# AC

### Framework

#### The standard is maximizing expected well being

#### Extinction o/ws under any framework, even under moral uncertainty – infinite future generations

Pummer 15 — (Theron Pummer, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford, “Moral Agreement on Saving the World“, Practical Ethics University of Oxford, 5-18-2015, Available Online at http://blog.practicalethics.ox.ac.uk/2015/05/moral-agreement-on-saving-the-world/, accessed 7-2-2018, HKR-AM) \*\*we do not endorse ableist language\*\*

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake. Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. We should also take into account moral uncertainty. What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, all minimally plausible moral views would converge on the conclusion that we should try to save the world. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

#### Rightness: they determine the degrees of rightness and wrongness for an action. Proving any non util calculus always collapses to util.

#### Intuitions: intuition within human proves that we always calculate actions with util.

#### Actor spec.

#### [A] Governments must aggregate since every policy benefits some and harms others, which also means side constraints freeze action.

#### [B] States lack wills or intentions since policies are collective actions.

### Plan

#### Thus resolved: the member nations of the WTO ought to reduce intellectual property protections for medicines.

#### I’ll answer any question before or during CX for clarification.

### Contention 1: Accessibility

#### millions across the world cannot afford basic drugs 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]

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.34One 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.40Brazil, 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.43Generic 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.45B. The Right to Health: Legal Ramifications of Inadequate AccessThat 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.52The 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.”58Finally, 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.62Despite 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.”100Under 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.108These 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.113Another 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

#### Current IPR ensure inaccessibility that cause pandemics more easily- 7 warrants- reduction in IPR ensures best balance between health sector and innovation

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[Prof Richard D Smith PhD, Prof Carlos Correa PhD, Cecilia Oh PhD, Trade, TRIPS, and pharmaceuticals, The Lancet, Volume 373, Issue 9664, 21–27 February 2009, Pages 684-691, <https://doi-org.libproxy.uwyo.edu/10.1016/S0140-6736(08)61779-1>, accessed 7-31-21]

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.9There 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 pharmaceuticalsInformation 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, 30Innovative 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.31Some 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.ConclusionIntellectual 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.

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

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

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

#### Inaccessibility causes extinction with pandemics and resource wars with closed borders

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Few people see this more clearly than Ron Klain, who oversaw our international response to the Ebola outbreak in West Africa: If my experience coordinating our Ebola response did not make me an infectious disease expert, it did give me a battle- field expertise in what works—and what does not—in our global policy and governmental frameworks in responding to an infectious disease outbreak and epidemic. And it left me with the perspective that while we did make some progress in preparedness—as a country and as a global community— during the Ebola epidemic, I'm sad to say that as we stand here today, the world still has gaping holes and glaring inade- quacies in its preparedness for a ghastly eventuality that is certain to come. Those gaps are not only in poorer countries with weaker medical systems, as one might expect, but even here in the United States, With our envy of the world institu- tions and resources. Why is this so worrisome? Because it seems likely that the world is living on borrowed time before one of these new infectious disease threats becomes the kind of global pandemic we have all been warned to expect. It is not hard to imagine that some time during the next president's term, his or her national security team may be summoned to the Oval Office to discuss a catastrophic pandemic of historic propor- tions: more than one million deaths in just a few weeks in a far corner of the world, sparking the fall of several governments, giving rise to a violent regional conflict over scarce resources, and unleashing a refugee crisis as fleeing victims encounter panic and closed borders at every turn. Worse still, the president will be told, there is an increasing risk that such death and disruption may soon arrive in the United States.

### Contention 2: income inequality

#### Income Inequality increasing after COVID

Peter Coy, 3-10-2021, "The Legacy of the Lost Year Will Be Devastating Inequality," Bloomberg, <https://www.bloomberg.com/news/articles/2021-03-10/covid-pandemic-made-racial-income-inequality-much-worse>

On March 11, 2020, the World Health Organization declared Covid-19 a pandemic. This magazine published a cover-to-cover special issue that week—our last in the office—called “[The Lost Year](https://www.bloomberg.com/magazine/businessweek/20_13).” At the time, though, fear of the disease was leavened with hope that it might bring people together. In one of his eagerly watched press conferences, New York Governor Andrew Cuomo called Covid a “great equalizer.” So did Madonna, who released a video of herself mostly immersed in a rose-petal-strewn bathtub saying, “We’re all in the same boat, and if the ship goes down we’re all going down together.”

The ship went down, all right, but we didn’t all go down together. Covid amplified inequality—by race as well as income, gender, occupation, and nationality. For many, the lost year threatens to become a lost decade akin to America’s doldrums after the deep recession of 2007-09 or Japan’s [long slump](https://www.bloomberg.com/features/2020-japan-lost-generation/) after its asset bubble popped in 1991. The cumulative future damage is likely to be even greater than the havoc Covid wrought in its first, acute year. Doctors coined the term “[long hauler](https://www.bloomberg.com/news/features/2020-11-09/coronavirus-long-haulers-tell-us-their-symptoms-and-the-aftereffects-of-disease)” to describe patients with lingering health problems; society itself will be a long hauler. And the least-advantaged will suffer the most in damaged health, derailed schooling, and wrecked careers. On the plus side, Covid has stimulated fresh thinking about ways to protect the most vulnerable. The Philippines used its universal health insurance, which was enacted in 2019, to cover testing for and treatment of Covid for everyone, including the 40% of Filipinos working in the informal sector. Rwanda, fearing the virus’s impact on its poorest citizens, used robots to take temperatures and drones to deliver medicines. In the U.S., President Biden’s [$1.9 trillion relief program](https://www.bloomberg.com/news/articles/2021-03-06/what-s-in-the-1-9-trillion-stimulus-bill-passed-by-the-senate) expands tax credits for low-income Americans with children, bolsters unemployment insurance, pays out $1,400 checks, and expands rental assistance and food stamps. The pandemic made long-present inequalities impossible to ignore. “A lot has gotten worse, but there’s one thing that’s gotten better, and that’s the opportunity for this nation and indeed the world to address equality seriously,” says Dayna Bowen Matthew, dean of George Washington University Law School and author of Just Medicine: A Cure for Racial Inequality in American Health Care. “It’s almost a reprieve, a mulligan, a do-over,” she says. “As a society we want to be better than this, and we have concrete evidence, reasons why and how to be better than this.” Thirty-six Americans had died of Covid in the week that Bloomberg Businessweek published “The Lost Year” cover. The death toll is now over half a million in the U.S. and [more than 2.5 million worldwide](https://www.bloomberg.com/graphics/2020-coronavirus-cases-world-map/). So it really was a lost year. But for the lucky ones, the loss was felt at a distance—sad stories on the news, forced separation from friends and family. For many there were offsetting advantages, such as working from home for full pay while the rising stock market fattened their retirement accounts. Federal relief dollars benefited a lot of people who didn’t need the money. This issue isn’t about those lucky ones. It’s about how to help people who are struggling to recover. Just as Covid permanently scars lungs, it can damage earnings potential for a lifetime. In February 2020 unemployment rates were just 3% for Whites, 4.4% for Hispanics, and 6% for Blacks. A year later the respective rates were 5.6%, 8.5%, and 9.9%. The longer you’re out of work, the harder it is to rejoin the labor force. The same goes for nations: “COVID-19 could leave lasting economic scars in the poorest countries; It’s in everyone’s best interest to act now,” reads the headline on a Feb. 4 blog post by World Bank officials Ayhan Kose and Akihiko Nishio.

#### Current economy on brink

Ramaa Vasudevan, 7-30-2021, "The Pandemic Alone Can’t Transform Capitalism," Jacobin Magazine, <https://www.jacobinmag.com/2021/07/pandemic-covid-world-economy-us-dollar-inequality-treasury-central-banks-ramaa-vasudevan-interview>

The pandemic was, in a sense, a kind of prism. It clarified the brutal dilemmas posed by the logic of capitalism. As businesses were forced to close, checking the spread of contagion, those whose lives and livelihoods depended on the capitalist economic engines were cut loose. With devastating clarity, the pandemic revealed how tenuous the access to even the most basic goods and services becomes when this access depends on precarious jobs. The pandemic and its implications are distinct and different from those of the global financial crisis. The collapse of the economic engines in the context of the pandemic was because of the shock of the COVID-19 outbreak. However, during the financial crisis in 2008, it was the outcome and expression of the economic contradictions of capitalism itself. These contradictions are visible in the economic tendencies of falling profitability and lagging demand, which disrupted accumulation. One should bear this in mind when comparing the pandemic to the crash of 2008. World GDP contracted by 3.3 percent during the pandemic, compared to the global financial crisis, when it fell by 1.7 percent in 2009. But it’s also important to note that GDP growth fell from around 4.3 percent in 2008 to 2.3 percent in 2020. This means that the fault lines that led to the financial crisis have continued to widen after the recovery. The pandemic has struck a global economy that was already fragile. Looking at employment numbers, in 2020, as a result of the pandemic and the shutdowns, 9 percent of global working hours were lost, relative to the end of 2019. This is the equivalent of 255 million full-time jobs. The fall in average working hours per week because of the pandemic was about 2.5 hours. This number is approximately four times greater than that which occurred in 2009. Weekly hours declined by just 0.6 hours between 2008 and 2009. These working-hour losses are particularly high in Latin America and the Caribbean, Southern Europe, and Southern Asia. Employment losses are very high in the United States. They’ve been higher for women by about 5 percent, and for younger workers by 8.7 percent. In contrast to the financial crisis of 2008, most of the global employment loss because of the pandemic was caused by rising inactivity rather than unemployment. This led to an additional 81 million people shifting to nonactive status alongside the actual global unemployment of 33 million. These people were actively seeking jobs. The proportion of people who entered the labor market fell by 2.2 percent. It became less than 60 percent of the labor force because of the COVID crisis. The fall during the financial crisis was about 0.2 percent. There’s a sharper fall in employment in terms of reduced working hours during the pandemic. There’s also a greater fall in participation rates. This is because the pandemic was not just a drop in investments leading to a fall in jobs; it posed a choice between life and livelihood, because, for a large section of working people, holding onto a livelihood meant you put your life on the line. That is one of the stark differences between the pandemic and other crises, and it shows why it has made working lives precarious. Another difference is that there were massive job losses in hard-hit sectors like accommodation, food services, arts and culture, retail, and construction. There was job growth in higher-skill sectors like information, communication, and financial and insurance activities. Job destruction has disproportionately affected low-paid, low-skilled informal jobs. This points not just to uneven recovery but to a kind of recovery that will lead to greater inequality. Without taking into account any of the income support measures launched by states in 2020, the share of wages in total income declined by 8.3 percent. This amounts to about $3.7 trillion. The greatest loss, about 12.3 percent, was experienced in lower-middle-income countries. At the same time that workers lost $3.7 trillion, the world’s biggest billionaires — about two thousand of them — enjoyed a $3.9 trillion boost to their belts in 2020. They increased their fortunes by 54 percent, from about $8 trillion to $12 trillion. Just five billionaires in the United States — Jeff Bezos, Mark Zuckerberg, Warren Buffet, Elon Musk, and Bill Gates — saw an 85 percent increase in their combined wealth, which is now about $61 billion. In the absence of interventions or collective action, the impact of inequality during COVID-19 is definitely worse than that of the great financial crisis.

#### IPR creates income inequality through creating a more skewed wage distribution with a bias for skilled labor

Saini, Swati and Mehra, Meeta K, Center for International Trade and Development, 2014 February 2, “Impact of Strengthening Intellectual Property Rights Regime on income inequality: and econometric analysis”, https://mpra.ub.uni-muenchen.de/75456/1/MPRA\_paper\_56710.pdf

As discussed in the introductory section, against the backdrop of TRIPs Agreement, our study focuses on the analysis of the impact of strengthening IPRs on income distribution in developing countries after they became members of WTO in 1995, and initiated the process of complying with the requirements of the TRIPs Agreement. We find that strengthening of IPRs has led to an increase in income inequality in WTO-member developing countries after they started modifying their national IPR regimes in accordance with the TRIPs requirements. Intuitively, IPRs tend to raise income inequality by generating a more skewed distribution of wages. The underlying notion is that stronger IPRs increase the demand for skilled labor force as it raises the return on R&D activities. This causes a relative increase in skilled labor wages, creating a wage bias in favor of skilled labor against unskilled labor, thus aggravating income inequality within a developing country. Moreover, the effect on inequality is more pronounced for countries that are experiencing higher per capita GDP growth rates. As for the developed countries included in the sample, our analysis seems to suggest that IPRs have led to a decline in income inequality over the study period. This can be due to the pre-existence of a strict IPR regime in developed countries way before the TRIPs Agreement came in to effect. This, combined with the fact that developed countries’ workforce is largely skilled, IPRs have little scope to worsen income inequality in developed countries. In terms of policy implications, the immediate impact of intellectual property protection is to benefit financially those who have the knowledge and inventive power, and to increase the costs of access to non- holders of knowledge. In a majority of developing countries, with weak scientific and technical infrastructure, the benefits in the form of stimulus to domestic innovation will be limited and in addition, they will face the costs arising from the protection of (mainly foreign) technologies. Thus, the costs and the benefits of the system as a whole may not be equitably distributed. IPRs should promote agricultural production by stimulating invention and new technologies in agricultural sector in developing countries. Most developing countries do not have a strong technological base which could benefit from IP protection but they do have genetic resources and traditional knowledge, which have value both to them and to the world at large. These are not necessarily IP resources in the sense that they are understood in developed countries, but they are certainly resources on the basis of which protected intellectual property can be, and has been, created (CIPR 2002). Therefore, this kind of resources also should be protected so that the owners of traditional form of knowledge and resources can get their due. Our research could be extended in several directions. In particular, the analysis could focus on the specific channels through which IPRs affect income inequality in developing countries, namely, through wage or asset inequality. This provides the scope for future research in this area. A second possible direction is to determine the impact of stronger IPRs on wages in different sectors of a developing economy. This will help in giving an insight into the sensitivity of wages in different productive sectors of a developing economy in response to more stringent IPRs.

#### Inequality creates economic rot which generates constant crises and deep economic collapse

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(Han, “Inequality and Its Perils,” September 27th 2012, <https://www.theatlantic.com/business/archive/2012/09/inequality-and-its-perils/426309/>)

Something potentially analogous is stirring among the Left. An emerging view holds that inequality has reached levels that are damaging not only to liberals' sense of justice but to the economy's stability and growth. If this narrative catches on, it could give the egalitarian Left new purchase in the national economic debate. "Widely unequal societies do not function efficiently, and their economies are neither stable nor sustainable in the long term," Joseph E. Stiglitz, a Nobel Prize-winning economist, writes in his new book, The Price of Inequality. "Taken to its extreme — and this is where we are now — this trend distorts a country and its economy as much as the quick and easy revenues of the extractive industry distort oil- or mineral-rich countries." Stiglitz's formulation is a good two-sentence summary of the emerging macroeconomic indictment of inequality, and the two key words in his second sentence, "extreme" and "distort," make good handles for grasping the arguments. Let's consider them in turn. INEQUALITY'S BROKEN PROMISE Equality and Efficiency: The Big Trade-off was a 1975 book written by the late Arthur Okun, a Harvard University economist and pillar of the economic establishment. Okun's title encapsulated an economic consensus: Inequality is the price America pays for a dynamic, efficient economy; we may not like it, but the alternatives are worse. As long as the bottom and the middle are moving up, there is no reason to mind if the top is moving up faster, except perhaps for an ideological grudge against the rich — what conservatives call the politics of envy. For years, the idea that inequality, per se, is economically neutral has been the mainstream view not just among conservatives but among most Americans outside the further reaches of the political Left. There might be ideological or ethical reasons to object to a growing gap between the rich and the rest. But economic reasons? No. "The debate for many years looked settled," said Robert Shapiro, an economist with Sonecon, a Washington consulting firm. "Changes in the economy and changes in the data have reopened the debate." Economists know more today than they did in Okun's day about the distribution of income. "There's been enormous progress in measuring inequality — Nobel Prize-level progress," said David Moss, an economist at Harvard Business School. As the data came in and the view got clearer, the picture that emerged was unsettling. "In the 1990s," Moss said, "it began to appear that income was being concentrated among the very highest earners and that stagnation was occurring not just at the low end but across most income levels." It wasn't just that the top was doing better than the rest, but that the very top was absorbing most of the economy's growth. This was a more extreme and dynamic kind of inequality than the country was accustomed to. According to a recent Congressional Budget Office report, those in the top 1 percent of households doubled their share of pretax income from 1979 to 2007; the bottom 80 percent saw their share fall. Worse, while the average income for the top 1 percent more than tripled (after inflation), the bottom 80 percent saw only feeble income growth, on the order of just 20 percent over nearly 30 years. The rising tide was raising a few boats hugely and most other boats not very much. It thus began to seem that the old bargain, in which inequality bought rising incomes for all, had failed — much as the Keynesian bargain (bigger government, faster growth) had failed two generations earlier. "The majority of Americans have simply not been benefiting from the country's growth," Stiglitz wrote, overstating things — but not by a lot. PATHWAYS TO PERIL So much for "extreme." Next came the financial-system meltdown of 2008 and the Great Recession, which bring us to "distort" — how an excess of inequality may have warped the economy. As the data on inequality came in, economists noticed something else: The last time inequality rose to its current heights was in the late 1920s, just before a financial meltdown. Might there be a connection? In 2010, Moss plotted inequality and bank failures since 1864 on the same graph; he found an eerily close fit. That is, in both the 1920s and the first decade of this century, inequality and financial crisis went hand in glove. Others noticed the same conjunction. Although Moss recognized that a simple correlation based on only two examples proves nothing, he wasn't alone in wondering if something might be going on. But what? Different economists suggest different pathways by which inequality at the microeconomic level might cause macroeconomic problems. What follows is a composite story based on common elements. As with supply-side, the case starts with the two extreme ends of a curve. Supply-siders pointed out that two tax rates produce no revenue: zero percent and 100 percent. Inequality traces an analogous curve. At both extremes of inequality — either perfect inequality, where a single person receives all the income, or perfect equality, where rewards and incentives cannot exist — an economy won't function. So, Moss said, "the question is: Where are the break points in between?" Suppose various changes (globalization, technology, increased demand for skills, deregulation, financial innovation, the rising premium on superstar talent — take your pick) drove most of the economy's income gains to the few people at the top. The rich save — that is, invest — 15 to 25 percent of their income, Stiglitz writes, whereas those on the lower rungs consume most or all of their income and save little or nothing. As the country's earnings migrate toward the highest reaches of the income distribution, therefore, you would expect to see the economy's mix of activity tip away from spending (demand) and toward investment. That is fine up to a point, but beyond that, imbalances may arise. As Christopher Brown, an economist at Arkansas State University, put it in a pioneering 2004 paper, "Income inequality can exert a significant drag on effective demand." Looking back on the two decades before 1986, Brown found that if the gap between rich and poor hadn't grown wider, consumption spending would have been almost 12 percent higher than it actually was. That was a big enough number to have produced a noticeable macroeconomic impact. Stiglitz, in his book, argues that an inequality-driven shift away from consumption accounts for "the entire shortfall in aggregate demand — and hence in the U.S. economy — today." True, saving and spending should eventually re-equilibrate. But "eventually" can be a long time. Meanwhile, extreme and growing inequality might depress demand enough to deepen and prolong a downturn, perhaps even turning it into a lost decade — or two. EASY CREDIT — UH-OH So inequality might suppress growth. It might also cause instability. In a democracy, politicians and the public are unlikely to accept depressed spending power if they can help it. They can try to compensate by easing credit standards, effectively encouraging the non-rich to sustain purchasing power by borrowing. They might, for example, create policies allowing banks to write flimsy home mortgages and encouraging consumers to seek them. Call this the "let them eat credit" strategy. "Cynical as it may seem," Raghuram Rajan, a finance professor at the University of Chicago's Booth School of Business, wrote in his 2010 book, Fault Lines: How Hidden Fractures Still Threaten the World Economy, "easy credit has been used as a palliative throughout history by governments that are unable to address the deeper anxieties of the middle class directly." That certainly seems to have happened in the years leading to the mortgage crisis. Marianne Bertrand and Adair Morse, also of Chicago's business school, have found that legislators who represent constituencies with higher inequality are more likely to support the easing of credit. Several papers by International Monetary Fund economists comparing countries likewise find support for the "let them eat credit" approach. And credit splurges, they find, bring on instability and current-account deficits. You can see where the logic leads. The economy, propped up on shaky credit, becomes more vulnerable to shocks. When a recession comes, the economy takes a double hit as banks fail and credit-fueled consumer spending collapses. That is not a bad description of what happened in the 1920s and again during these past few years. "When — as appears to have happened in the long run-up to both crises — the rich lend a large part of their added income to the poor and middle class, and when income inequality grows for several decades," the IMF's Michael Kumhof and Romain RanciÃ¨re wrote, "debt-to-income ratios increase sufficiently to raise the risk of a major crisis." But wait. Which is it? Does inequality depress demand? Or does it inflate credit bubbles that maintain demand? Unfortunately, the answer can be both. If inequality is severe enough, there could be enough of it to cause the country to inflate a dangerous credit bubble and still not offset the reduction in demand. And, no, we're not finished. Inequality may also be destabilizing in another way. "Of every dollar of real income growth that was generated between 1976 and 2007," Rajan wrote, "58 cents went to the top 1 percent of households." In other words, for decades, more than half of the increase in the country's GDP poured into the bank accounts of the richest Americans, who needed liquid investments in which to put their additional wealth. Their appetite for new investment vehicles fueled a surge in what Arkansas State's Brown calls "financial engineering" — the concoction of exotic financial instruments, which acted on the financial sector like steroids. Those changes, the French economists Jean-Paul Fitoussi and Francesco Saraceno wrote in a 2010 paper, "help explain why the expansion of the financial sector was so out of touch with the economy. And why, for example, in the U.S., the financial sector represented about 40 percent of the total profit of the economy."Alas, when the recession struck, the financial sector's gigantism and complexity helped turn what might have been a brush fire into a meltdown.

#### Econ decline and collapse cause global nuclear war

Stein Tønnesson 15, Research Professor, Peace Research Institute Oslo; Leader of East Asia Peace program, Uppsala University, 2015, “Deterrence, interdependence and Sino–US peace,” International Area Studies Review, Vol. 18, No. 3, p. 297-311

Several recent works on China and Sino–US relations have made substantial contributions to the current understanding of how and under what circumstances a combination of nuclear deterrence and economic interdependence may reduce the risk of war between major powers. At least four conclusions can be drawn from the review above: first, those who say that interdependence may both inhibit and drive conflict are right. Interdependence raises the cost of conflict for all sides but asymmetrical or unbalanced dependencies and negative trade expectations may generate tensions leading to trade wars among inter-dependent states that in turn increase the risk of military conflict (Copeland, 2015: 1, 14, 437; Roach, 2014). The risk may increase if one of the interdependent countries is governed by an inward-looking socio-economic coalition (Solingen, 2015); second, the risk of war between China and the US should not just be analysed bilaterally but include their allies and partners. Third party countries could drag China or the US into confrontation; third, in this context it is of some comfort that the three main economic powers in Northeast Asia (China, Japan and South Korea) are all deeply integrated economically through production networks within a global system of trade and finance (Ravenhill, 2014; Yoshimatsu, 2014: 576); and fourth, decisions for war and peace are taken by very few people, who act on the basis of their future expectations. International relations theory must be supplemented by foreign policy analysis in order to assess the value attributed by national decision-makers to economic development and their assessments of risks and opportunities. If leaders on either side of the Atlantic begin to seriously fear or anticipate their own nation’s decline then they may blame this on external dependence, appeal to anti-foreign sentiments, contemplate the use of force to gain respect or credibility, adopt protectionist policies, and ultimately refuse to be deterred by either nuclear arms or prospects of socioeconomic calamities. Such a dangerous shift could happen abruptly, i.e. under the instigation of actions by a third party – or against a third party.

Yet as long as there is both nuclear deterrence and interdependence, the tensions in East Asia are unlikely to escalate to war. As Chan (2013) says, all states in the region are aware that they cannot count on support from either China or the US if they make provocative moves. The greatest risk is not that a territorial dispute leads to war under present circumstances but that changes in the world economy alter those circumstances in ways that render inter-state peace more precarious. If China and the US fail to rebalance their financial and trading relations (Roach, 2014) then a trade war could result, interrupting transnational production networks, provoking social distress, and exacerbating nationalist emotions. This could have unforeseen consequences in the field of security, with nuclear deterrence remaining the only factor to protect the world from Armageddon, and unreliably so. Deterrence could lose its credibility: one of the two great powers might gamble that the other yield in a cyber-war or conventional limited war, or third party countries might engage in conflict with each other, with a view to obliging Washington or Beijing to intervene.

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#### A focus on purely intent based frameworks crush our ability to respond to violence.

McCluskey 12 – JSD @ Columbia, Professor of Law @ SUNY-Buffalo (Martha, “How the "Unintended Consequences" Story Promotes Unjust Intent and Impact,” Berkeley La Raza, doi: dx.doi.org/doi:10.15779/Z381664)

**By similarly making structures of inequality appear beyond the reach of law** reform, **the "unintended consequences" message helps update and reinforce the narrowing of protections against intentional racial harm. Justice is centrally a question of whose** interests and whose **harms should count**, in what context and in what form and to whom. **Power is centrally about being able to act without having to take harm to others into account**. **This power to gain by harming others is strongest when it operates through** systems and **structures that make disregarding that harm appear** routine, rational, and beneficial or at least **acceptable** or perhaps inevitable. By portraying law's unequal harms as the "side effects" of systems and structures with unquestionable "main effects," **the** "**unintended consequences" story helps affirm the resulting harm** even as it seems to offer sympathy and technical assistance. In considering solutions to the financial market problems, the policy puzzle is not that struggling homeowners' interests are overwhelmingly complex or uncertain. Instead, the bigger problem is that overwhelmingly powerful interests and ideologies are actively resisting systemic changes that would make those interests count. The failure to criminally prosecute or otherwise severely penalize high-level financial industry fraud is not primarily the result of uncertainty about the harmful effects of that fraudulent behavior, but because the political and justice systems are skewed to protect the gains and unaccountability of wealthy executives despite the clear harms to hosts of others. **The unequal effects of** the prevailing **policy** response to the crisis **are foreseeable and obvious, not accidental or surprising**. It would not take advanced knowledge of economics to readily predict that modest-income homeowners would tend to be far worse off than bank executives by a policy approach that failed to provide substantial mortgage forgiveness and foreclosure protections for modest-income homeowners but instead provided massive subsidized credit and other protections for Wall Street. Many policy actions likely to alleviate the unequal harm of the crisis similarly are impeded not because consumer advocates, low-income homeowners, or racial justice advocates hesitate to risk major changes in existing systems, or are divided about the technical design of alternative programs or more effective mechanisms for enforcing laws against fraud and racial discrimination. Instead, the problem is that these voices pressing for effective change are often excluded, drowned out or distorted in Congress and in federal agencies such as the Treasury Department and the Federal Reserve, or in the media, in the mainstream economics profession, and to a large extent in legal scholarship about financial markets. More generally, those diverse voices from the bottom have been largely absent or marginalized in the dominant theoretical framework that constructs widespread and severe inequality as unforeseeable and largely inevitable, or even beneficial. Moreover, **justice requires careful attention to both harmful intent and to complex harmful effects**. But **the concept of "unintended consequences" inverts justice by suggesting that the best way to care** for those at the bottom **is to not care to make law more attentive** to the bottom. "**Unintended consequences" arguments promote a simplistic moral message in the guise of sophisticated intellectual critique**-the message that those who lack power should not seek it because the desire for more power is what hurts most. Further, **like Ayn Rand's overt philosophy of selfishness, that message promotes the theme that those who have power to ignore** their **harmful effects on others need not-indeed should not-be induced by law to care about this harm**, because this caring is what is harmful. One right-wing think tank has recently made this moral message more explicit with an economic values campaign suggesting that the intentional pursuit of economic equality is a problem of the immoral envy of those whose economic success proves they are more deserving.169 **Legal scholars and advocates who intend to put intellectual rigor and justice ahead of service to** financial **elites should reject stories of "unintended consequences" and instead scrutinize the power and laws that have so effectively achieved the intention of making devastating losses to so many of us seem natural, inevitable, and beneficial**.