bill Gates claims governments have not seriously considered yet.

## Plan

#### Plan: The member nations of the World Trade Organization ought to allow exceptions to reduce intellectual property protections for medicines during a potential bioterrorism attack.

#### The aff solves – most credible studies agree CL with bioterrorism are key and the only option.

#### Oriola 07

JOUR AU - Oriola, Taiwo PY , 2007/01/01, Against the plague: pharmaceutical patents exemption right as a biosecurity strategy

This Article proposes the inclusion of a bioterrorism-specific pharmaceutical patents appropriation clause in national and international patent regimes. The thesis is predicated on the impropriety of the current bureaucracy-prone access to medicines paradigms in international and national patent regimes for bioterrorism-induced public health crises situations. Using highly plausible, worst-case scenarios of bioterrorism attacks, this Article argues that vast swathes of the population could become simultaneously vulnerable to deadly bioweapons, exposing millions of people to inevitable deaths, in override patents on crucial drugs or vaccines without the consent of patent 426. Audrey R. Chapman, Approaching Intellectual Property as a Human Right: Obligations Related to Article 15 (1) (c), COPYRIGHT BULL., July-Sept. 2001, at 4, 6-7, http://unesdoc.unesco.org/images/0012/ 001255/125505e.pdf#page=4. 427. See PERELMAN, supra note 219 at 2-3 (acquiescing to the creativity promotion rationale for intellectual property protection, but railing at the regime’s degeneration into a system which now “threatens to exhaust creative activity”). 428. Lawrence O. Gostin, When Terrorism Threatens Health: How Far Are Limitations on Human Rights Justified?, 55 FLA. L. REV. 1105, 1168 (2003) 429. LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 20 (2000). 430. George G. Djolov, Patents, Price Controls, and Pharmaceuticals: Considerations from Political Economy, 6 J. WORLD INTELL. PROP. 611, 611-31 (2003); James Thuo Gathii, Rights, Patents, Markets and the Global Aids Pandemic, 14 FLA. J. INT’L L. 261, 263-351 (2002); Faizel Ismail, The Doha Declaration on Trips and Public Health and the Negotiations in the WTO on Paragraph 6: Why PhRMA Needs to Join the Consensus!, 6 J. WORLD INTELL. PROP. 393, 393-401 (2003); Nadia Natasha Seeratan, The Negative Impact of Intellectual Property Patents Rights on Developing Countries: An Examination of the Indian Pharmaceutical Industry, 3 SCHOLAR 339, 339 (2001). No. 2] AGAINST THE PLAGUE 343 holders, thus avoiding lengthy ight be destined for failure. Moreover, this Article deems a bioterrorism-specific appropriation clause in global negotiations that patents regimes expedient, in light of the pervasive and dominant propatents forces intent on a stronger intellectual property regime. This regime rationalizes patent protection solely on utilitarianism, and would cast attempts at proportionality of rights as campaigns against innovation.

A fortiori, absent a bioterrorism-specific pharmaceutical patent appropriation clause, authorities could be bogged down by political and economic expediencies of pharmaceutical patent appropriation, fostering indecision that would make securing critical medicines in bioterrorism pandemics situations nigh impossible. This Article justifies the case for bioterrorism-specific pharmaceutical patents appropriation on ethical grounds, overriding public interests, and fundamental rights to health and life.

#### It solves reducing IP protections is k2 innovation and production of medicines in low-income countries

#### Chao and Mody 15

Tiffany Chao and GitaMody**,** March52015 “The impact of intellectual property regulation on global medical technology innovation” <https://innovations.bmj.com/content/1/2/49>

Technology innovation has the potential to expand equitable healthcare to underserved populations in global health. At the same time, device patents and their legislation can be barriers to innovation for developing countries. For example, the WHO has developed a ‘Compendium of innovative health technologies for low-resource settings’. 1 Most of these technologies are inexpensive to develop, inexpensive to manufacture and relatively easy to use. Nevertheless, the WHO clearly states that inclusion in their Compendium does not necessarily mean “the use of the technologies is…in accordance with the national laws and regulations of any country, including… patent laws.” Of course, it would be a challenge to innovate in the absence of legislation on trademark laws and trade secrets. Since the profitability of devices depends on leveraging existing pathways for device development, manufacturing and distribution, intellectual property (IP) protection is a major aspect of commercialisation of technologies. Certainly investors in new start-ups look for IP protection as a high priority. Regulation of IP, therefore, is necessary to stimulate invention and new technologies. However, for technologies in lowresource settings, IP protection has historically been sparse. The World Intellectual Property Organisation reports that in 2012, high-income countries shared 64.5% of the world’s total number of patents, while lower-middle-income countries held only 2.9%, with low-income countries owning only 0.4%.2 This disparity clearly demonstrates limited IP support for frugal innovation emerging from developing countries. Ironically, inventors in low-resource settings are presented with an abundance of important clinical needs and fewer established infrastructure constraints, so that there is a vast untapped potential for innovations to originate in these settings and move to the more developed world (known as reverse innovation).3 Inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices.i High cost, time and logistics are oftcited reasons for not pursuing patents. Factors influencing the cost include not just the expense of filing (which can be thousands of dollars) but also fees for legal counsel and maintenance of the patent. These costs are a barrier in their own right, and they can also lead to increases in the price of the end product, which can be significant in a highly cost-sensitive market.