# 1AC

**UNDERVIEW AT THE BOTTOM**

## Plan

#### The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by eliminating TRIPS-Plus patent policies.

## Access Advantage

#### Basic, life-saving drugs are widely inaccessible in the squo – millions across the world cannot afford them due to high prices.

Bhatt, 8 -- member at Landman Corsi Ballaine & Ford [Tina S., Amending TRIPS: A New Hope for Increased Access to Essential Medicines, 33 Brook. J. Int'l L., 2008, <https://brooklynworks.brooklaw.edu/bjil/vol33/iss2/6>, accessed 8-1-21]

I. THE NEED FOR CHANGE A. The Current Lack of Access Eighty percent of people in low- and middle-income countries that need antiretroviral therapy (“ART”) to treat HIV/AIDS do not have access to it.27 Eighty-three percent of sub-Saharan Africans and ninety-five percent of northern Africans and Middle Easterners do not receive needed medicines.28 In East, South, and Southeast Asia, eighty-four percent of those requiring ART do not receive it. In low- and middle-income countries in Europe and Central Asia, eighty-seven percent do not receive ART.29 In Latin America and the Caribbean, ART coverage is better but still inadequate at sixty-eight percent.30 While these statistics represent the situation in a substantial part of the world, they do not represent what the standard of care can be, especially considering that ART coverage in high-income countries, such as the United States, the United Kingdom, and France reaches above seventyfive percent.31 Also disconcerting is the fact that access to treatment is uneven between similarly situated countries. For example, Thailand’s coverage reaches up to sixty percent32 while in India, ART is accessible to a mere seven percent of those that need it.33 Botswana and Uganda have over fifty percent coverage while coverage in other sub-Saharan countries is well below ten percent.34 One reason why essential medicines are not reaching all who need them is their high price.35 Though prices have dropped over the last few years in some low-income countries, they remain “unacceptably high in some countries” and have remained “almost stable” in middle-income countries.36 Additionally, drugs that have decreased in price represent mostly first-line treatment37 while second-line treatment (used after patients develop immunities to first-line drugs 38) costs are “prohibitive” in most countries 39 and vary greatly amongst countries of similar income level.40 Brazil, where ART coverage is at eighty-three percent,41 presents a prime example of the dramatic effect drug prices have on access to treatment. Brazil was the first developing nation to provide universal free AIDS treatment and has “the best anti-AIDS program of any developing country.”42 It has been able to afford this by manufacturing generic versions of brand name drugs, thus reducing costs by up to almost half.43 Generic manufacturers have been identified favorably as contributing to the price drops that have occurred within the last few years.44 Moreover, in addition to making cheaper and therefore more accessible drugs, generic manufacturers are better able to serve the treatment needs of individuals in middle- and low-income countries because they provide drugs in therapy combinations not supplied by brand-name manufacturers.45 B. The Right to Health: Legal Ramifications of Inadequate Access That treatments for HIV/AIDS are available yet so many cannot access them is a great social tragedy. However, it is also a legal dilemma. On December 12, 1948, the General Assembly of the United Nations adopted the Universal Declaration of Human Rights (“UDHR”).46 From this list of principles emerged two binding treaties: the International Covenant on Civil and Political Rights (“ICCPR”)47 and the International Covenant on Economic, Social and Cultural Rights (“ICESCR”).48 These three documents together constitute the International Bill of Human Rights and have enabled the modern day human rights movement.49 They also officially established every individual’s right to health, thus making access to treatment for medical illness a human rights and international law issue. Article 25.1 of the UDHR proclaims that “[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.”50 This concept is comprehensively enshrined in and given binding effect by article 12 of the ICESCR. Section 1 of the article defines the right and section 2 lays out the correlative governmental obligations to protect the right by providing an “illustrative, nonexhaustive” list of examples.51 Article 12 reads in relevant part: 1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: . . . (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions, which would assure to all medical service and medical attention in the event of sickness.52 The right to health is also recognized in various other international and regional agreements.53 None of these documents explicitly grant a right of “access to pharmaceuticals,” however, the language of the provisions clearly contemplates access to essential medicines and article 25 has been interpreted to include such a right.54 Moreover, other rights also imply a right of access to pharmaceuticals. The UDHR states that everyone has the right to “share in scientific advancement and its benefits.”55 The ICESCR confers on everyone “the right to enjoy the benefits of scientific progress and its applications.”56 There is also the right to life itself,57 to which the right to health is regarded as “closely related” and “dependent upon.”58 Finally, access to essential medicines is acknowledged as a legitimate and important concern in non-human rights contexts as well. The WTO has most prominently addressed the issue.59 The World Bank has issued statements recognizing its importance.60 Even the World Intellectual Property Organization (“WIPO”),61 which downplays both the impact of patent protection on drug prices and the impact of drug prices on access to drugs, acknowledges the importance of striking a balance between health concerns such as access to medicine and the benefits of a robust patent regime.62 Despite the fact that the concept has been a part of the human rights movement for quite some time and is recognized in a number of instruments, the right to health does not enjoy the same legal force as rights that are considered “fundamental,” such as rights protecting against torture and genocide. There are a number of reasons for this. First, the right to health suffers from a degree of “conceptual unclarity.”63 Although certain core concepts, including access to essential medicine, have emerged over the years,64 “[i]t is difficult to pinpoint exactly what the right to health contains. Health is a very broad and subjective concept . . . [and] there exists a certain normative overlap with other human rights . . . .”65 Second, the right to health is different from other human rights in that it is subject to progressive realization over time.66 However, “[r]ecognition of core content underlines the fact that some elements are not subject to progressive realization and should be realized immediately, a notion which makes the right to health more tangible.”67 Additionally, the right to health does impose an immediate obligation to take meaningful steps towards its fulfillment.68 Finally, there is a presumption that the right prohibits states from taking steps that would undermine progress towards its realization69 as well as an obligation to “refrain from interfering directly or indirectly with the enjoyment” of it.70 Another challenge is that the right to health is not universally binding. One hundred fifty-seven countries have ratified the ICESCR.71 Thus, five countries, including the United States, are not bound to its expression of the right to health.72 Moreover, the right to health does not enjoy the status of customary international law,73 which would be binding on the United States in certain contexts despite the absence of a formal recognition of the right.74 Additionally, unlike the ICCPR, there currently is no formal system in place for adjudicating violations of the ICESCR.75 Fi-nally, many governments are ambivalent or hostile to economic and social rights generally in part because they believe civil and political rights are more basic and urgent and should be prioritized.76 The fact that the right to health is a progressive right, lacks binding force, and struggles along with other economic and social rights to be taken seriously leaves individuals hoping to assert it with no venue to challenge general violations. However, as will be argued in Part II of this Note, the access to essential medicines component of the right to health is now ripe for elevation to customary international law. Assigning such status to the access issue is a step towards judicial enforcement. C. The Legal Dilemma: The Conflict between Intellectual Property Rights and Health Rights Another issue that complicates the realization of the right to health is that, like all rights, it competes and conflicts with other rights. Often, these other rights are more widely accepted and are supported by a much more robust jurisprudence consisting of generations of statutes, treaties, and case law.77 It is, in a sense, an uneven fight. Consequently, right to health issues are not prioritized.78 The right to access to essential medicines, in particular, is in direct competition most significantly with patent rights. Unlike the right to health, patent rights are longstanding79 and universally accepted.80 They are a component of intellectual property rights81 and give inventors the ability to legally exclude others from profiting from their innovations.82 The theory of patent rights is based on the premise that inventions are “public goods that are costly to make and that are difficult to control once they are released into the world.”83 Thus, patent rights provide the economic incentive necessary to spur invention by giving inventors the ability to take legal action against those that attempt to profit from the their invention, whether by stealing it, reverse engineering it, or discovering it independently.84 Patent protection directly conflicts with access to essential medicine because it prevents the production and sale of generic versions of patented drugs.85 Generic drugs significantly increase the accessibility of medicine because they are cheaper than the patented brand name versions. “It is well documented that drug prices drop when countries promote the use of generics, abolish patents, or impose direct price controls.”86 At the international level, the production of generic drugs was primarily impeded by TRIPS, an agreement passed in 1994 by the WTO.87 The agreement “brings together . . . a broad range of intellectual property rights (“IRPs”) previously protected by subject-specific agreements”88 and is “the first significant multilateral agreement requiring member countries to provide certain minimum levels of protection to owners of intellectual property.”89 It also contains an enforcement mechanism. A state party alleging violations of the agreement by another state party may have its claim adjudicated by WTO dispute settlement procedures.90 Member states that fail to comply with the provisions of the agreement may be subject to trade sanctions.91 Additionally, TRIPS requires member states to maintain both civil and criminal enforcement procedures within their own borders to protect individual rights holders.92 Currently, 151 countries are members of the WTO and TRIPS.93 Part II, section 5 of TRIPS governs patents. It sets the minimum substantive protections that all member governments must provide to eligible innovations and provides criteria that tightly control the circumstances under which derogation of patent rights is permitted.94 Under article 27, pharmaceutical drugs are generally eligible for patent protection.95 However, products must be new and innovative in order to receive protection.96 Article 28 defines the patent holder’s rights. These include the right to exclude third parties from making, using, selling, or importing the patented product or process without consent97 as well as the right to assign, transfer, and license the patent.98 Under article 33, the patent holder has the right to exercise these rights for a term of twenty years.99 Article 30 allows the government of a member state to limit a patent holder’s right to exclude other generic manufacturers “provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”100 Under article 27, a member government is permitted to deny a patent to an otherwise eligible invention if preventing the commercialization of the invention “is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment . . . .”101 This provision is known as the public health exception.102 Article 31 establishes parameters under which a member government may exercise the public health exception by breaking a pharmaceutical drug patent, also known as compulsory licensing.103 The decision to break a patent in this manner must be made on a case-bycase basis.104 Additionally, the patent can only be broken for a limited scope and duration.105 The majority of the goods produced as a result of the patent break must be used domestically106 and thus they cannot be exported to another country.107 The member government must also pay the patent holder remunerations if it breaks the patent.108 These mechanisms that allow member governments to loosen patent protection in cases of national emergencies are commonly referred to as “flexibilities.”109 The flexibilities make TRIPS compatible with an international patent system that adequately balances patent interests with the need for access to essential medicines. The system was able to address the concerns of the pharmaceutical industry 110 while allowing member governments the ability to modify their patent rules where necessary to secure the citizens’ right to health. Unfortunately, these flexibilities proved unsuccessful. Despite the inclusion of a public health exception in TRIPS, patent protection still prevented access to essential medicine. The TRIPS flexibilities were underutilized because they were unclear and developing nations feared retaliation from other countries if they invoked them.111 For example, when South Africa attempted to invoke the flexibilities for patented AIDS drugs, forty-two pharmaceutical companies filed suit alleging violation of TRIPS and the United States Trade Representative (“USTR”)112 pressured the South African government to maintain normal patent protection.113 Another problem with the public health exception was the “Paragraph 6 Problem,” a reference to TRIPS article 31(f) (the sixth paragraph of article 31).114 As discussed above, article 31(f) requires that goods produced pursuant to compulsory licensing115 be used “predominantly for the domestic market.”116 The problem with this provision is that many countries able to efficiently to produce generic drugs117 could not export them to countries that needed cheaper versions but lacked the infrastructure and industry to produce them domestically.118 “Thus, for a state lacking a drug manufacturing base, the ability to issue a compulsory license [was] largely academic.”119 Others have argued that the language of TRIPS itself does not impede access as much as the power disparity between developed and developing nations.120

#### TRIPS-Plus standards shred equitable and affordable access to developing countries because they undermine TRIPS flexibilities – 7 warrants.

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Introduction The effect of stringent intellectual-property protection in the pharmaceutical market is contentious, focused in recent years on the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In January, 1995, the TRIPS agreement established global minimum standards for the protection of intellectual property, including a minimum 20 years' patent protection on pharmaceuticals. Compliance was postponed until 2005 for developing countries and 2016 for least developed countries. The agreement greatly expanded intellectual-property rights, including rules on the protection of test data for the effectiveness and safety of drugs. This change in intellectual-property rights generated clear gains for industry and the developed world, but the crucial question is whether it generated gains for developing countries in the form of increased exports. This question is addressed in this paper by consideration of the importance of pharmaceuticals in health-care trade, and then the essential elements, implications and issues related to TRIPS, and the new emerging issue of TRIPS-plus (in which increased restrictions are imposed as part of bilateral free-trade agreements) are outlined, concentrating on options open to the health community in negotiating to their advantage under TRIPS, and within the presence of TRIPS-plus. The experience in Malaysia in dealing with these issues is discussed, providing an example from which lessons might be learnt and extrapolated to low-income and middle-income countries. Global pharmaceutical market Pharmaceuticals are the most important health-related products that are traded, accounting for 55% of all health-related trade (the share of the next most substantially traded health-related goods—small devices and equipment—is 19%1). In 2006, the global pharmaceutical market was valued at US$650 billion, of which the generic market contributed less than 10% ($60 billion), growing at a compound yearly growth rate of 10% between 1999 and 2006, and forecast to grow to $900 billion by 2011, equivalent to a compound yearly growth of 7% over the next 5 years. This reduction is mainly the result of increased competition from generic products and the effects of cost-containment measures across major markets, although there are expectations of strong growth in the ten European markets that joined the European Union in 2004 and continued double-digit market growth in China, which will become the seventh largest sales market by 2010. The global market is highly polarised, with North America, Europe, and Japan accounting for around 75% of sales.2 A clear divide exists within the global market between developed countries, producing and exporting high-value patented pharmaceuticals, and developing countries importing these products and involved in the production of low-value generic or alternative medicines. This difference leads to many developing countries having a trade deficit in modern medicines, which often results in an overall health-sector deficit. There is little evidence that this pattern has reversed through adoption of improved intellectual-property rights. For instance, Thailand over the past decade has increased dependency on pharmaceutical imports despite strengthened intellectual-property rights, market exclusivity, and differential pricing.3 The promise of increased foreign direct investment seems elusive and the comparative advantage of adoption of stronger intellectual-property rights tends to last only as long as the next developing country does not adopt them; once these rights are harmonised globally, no advantage accrues to one country compared with another. The pharmaceutical market is also characterised by substantial concentration within a few very large transnational corporations; the ten largest account for nearly 50% of the total market (table 1). This market consists of the major element of foreign investment in health.5 The top 20 transnational corporations, based in the USA, the UK, Germany, Switzerland, and France, each have an average of more than 100 foreign affiliates in more than 40 countries (including 19 developing countries), with average sales of over $20 billion.6 However, the sales market is similarly concentrated, with North America, Europe, Japan, and Latin America accounting for more than 85% of sales.2 Thus, although developed countries hosting these large transnational corporations have considerable gains in revenue (table 2), the overall consumption of medicines means that even in some of these countries (notably the USA) a trade deficit remains. [Table 1 Omitted] [Table 2 Omitted] Industry consolidation, which generates this concentration, continues for several reasons. For instance, companies might acquire generic manufacturers to reduce generic competition (eg, acquisition of Hexel and Eon by Novartis in 2005), or national companies might merge to reduce threats of foreign acquisition (eg, Sankyo and Daiichi in 2005 before the introduction of a new Japanese law in 2006 making foreign investment easier). However, the main reasons remain the need to bolster flagging research and development through merger and acquisition, creation of economies of scale from pooled research and development resources, and positioning for new markets in biotechnologies. For most developing countries, the domestic industry is small, usually focused on generic production and traditional medicines. These countries consequently have to pay high prices for imported medicines, and are affected by intellectual-property rights, especially TRIPS and TRIPS-plus standards. For most countries, developed and developing, the escalating cost of medicines—even those recognised as essential (panel)—means that aspects of the pharmaceutical industry (especially in the context discussed here), trade, TRIPS, and TRIPS-plus are thus a major global concern at the moment.9 There are some exceptions—eg, Brazil, Thailand, and India that have substantial capacity to produce generic medicines. For India, a thriving competitive domestic pharmaceutical industry has kept generic prices at amongst the lowest in the world, helped by not granting patents on medicines until 2005, when it was required to do so by the WTO (table 3). Two-thirds of these drugs are now exported to the developed world, although potentially threatened by enhanced patent protection (likely to drive prices up unless voluntary or compulsory licences to continue production are granted), making the TRIPS and TRIPS-plus process essential.11 Noteworthy, Ranbaxy—India's largest pharmaceutical company and ranked among the top ten generic companies worldwide—was sold to the Japanese company Daichi-Sankyo in June, 2008, raising concerns for generic manufacture and access to generic medicines, within India and several other countries in which Ranbaxy has operations. [Table 3 Omitted] Patents, trade, and pharmaceuticals Information is a public good, meaning that it is impossible to exclude anyone from consuming it once it is produced, providing no market incentive for its production. Intellectual-property rights—and patents more specifically—grant legal excludability to information to remove this disincentive.12, 13 Patents have been the mainstay of policy to ensure investment in pharmaceutical research and development, acting as guarantor of monopoly rents. However, by their nature, these rents are indicated in the final product's pricing, and are a barrier to affordability. Additionally, patents only generate investment when profitable markets exist; they do not work for drugs needed to address the diseases that prevail in developing countries (such as malaria). Further, in many cases, as with penicillin or paromomycin, patents are not necessary for development. Increasing globalisation of the pharmaceutical industry, complexity of dealing with many different national intellectual-property-rights systems, and absence of patent protection for pharmaceuticals in most of the world led developed countries to push for the adoption of TRIPS agreement at the WTO in 1994. The agreement brought about a giant shift in the global market for medicines. With the temporary exception of the poorest countries, it obligates WTO members to recognise pharmaceutical product patents under the threat of trade sanctions. The implications for public health of the TRIPS agreement led developing countries to propose, and obtain adoption in 2001, of the WTO ministerial declaration on the TRIPS agreement and public health (the Doha Declaration). This declaration confirmed WTO-members' rights under article 8 to “adopt measures necessary to protect public health and nutrition” through certain flexibilities in the TRIPS agreement designed for that purpose. These include identification of patentability standards that might exclude the patenting of trivial developments (often called evergreening patents [panel]); grants for compulsory licences to allow third parties to produce or sell a drug, against payment of a royalty to the patent owner when drugs are not sufficiently supplied or are not affordable; and admittance of parallel imports (panel) that allow access to patented drugs legitimately sold in a foreign country at reduced prices without the consent of the patent holder. These flexibilities have been emphasised through the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. The 59th World Health Assembly in May, 2006, mandated this group to prepare a global strategy and plan of action for public health, innovation, and intellectual property to address conditions disproportionately affecting developing countries (resolution WHA59.24). Their work culminated in the adoption of resolution WHA 61.21 at the 61st World Health Assembly in May, 2008, with a medium-term framework (2008–15) to secure an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area (WHA 61:21). Progress is to be monitored and reported to the World Health Assembly twice a year from 2010. The plan of action contains several specific actions for relevant stakeholders classified according to eight core elements designed to promote innovation, build capacity, improve access, and mobilise resources: assess and prioritise research and development needs; promote research and development; build and improve innovative capacity; improve transfer of technology between developed and developing (and between developing) countries; encourage and support the application and management of intellectual property in a manner that promotes access to medicines; improve delivery and access to all medicines; secure and promote sustainable financing mechanisms for research and development; and establish mechanisms for monitoring and evaluation for implementation of the plan of action. The plan is relevant for TRIPS according to the fifth action, which seeks to support the application and management of intellectual property in a manner that maximises health-related innovation, especially to meet the research and development needs of developing countries, protects public health, and promotes access to medicines for all (WHA 61:21, annex). It seeks to achieve this mainly though use of TRIPS flexibilities. The plan recognises that TRIPs flexibilities provide for measures to protect public health, and that new mechanisms to generate research and development focussed on developing country needs, and to promote technology transfer, might be consistent with this provision within TRIPS. One practical recommendation as a result is the call for improved education and training in the application and management of TRIPS from a public-health perspective so that flexibilities might be understood clearly and used. Although these flexibilities might allow reconciliation of the protection of intellectual-property-rights with public-health needs, the pharmaceutical industry, supported by the US Government and European Commission, continued to seek increased protection,14 resorting to unilateral or bilateral routes to obtain TRIPS-plus conditions, when protection of intellectual-property-rights standards beyond TRIPS are incorporated in exchange for trade concessions, particularly the promise of free access to markets for agricultural goods. Free-trade agreements, signed by the USA and European Union, especially with an increasing number of developing countries, have constituted one of the main routes for TRIPS-plus standards, which might typically be found in seven main areas.15 First, TRIPS obliges members to protect product and process patents in all specialties of technology. Although many developing countries granted process patents for pharmaceuticals in the pre-TRIPS era, such patents did not ban the use of alternative processes to legally produce the same drug. However, under TRIPS there is an obligation to grant product patents, giving the patent holder the possibility of monopolising the drug independently of the process used to obtain the drug. Yet some free-trade agreements go further. For instance, the US free-trade agreements with Australia, Morocco, Bahrain, and Oman require the protection of second indications of a known product (eg, nimodipine, a known cardiovascular drug that has an application for the treatment of cerebral disorders). Thus, off-patent products can come under patent protection for an important therapeutic use. Second, many patent laws, including those in developed countries, provide procedures to oppose a patent application or to review a granted patent. Constraints to such opposition (such as those included in the US free-trade agreements with Singapore, Morocco, Bahrain, and Oman) remove an important mechanism for developing countries to challenge patents. For example, the opposition filed in India to prevent the grant of a patent filed by Novartis on a polymorphic form of imatinib mesilate (an anticancer drug) might avoid concerns over non-accessibility to the drug if priced on the basis of patent monopoly. Third, under TRIPS, patents must last for at least 20 years from the filing date, yet US free-trade agreements often require an extension of this patent term, ostensibly to compensate for delays in assessment of a patent or approve a medicine for marketing. Drugs can remain unaffordable to a large part of the population under these extensions. Fourth, TRIPS-plus standards require a period of exclusivity for test data relating to the effectiveness and safety of drugs. When adopted, this period of exclusivity prevents generic companies from relying on data developed by the originator company to obtain approval for cheaper versions of a medicine, even when patent protection does not exist, and can substantially increase the price of, and reduce access to, medicines.16 Fifth, although TRIPS lets countries identify the reasons for granting compulsory licences (eg, to address public-health needs), limitations have been imposed in some cases about the reasons that might be invoked. For instance, the USA–Jordan free-trade agreement only allows compulsory licences to remedy anticompetitive practices in cases of national emergency or other extreme urgency and for non-commercial public use. By contrast, the Italian Competition Authority granted a compulsory licence to produce an active ingredient (imipenem and cilastatin) needed for the production of an antibiotic (carbapenem) used in the treatment of infectious diseases.17 In another competition case, Merck was required to grant free licences to allow the manufacture and sale in Italy of the active ingredient finasteride and related generic drugs.18 Sixth, article 6 of TRIPS allows parallel import of products. This important flexibility is also restricted, for instance, in the US free-trade agreements signed with Morocco and Singapore. Last, pharmaceutical products can be subject to additional protection in countries where, because of the demands of the USA, the drug regulatory authority is prevented from approving a medicine for marketing when patents are in force. With the wide proliferation of evergreening patents, this linkage can become an important barrier to generic competition. Even in the USA, the drug approval-patent protection linkage has been misused considerably.19 Implementation of TRIPS-plus TRIPS provides high standards of protection that ensure recognition of pharmaceutical patents for products and processes, and measures to enforce conferred intellectual-property rights. There is no first-sight justification to further increase such protection (often in excess of that applied in developed countries) in countries with weak scientific and technological infrastructures or where a large part of the population is poor.20 In this respect, a bipartisan agreement was reached in June, 2007, between the Republican and Democratic parties at the US Congress, when suggestions were made to revise TRIPS-plus standards contained in free-trade agreements signed by the government. Although restricted to agreements with Peru and Panama, such revision mitigated the TRIPS-plus requirement in public-health-sensitive areas, notably data exclusivity, linkage, and patent-term extensions, which might set a wider precedence. Nevertheless, the objectives of TRIPS-plus can be implemented in other ways. First, countries can adopt TRIPS-plus standards without explicit obligations to do so in the belief that they might attract foreign technology and investment, or political or other support from developed countries.21 Adoption of such standards is often encouraged by active lobbying from industry, and through technical assistance provided by the World Intellectual Property Organization and patent offices of some developed countries, such as the USA, Australia, and the European Patent Office (panel). Such advice often does not contain all legislative options that countries have or directly promote protection that is suitable to the country's condition. For instance, the European Patent Office greatly determines the policies of the Chinese and Vietnamese patent offices, notably with regard to granting patents on second indications.22 Second, there might be the threat of trade sanctions under unilateral mechanisms, such as the special 301 section of the US Trade Act.23 For, China is on the 301 priority watch list because it allows for a “narrow scope of patentable subject matter” that “makes patents for…methods of treatment or diagnosis virtually unobtainable”.23 China is not obliged under TRIPS instance, however, to protect such information. Argentina is on the same list on the basis of the argument that it “still does not provide adequate protection against unfair commercial use for data generated to obtain marketing approval” and there is no “effective coordination system between its health and patent authorities to prevent the issuance of marketing approvals for patent-infringing pharmaceutical products”.23 However, Argentina protects test data under the discipline of unfair competition, as required by TRIPS, and is not obliged to establish the effective coordination system, which is generally known as the linkage between drug registration and patent protection. Many countries have ceded to pressures exerted through the threat of special section 301 application, thereby accepting to introduce TRIPS-plus standards. For instance, Australia introduced data exclusivity as a result of a complaint by the USA.24 Third, a feature of the WTO accession process is that an applicant for membership is expected to satisfy all existing members, so that one member can effectively veto an application. Countries negotiating their accession have been compelled to accept a large list of TRIPS-plus conditions either directly (as part of commitments made) or indirectly as a result of demands posed during the negotiation process. Some of those conditions affect public-health policies, notably the commitments to provide data exclusivity. For instance, Jordan and China agreed to protect test data under exclusive rights for a period of 6 years (beyond what is required in the USA), whereas Saudi Arabia and Cambodia committed to provide 5 years exclusive protection and to establish a linkage between drug registration and patent protection.25 Last, in some cases, the adoption of high protection of intellectual-property rights has been the result of signing bilateral agreements focused on these rights. The USA promoted such agreements in the 1990s, many with former socialist countries and with some developing countries (panel). Unlike free-trade agreements, these bilateral agreements did not offer trade concessions in exchange for the high protection of intellectual-property rights. Some countries were willing to accept them for political reasons or with the hope of creating a more favourable climate for foreign direct investment (there is no conclusive evidence, however, suggesting that enhanced protection of intellectual-property rights leads to an increase in foreign direct investment).26 Intellectual property became, with the adoption of TRIPS, essential in trade agreements. High protection for pharmaceutical patents is increasingly traded against potential access to developed-country markets. The impetus behind changes in intellectual-property rights is hence not health improvement, but the need to pay for trade concessions. The immediate effect of such deals is to prevent access to medicines. This outcome is questionable not just from a public-health perspective and on ethical grounds, but also on economic grounds, as there seems no clear evidence that the costs incurred will be compensated by the often volatile trade advantages obtained in exchange. Trade and the pharmaceutical market in Malaysia Malaysia provides a good example of how patent protection can create inequalities in pharmaceutical trade between developed and developing countries; with developed countries exporting high-value patented drugs, and developing countries prevented from producing them, compelled to import them, with consequent issues for access to affordable medicines. Although Malaysia's health system has been a model for other developing countries (eg, ranked 31 of 191 countries in the 2000 World Health Report), increasing health-care expenditure (from 3·6% of gross domestic product in 1993 to 6·33% in 2003) is an increasing challenge, especially with respect to medicines,27 which is likely to become more acute in the future. Although at the moment a young population, the proportion of those older than 60 years is expected to increase from 5% to 11% by 2020. This rise, along with increasing incidence of cardiovascular diseases, cancer, and diabetes, is likely to increase demand for medicines. Medicine prices rose by 28% on average each year between 1996 and 2005.28 WHO-Health Action International survey showed essential medicines to be “very expensive and not universally available”, and priced much higher (2·4-fold to 16 times higher) than the international reference price (panel).27 The absence of government regulation or control, which leaves industry to set prices, is blamed for much of this price rise.29 Some 65–80% of Malaysia's pharmaceutical needs, especially new generation antibiotic, cholesterol-lowering, anti-diabetic, cardiovascular, and anticancer drugs, are imported, mainly from Germany (8·3%), France (8·0%), and the UK (7·7%).30 The heavy reliance on imported medicines is similar to most developing countries. Local industry is small, with sales in 2006 of about $272 million (compared with chemicals [$39 billion] and manufacturing [$139 billion]). 80% accounts for low-value generics, over-the-counter treatments, vitamins or food supplements, and medical devices.30, 31 The export revenue of the industry was about $137 million in 2006, largely caused by vitamin manufacture.28, 30 Innovative domestic pharmaceutical research and development is restricted. Only 87 of 246 pharmaceutical companies registered with the Drug Control Authority manufacture modern medicines; most produce traditional and herbal medicines. The Malaysian Organisation of Pharmaceutical Industry claims capacity to manufacture almost 80% of various categories from the Malaysian essential drugs list, but these are restricted to off-patent generic versions of medicines. Although some off-patent medicines within the high-selling therapeutic classes (antibiotics, and antiviral, antiulcer, and cholesterol-lowering drugs) are produced, most manufacturers are small-sized or medium-sized enterprises, producing low-value generic versions of antibiotics and pain-killers. The actual production of patented medicines in Malaysia is largely through contract manufacture by a few local companies.31 Some product modification does take place, such as innovations in drug-delivery mechanisms to meet local needs, but the absence of technological capacity, high investment costs, and heavy reliance on imported active ingredients restrict research and development.29 Additionally, patent protection is also a factor that restricts innovations. Malaysia, like most developing countries, is thus a technology importer; 94% of patent applications and 97% of patents granted in Malaysia are from outside the country.32 It is TRIPS-compliant; its 1983 patents act has provided protection for both processes and products since 1988. The act was amended in 2000 to extend patent terms from 15 to 20 years, as required by TRIPS. Although foreign transnational corporations tend to consider the Malaysian patent system to be sufficiently robust, they have not promoted the transfer of technology (in terms of location of research and development, and manufacturing facilities) to Malaysia. Although the patents act incorporates several TRIPS flexibilities, including government use, compulsory licensing, and parallel importation,33, 34 there is no record of flexibilities having been used in pharmaceutical specialty, other than compulsory licence. In 2003, a compulsory licence was granted to permit the import of generic antiretroviral drugs from India. The decision was compelled mainly by pressure from health activists and civil-society organisations to put into effect a policy of free antiretroviral drugs, and the failure of negotiations with the patent-holding drug companies to produce the desired price reductions. The adoption of the Doha Declaration might have reinforced the government's decision; its confirmation of the right of countries to use compulsory licensing alleviated concerns that an emergency situation was a prerequisite to a compulsory licence being granted. The importation of generic antiretroviral drugs in Malaysia reduced the cost of treatment, with both generic and originator products. For example, in 2001 Combivir (lamivudine plus zidovudine) and efavirenz cost $363 per month; in 2004, with the introduction of generic version of Combivir, the monthly cost of generic Combivir and patented efavirenz was $115.34 The 2-year compulsory licence has since expired and was not renewed; ostensibly because the government was keen to promote the local production of generic antiretroviral drugs. The debate about the effect of patents on the accessibility and affordability of medicines continues, however, to be at the forefront as a result of Malaysia's negotiations for a free-trade agreement with the USA. As stated already, US free-trade agreements have been a means by which tighter patent provisions have been introduced in developing countries. Unsurprisingly, negotiations caused consternation in the local industry on the potential tightening of the patent laws, such that one of the large generic manufacturers announced plans to establish a manufacturing facility in India ostensibly to “offset any disadvantage that we might come up against from the upcoming US Free Trade Agreement (USFTA). Malaysian pharmaceutical companies may no longer be competitive in international markets with the proposed data exclusivity constraint in the USFTA”.35 The negotiations, however, were put on hold, pending the US Presidential elections and changes in the Malaysian government. Intellectual-property rights will have implications for the pharmaceutical industry in Malaysia. Yet the chapter on the pharmaceutical industry in the Third Industrial Masterplan 2006–20, although identifying the importance of the production of newly off-patent drugs, cancer treatments, and drug-delivery technologies for the growth of the local pharmaceutical industry, makes no mention of intellectual-property rights, which are an essential consideration for the future of the industry. Conclusion Intellectual property is a strategic asset for industry and public health. The growth of new global public–private partnerships, such as the malaria vaccine initiative, have shown that the management of an intellectual-property system is essential for development of, and subsequent access to, medicines. Work, including that done by WHO Commission on Intellectual Property and Innovation, also shows that the creative management of intellectual property is required to help product development and dissemination.36, 37 However, the intellectual-property system is managed poorly, and can perpetuate high prices and reduce access. Importantly, developing countries are not making full use of flexibilities built in to TRIPS to overcome patent barriers, such as compulsory licences and parallel imports, as in Malaysia. The main reason might be due to the absence of domestic resources and capacity, resulting in dependency on donor financing and in turn constraining the ability to exploit international trade provisions.38 Similarly, inequalities in power and influence between countries leave many vulnerable to pressure to protect broad trade and economic interests.39 However, widespread misunderstandings also exist, such as the misconception that countries have to declare a national emergency before invoking a compulsory licence. An immediate policy priority is therefore to address these misunderstandings and misperceptions, together with greater support for development within developing countries of legal and technical expertise to incorporate and implement TRIPS flexibilities in national policy. There might also be value in countries developing a south–south framework for collectively undertaking to implement TRIPS flexibilities, as regional economic blocs.40 A major impediment to incorporation of TRIPS flexibilities is the concern that it might provoke wide repercussions in the form of trade sanctions from developed countries in bilateral trade agreements. The pharmaceutical industry is dominated by transnational corporations based in a few developed countries. Developing countries are therefore under considerable political pressure from the governments of developed countries, representing the interests of these corporations not to invoke flexibilities. However, unfettered, TRIPS-plus will lead to increases in market exclusivity and prices, which will in turn lead to increased health-care expenditure and reduced accessibility to new essential medicines besides having a negative effect on domestic pharmaceutical manufacturers. Although most free-trade agreements, including elements of TRIPS-plus, are recent, increasing evidence suggests that they subvert TRIPS flexibilities, reducing access to medicines yet further and thus have a detrimental effect on public health.15 However, few studies have investigated why developing countries enter in to such agreements and the extent to which any perceived benefits from agreeing to TRIPS-plus conditions outweigh any public-health costs. Therefore global surveillance and management of cases when TRIPS-plus additional conditionality is contained in any free-trade agreements are urgently needed. Several other measures can be undertaken or advocated for by the public-health community in this respect. For example, developing countries with substantial markets, such as India, Brazil, and Thailand, could establish precedence by adopting TRIPS flexibilities into national patent laws; south–south partnerships could mitigate resource and capacity constraints; and pharmaceutical companies might recognise that creation and development of these markets is vital to long-term sustainability and growth.39, 40 The key to these and other measures is the recognition that protection of public health under TRIPS must take precedence over measures subsequently adopted under other trade agreements, as already stressed in many World Health Assembly resolutions since 1996 (eg, WHA49.14, WHA52.19, WHA54.11, WHA55.14, WHA56.27, WHA59.24, WHA60.30, and WHA61.21). This recognition will require strong advocacy from all in the public-health community in both developing and developed countries.

#### Restrictions on data sharing and compulsory licensing severely impede access to generic drugs for indigent populations globally

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I. The Development of TRIPS-Plus Provisions in U.S. Free Trade Agreements 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

## R&D Advantage

#### Extensive IP restrictions encourage the production of trivial patents that stifle research and development by creating legal minefields.

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When we take the longer view, **we can see a fundamental mismatch between** the policy design of **intellectual property protection and** the policy requirements of **effective pandemic response**. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs. Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices. The imposition of these short-run costs, however, can bring net long-term benefits by sharpening the incentives to invent new products. In the absence of patent protection, the prospect of easy imitation by later market entrants can deter would-be innovators from incurring the up-front fixed costs of research and development. But with a guaranteed period of market exclusivity, inventors can proceed with greater confidence that they will be able to recoup their investment. For the tradeoff between costs and benefits to come out positive on net, patent law must strike the right balance. Exclusive rights should be valuable enough to encourage greater innovation, but not so easily granted or extensive in scope or term that this encouragement is outweighed by output restrictions on the patented product and discouragement of downstream innovations dependent on access to the patented technology. Unfortunately, **the U.S.** patent **system** at present **is out of balance.** Over the past few decades, the expansion of patentability to include software and business methods as well as a general relaxation of patenting requirements have led to wildly excessive growth in these temporary monopolies: **the number of patents** granted annually **has skyrocketed** roughly fivefold since the early 1980s. One unfortunate result has been the rise of “non-practicing entities,” better known as **patent trolls**: firms that make nothing themselves but buy up patent portfolios and monetize them through aggressive litigation. As a result, **a law** that is **supposed to encourage innovation has turned into a legal minefield** for many would-be innovators. In the pharmaceutical industry, firms have abused the law by **piling up patents for** trivial, therapeutically **irrelevant “innovations” that allow them to extend** their **monopolies and** keep raising **prices** long beyond the statutorily contemplated 20 years. Patent law is creating these unintended consequences because policymakers have been caught in an ideological fog that conflates “intellectual property” with actual property rights over physical objects. Enveloped in that fog, they regard any attempts to put limits on patent monopolies as attacks on private property and view ongoing expansions of patent privileges as necessary to keep innovation from grinding to a halt. In fact, patent law is a tool of regulatory policy with the usual tradeoffs between costs and benefits; like all tools, it can be misused, and as with all tools there are some jobs for which other tools are better suited. A well-designed patent system, in which benefits are maximized and costs kept to a minimum, is just one of various policy options that governments can employ to stimulate technological advance—including tax credits for R&D, prizes for targeted inventions, and direct government support.

#### Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.

Marjanovic and Fejiao ‘20 Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### Bioterror is the largest medical threat—it outweighs natural pandemics

Bakerlee ‘21 Chris Bakerlee is a Ph.D. candidate studying evolutionary genetics at Harvard University and a fellow in the Council on Strategic Risks’s Fellowship for Ending Bioweapons Programs. "Mother Nature is not 'the ultimate bioterrorist' - STAT." STAT, 8 Jan. 2021, www.statnews.com/2021/01/08/mother-nature-is-not-the-ultimate-bioterrorist. [Quality Control]

Taken together, these examples show that this meme no longer serves us well. It is undoubtedly a **mistake** to underestimate the **threats from natural pathogens**. At the same time, it is equally unwise to wield this 19-year-old expression like a magic wand, intending to briskly banish concerns about people causing harm with biology. We can’t afford to blind ourselves or others to the uncomfortable truth that, with each passing day, humans grow more capable of outdoing nature and harnessing biotechnology **to cause harm on a staggering scale**, by either cruelty or carelessness. Nature has no interests, motives, or political goals. To the extent it can be said to “want” anything, it is to perpetually enhance populations’ differential reproductive success, which only rarely aligns with causing greater harm to humans. Notably, the trillions of bacteria living in the average human’s colon appear to have adapted toward a peaceful and often mutually beneficial coexistence with their host. And even deadly pathogens may theoretically evolve toward making humans less sick if doing so opens up more opportunities for transmission between hosts. The process of natural selection, for all its power, is highly constrained in its ability to generate “superbugs” possessing a diabolical suite of traits. Like human bioengineers, natural selection must work around stubborn physiological trade-offs between traits, such as genome replication rate and mutation rate. But natural selection is also handicapped by near-sightedness, driving improvements in traits that enhance a population’s fitness in its current environment with **no attention to** maintaining or improving **traits that enhance fitness in other environments**. If creating an especially deadly pathogen were like winning a soccer match against a formidable opponent, natural selection would be competing with all the cunning of **a**n especially persistent **horde of 5-year-olds**, glued to the ball and only ever capable of playing offense, defense, or goalie at any one time. By contrast, modern **biologists are gaining the ability to see the whole field**, develop an intuition about where the ball will be next, and play multiple positions simultaneously. Through a combination of rational design, directed evolution, breeding, and brute force trial and error, they can increasingly engineer organisms that excel in multiple desired functions at once, such as the ability to grow quickly in a massive industrial fermenter while churning out commercially valuable biomolecules. This growing capability promises tremendous benefits for agriculture, industry, and human health, but its potential application to the creation of pathogens **poses serious concerns**. It is worth emphasizing that trained biologists — let alone terrorists — still have difficulty one-upping natural selection’s creative output. Our understanding of biology is very much in its infancy. Yet our knowledge and capabilities are maturing rapidly, as evidenced by Twist’s prolific gene synthesis capabilities, along with recent feats in predicting protein structure, gene editing, and genome assembly. We are much closer to this exciting but frightening horizon today than we were in 2001, and this trend will likely persist. It’s also worth noting that, when it comes to weapons-grade biotechnology, states likely pose a greater risk than non-state terrorists. States have vastly more resources to support the development of biological weapons, and about **23 are known or suspected to have** maintained **biological weapons** programs in the 20th century. Some programs, like North Korea’s, likely persist to this day. As countries jockey for advantage, state biological weapons programs remain an ever-present danger, despite the treaties and export controls designed to rein them in. Covid-19, which has exposed countries’ **vulnerability to biological threats**, has done little to mitigate this danger. **Accidental releases pose** an **additional** source of **anthropogenic biorisk.** Thanks to the U.S. government’s monitoring program, we know that **dozens of agents** and toxins with the potential to pose a severe threat to public health and agriculture **are** reported **accidentally lost or released** from U.S. labs **every year**. We also know that accidental releases around the world have already caused significant harm. Such risks increase as biotechnology expands across the world and gains in strength. Biotechnology, with all its promise and peril, is moving fast. It’s irresponsible of us to shrug off current and emerging biotechnological threats by reciting “Nature is the ultimate bioterrorist” like some article of faith. As with global warming, the cost of willful ignorance and inaction is high — and increasing. Our health security requires that we engage cautiously but honestly with the full spectrum of evolving biological risks, striving toward solutions with open eyes and moral courage.

#### Bioterrorism leads to extinction – modern technologies can be used to isolate deadly pathogens and target vast populations.

Kellman ‘08 (Barry, Professor of Law, Director, International Weapons Control Center, International Human Rights Law Institute @ DePaul U., Futurist, May 2008, “Bioviolence: A Growing Threat,” http://www.britannica.com/bps/additionalcontent/18/31535413/Bioviolence-A-Growing-Threat)

According to the National Academies of Science, "The threat spectrum is broad and evolving – in some ways predictably, in other ways unexpectedly. In the future, genetic engineering and other technologies may lead to the development of pathogenic organisms with unique, unpredictable characteristics." For as far into the future as we can possibly see, every passing day it be- comes slightly easier to commit a vio lent catastrophe than it was the day before. Indeed, the rapid pace of advancing science helps explain why policies to prevent such a catastrophe are so complicated. Bioviolence Jihad? Some experts argue that terrorists and fanatics are not interested in bio- violence and that the danger might therefore be overblown. Since there have been no catastrophic bioviolence attacks, these experts argue, terrorists lack the intention to make bioweapons. Hopefully, they are correct. But an enormous amount of evidence suggests they are wrong**. From the dawn of biology's ability to isolate pathogens, people have pursued hostile applications** of biological agents. It is perilous to ignore this extensive history by presuming that today's villains are not fervent about weaponizing disease. Not a single state admits to having a bioweapons program, but U.S. intelligence officials assert that as many as **10 states** might have active programs, including North Korea, Iran, and Syria. Moreover, many **terrorist organizations have expressed interest** in acquiring biological weapons. Whatever weight the taboo against inflicting disease might have for nation-states, it is obviously irrelevant to terrorists, criminals, and lunatics. Deterrence by threat of retaliation is essentially meaningless for groups with suicidal inclinations who are likely to intermingle with innocent civilians. Al-Qaeda and affiliated Islamic fundamentalist organizations have abling them to spread in regions where there is no natural immunity. The **polio** virus **has been synthesized from scratch**; its creators called it an "animate chemical." Soon, it may be resynthesized into a form that is contagious even **among vaccinated populations**. Recreation of long-eradicated livestock diseases could **ravage herds** severely lacking in genetic diversity, **damage food supplies, and cause devastating economic losses**. Perhaps the greatest biothreat is the manipulation of the flu and other highly contagious viruses, such as Ebola. Today, scientists can change parts of a virus's genetic material so that it can perform specific functions. The genomic sequence of the Spanish flu virus that killed upwards of 40 million people nearly a century ago has been widely published; **any** savvy **scientist could reconstruct it**. The avian flu is even more lethal, albeit not readily contagious via casual aerosol delivery. A malevolent bio- scientist might augment its contagiousness. The Ebola virus might be manipulated so that it kills more slowly, allowing it to be spread farther before its debilitating effects al- together consume its carrier. A bit further off is genetic manipulation of the measles virus--one of the great killers in human history--rendering useless the immunizations that most of us receive in early childhood. Soon, laboratory resynthesis of smallpox may be possible. Advanced drug delivery systems can be used to **disseminate lethal agents to broad populations**. Bio- regulators--small organic compounds that modify body systems-- could enhance targeted delivery technologies. Some experts are concerned that new weapons could be aimed at the immune, neurological, and neuroendocrine systems. Nanotechnology that lends itself to mechanisms for advanced disease detection and drug delivery--such as gold nanotubes that can administer drugs directly into a tumor--could also de- liver weaponized agents deep into the body, substantially raising the weapon's effectiveness. Altogether, techniques that were on the frontiers of science only a dec- ade or two ago are rapidly mutating A looming danger confronts the world--the threat of bioviolence. It is a danger that will only grow in the future, yet we are increasingly failing to confront it. With every passing day, committing a biocatastrophe becomes a bit easier, and this condition will perpetuate for as long as science progresses. Biological warfare is as old as conflict, of course, but in terms of the objectives of traditional warfare-- gaining territory or resources, compelling the surrender of an opposing army--biological weapons weren't very effective. If the objective is to inflict mass death and panic on a mixed population, however, emerg- ing bioweapons offer remarkable potential. We would be irresponsible to presume that radical jihadists like al- Qaeda have ignored said potential.

## Framing

#### The standard is saving lives:

#### Death outweighs

#### 1] Death is the worst form of evil since it destroys the subject itself.

Paterson 3 – Department of Philosophy, Providence College, Rhode Island (Craig, “A Life Not Worth Living?”, Studies in Christian Ethics.

Contrary to those accounts, I would argue that it is death per se that is really the objective evil for us, not because it deprives us of a prospective future of overall good judged better than the alter- native of non-being. It cannot be about harm to a former person who has ceased to exist, for no person actually suffers from the sub-sequent non-participation. Rather, death in itself is an evil to us because it ontologically destroys the current existent subject — it is the ultimate in metaphysical lightening strikes.80 The evil of death is truly an ontological evil borne by the person who already exists, independently of calculations about better or worse possible lives. Such an evil need not be consciously experienced in order to be an evil for the kind of being a human person is. Death is an evil because of the change in kind it brings about, a change that is destructive of the type of entity that we essentially are. Anything, whether caused naturally or caused by human intervention (intentional or unintentional) that drastically interferes in the process of maintaining the person in existence is an objective evil for the person. What is crucially at stake here, and is dialectically supportive of the self-evidency of the basic good of human life, is that death is a radical interference with the current life process of the kind of being that we are. In consequence, death itself can be credibly thought of as a ‘primitive evil’ for all persons, regardless of the extent to which they are currently or prospectively capable of participating in a full array of the goods of life.81  In conclusion, concerning willed human actions, it is justifiable to state that any intentional rejection of human life itself cannot therefore be warranted since it is an expression of an ultimate disvalue for the subject, namely, the destruction of the present person; a radical ontological good that we cannot begin to weigh objectively against the travails of life in a rational manner. To deal with the sources of disvalue (pain, suffering, etc.) we should not seek to irrationally destroy the person, the very source and condition of all human possibility.82

#### 2] Trillions of people in future generations means the future holds a lot of value – outweighs their offense under any framework.