# 1AC

### Framing

#### I affirm and value morality as implied by the word “ought” in the resolution.

#### A legitimate social and political order must require recognition of basic human rights

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[Rainer Forst, Transnational Justice, Democracy and Human Rights Draft, January 2011 <http://www.ucl.ac.uk/laws/jurisprudence/docs/2011/2011_forst.pdf>]

Human rights are essential and fundamental standards of the legitimacy of a social and political order; even though such an order is their primary context and addressee, there are a number of reasons for an international order that aims to secure these rights. But their main point remains that, insofar as these rights are to establish the core of a justified social order, their normative ground is the basic claim to be respected as an agent who has a right to justification. The logic of justification combines reflexive, procedural as well as substantive, arguments for human rights, and every such right is to be seen as a claim that cannot be reciprocally rejected between persons who recognize that they owe one another a legal and political protection of their right to be a socially and politically autonomous agent of justification. Rights have to be understood horizontally, so to speak, as reciprocally justified and binding claims to a certain moral, as well as a legal, a political, and a social, status. They express forms of mutual recognition, and in their concrete form they are results of procedures of discursive construction. Rights are not goods received from some higher authority; rather, they are expressions of reciprocal respect between persons who accept that, whatever form these rights take, everyone to whom they apply has a basic right to be an agent of justification, such that no set of rights can be determined without adequate justification. The view I have explained is at odds with two rival ones. The first is a teleological view which grounds human rights in basic interests in well-being and derives basic rights to certain protections and realizations of these interests from them. The second regards human rights as having primarily a legal international existence, leaving their moral justification open. It seems to me these two views downplay the social and political point of human rights. They are not simply means to achieve or enjoy certain goods, and they are not primarily means to evaluate social structures from the outside in the international arena; rather, they are autonomous achievements of those who regard themselves and others as agents who resist being “mere” subjects of norms or institutions that are not responsive towards them. Their basic claim is one of status, but of a dynamic kind, namely no longer to be treated as a justificatory nullity, and thus the claim to “count” socially and politically. Rights confer upon agents social and political power, in the sense of “normative power”: the power to codetermine the conditions of one's social and political life. Human beings have a claim to such power, and human rights are a way to express that.

#### Thus, the standard is respecting human rights

#### Health is a basic human rights that private corporations must think about and maximize as well. Ahmadiani and Nikfar ‘16

[Ahmadiani, Saeed, and Shekoufeh Nikfar. “Challenges of access to medicine and the responsibility of pharmaceutical companies: a legal perspective.” Daru : journal of Faculty of Pharmacy, Tehran University of Medical Sciences vol. 24,1 13. 4 May. 2016, doi:10.1186/s40199-016-0151-z]kitkat

Previously in 2000, United Nations established eight goals as Millennium Development Goals and 190 countries agreed to help to achieve these goals by 2015. **At least three of these goals- reduction of child mortality, improve of maternal health, and combating HIV/AIDS, malaria, and other diseases- are extremely dependent on accessible and affordable medicine.** Even the role of pharmaceuticals is clearly mentioned in the millennium declaration: “Develop a global partnership for development- In co-operation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries; proportion of population with access to affordable essential drugs on a sustainable basis” [15]. The strong influence of pharmaceutical companies on accessibility and affordability of medicine is clear. But should they be responsible for the realization of access to medicines? As first point, health is considered as a basic human right, as it is stated in article 12 of International Covenant on Economic, Social and Cultural Rights, “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” [16]. And we should beware that, according to UN, the responsibilities which are stated in human rights declaration are not solely an obligation for the member states, but the private sector is equally subjected to human rights responsibilities [17].

#### Prefer this standard:

#### [1] Topic Literature – WTO member states and the discussion of medical patents are inexplicably tied to human rights – human rights in developing countries, to be more specific – prefer our fw for education. Cullet ‘03

[Phillipe Cullet, “Patents and medicines: the relationship between TRIPS and the human right to health”, International Affairs 79 I (2003), 139-160]kitkat

**The link between medical patents and the human right to health has become a subject of central concern at the international level, as exemplified by the debates at the 2001 World Trade Organization (WTO) ministerial conference.** 1 International attention to the issue has focused in large part on the HIV/AIDS crisis and the question of access to drugs for patients in developing countries, which are the most severely affected by the epidemic. 2 **The issue of access to drugs is acute in the case of HIV/AIDS but is of general concern in most developing countries**. From a legal perspective, two main areas of law are relevant in current debates. First, the question of access to medicines is a central issue in any consideration of the human right to health. Human rights law, in particular through the Covenant on Economic, Social and Cultural Rights, has made a significant contribution to the codification of the human right to health and our understanding of its scope. 3 Second, **debates on access to drugs are now strongly linked to the questions of whether drugs can, and should, be patentable**. The increasing scope of patentability in the health sector, codified in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), constitutes one of the most significant changes in law for developing countries that are WTO members. 4

#### [2] Solvency – only a HR approach can effectively question the validity of the intellectual property rights. Cullet ‘03

A human rights perspective on health neither entails an a priori rejection of all intellectual property rights in the field of health nor provides another avenue for developing countries to claim preferential treatment. However, **it does call into question some of the tenets of intellectual property law.** As noted**, patent protection does not ensure that the most common diseases will attract the most research even though it entails higher drug prices.** This implies that even if patent protection can be justified in markets where all consumers can afford to pay (directly or indirectly) the price of patented drugs, this is not so in other situations. While there is a general divide between developed and developing countries with regard to the issues of drug prices and the development of medicines directly related to developing country diseases, a human rights approach to health is not strictly concerned with the level of economic development of countries. **What is more fundamental from a human rights perspective is a focus on the most disadvantaged and marginalized individuals and communities.** While human rights are universal entitlements, their effective realization is to be judged against the level of implementation among the most disadvantaged. The issue is therefore not whether developing countries can afford patent rights in general, but whether the majority of their poor population will benefit. 92 **One of the first steps in tackling the problems faced by the most disadvantaged sections of society would be to make sure that all essential medicines remain free from patent protection. This conceptual framework is what informed the 1970 Indian Patents Act, which rejected product patents on drugs, and, to a more limited degree, the Brazilian decree on compulsory licensing, which seeks to provide an extensive definition of the public interest.** 93

#### [3] People have a cognitive bias towards specific link chains. You should evaluate link chain scenarios as innately less probable than broad, nonlinear impacts like human rights violations. Yudkowsky 6

Eliezer Yudkowsky, 8/31/2006. Singularity Institute for Artificial Intelligence Palo Alto, CA. “Cognitive biases potentially affecting judgment of global risks, Forthcoming in Global Catastrophic Risks, eds. Nick Bostrom and Milan Cirkovic, singinst.org/upload/cognitive-biases.pdf

4. The Conjunction Fallacy Linda is 31 years old, single, outspoken, and very bright. She majored in philosophy. As a student, she was deeply concerned with issues of discrimination and social justice, and also participated in anti-nuclear demonstrations. Rank the following statements from most probable to least probable: 1. Linda is a teacher in an elementary school. 2. Linda works in a bookstore and takes Yoga classes. 3. Linda is active in the feminist movement. 4. Linda is a psychiatric social worker. 5. Linda is a member of the League of Women Voters. 6. Linda is a bank teller. 7. Linda is an insurance salesperson. 8. Linda is a bank teller and is active in the feminist movement. 89 of 88 undergraduate subjects ranked (8) as more probable than (6) (Tversky and Kahneman 1982). Since the given description of Linda was chosen to be similar to a feminist and dissimilar to a bank teller, (8) is more representative of Linda’s description. However, ranking (8) as more probable than (6) violates the conjunction rule of probability theory which states that p(A and B) \_ p(A). Imagine a sample of 1,000 women; surely more women in this sample are bank tellers than are feminist bank tellers. Could the conjunction fallacy rest on subjects interpreting the experimental instructions in an unanticipated way? Perhaps subjects think that by “probable” is meant the probability of Linda’s description given statements (6) and (8), rather than the probability of (6) and (8) given Linda’s description. Or perhaps subjects interpret (6) to mean “Linda is a bank teller and is not active in the feminist movement.” Although many creative alternative hypotheses have been invented to explain away the conjunction fallacy, the conjunction fallacy has survived all experimental tests meant to disprove it; see e.g. Sides et al. (2002) for a summary. For example, the following experiment excludes both of the alternative hypotheses proposed above: Consider a regular six-sided die with four green faces and two red faces. The die will be rolled 20 times and the sequence of greens (G) and reds (R) will be recorded. You are asked to select one sequence from a set of three and you will win $25 if the sequence you chose appears on successive rolls of the die. Please check the sequence of greens and reds on which you prefer to bet. 1. RGRRR 2. GRGRRR 3. GRRRRR 125 undergraduates at UBC and Stanford University played this gamble with real payoffs. 65 of subjects chose sequence (2) (Tversky and Kahneman 1983). Sequence (2) is most representative of the die, since the die is mostly green and sequence (2) contains the greatest proportion of green faces. **However, sequence (1) dominates sequence (2) because (1) is strictly included in (2), to get (2) you must roll (1) preceded by a green face**. In the above task, the exact probabilities for each event could in principle have been calculated by the students. However, rather than go to the effort of a numerical calculation, it would seem that (at least 65 of) the students made an intuitive guess, based on which sequence seemed most “representative” of the die. Calling this “the representativeness heuristic” does not imply that students deliberately decided that they would estimate probability by estimating similarity. Rather, the representativeness heuristic is what produces the intuitive sense that sequence (2) “seems more likely” than sequence (1). In other words the “representativeness heuristic” is a built-in feature of the brain for producing rapid probability judgments rather than a consciously adopted procedure. We are not aware of substituting judgment of representativeness for judgment of probability. The conjunction fallacy similarly applies to futurological forecasts. Two independent sets of professional analysts at the Second International Congress on Forecasting were asked to rate, respectively, the probability of “A complete suspension of diplomatic relations between the USA and the Soviet Union, sometime in 1983” or “A Russian invasion of Poland, and a complete suspension of diplomatic relations between the USA and the Soviet Union, sometime in 1983.” The second set of analysts responded with significantly higher probabilities (Tversky and Kahneman 1983). In Johnson et al. (1993), MBA students at Wharton were scheduled to travel to Bangkok as part of their degree program. Several groups of students were asked how much they were willing to pay for terrorism insurance. One group of subjects was asked how much they were willing to pay for terrorism insurance covering the flight from Thailand to the US. A second group of subjects was asked how much they were willing to pay for terrorism insurance covering the round-trip flight. A third group was asked how much they were willing to pay for terrorism insurance that covered the complete trip to Thailand. These three groups responded with average willingness to pay of $17.19, $13.90, and $7.44 respectively. According to probability theory, adding additional detail onto a story must render the story less probable. It is less probable that Linda is a feminist bank teller than that she is a bank teller, since all feminist bank tellers are necessarily bank tellers.Yet human psychology seems to follow the rule that adding an additional detail can make the story more plausible. People might pay more for international diplomacy intended to prevent nanotechnological warfare by China, than for an engineering project to defend against nanotechnological attack from any source. The second threat scenario is less vivid and alarming, but the defense is more useful because it is more vague. More valuable still would be strategies which make humanity harder to extinguish without being specific to nanotechnologic threats—such as colonizing space, or see Yudkowsky (2008) on AI. Security expert Bruce Schneier observed (both before and after the 2005 hurricane in New Orleans) that the U.S. government was guarding specific domestic targets against “movie-plot scenarios” of terrorism, at the cost of taking away resources from emergency-response capabilities that could respond to any disaster (Schneier 2005). Overly detailed reassurances can also create false perceptions of safety: “X is not an existential risk and you don’t need to worry about it, because A, B, C, D, and E”; where the failure of any one of propositions A, B, C, D, or E potentially extinguishes the human species. “**We don’t need to worry about nanotechnologic war, because a UN commission will initially develop the technology and prevent its proliferation until such time as an active shield is developed, capable of defending against all accidental and malicious outbreaks that contemporary nanotechnology is capable of producing, and this condition will persist indefinitely.”** Vivid, specific scenarios can inflate our probability estimates of security, as well as misdirecting defensive investments into needlessly narrow or implausibly detailed risk scenarios. More generally, people tend to overestimate conjunctive probabilities and underestimate disjunctive probabilities (Tversky and Kahneman 1974). That is, people tend to overestimate the probability that, e.g., seven events of 90 probability will all occur. Conversely, people tend to underestimate the probability that at least one of seven events of 10 probability will occur. Someone judging whether to, e.g., incorporate a new startup, must evaluate the probability that many individual events will all go right (there will be sufficient funding, competent employees, customers will want the product) while also considering the likelihood that at least one critical failure will occur (the bank refuses a loan, the biggest project fails, the lead scientist dies). This may help explain why only 44 of entrepreneurial ventures2 survive after 4 years (Knaup 2005). Dawes (1988, 133) observes: “In their summations lawyers avoid arguing from disjunctions (‘either this or that or the other could have occurred, all of which would lead to the same conclusion’) in favor of conjunctions. Rationally, of course, disjunctions are much more probable than are conjunctions.” The scenario of humanity going extinct in the next century is a disjunctive event. It could happen as a result of any of the existential risks we already know about—or some other cause which none of us foresaw. Yet for a futurist, disjunctions make for an awkward and unpoetic-sounding prophecy.

### Adv

#### Lack of equitable access is a violation of established IHRL- millions across the world cannot afford basic drugs due to high prices, violating their right to health and life

Bhatt, 8 -- member at Landman Corsi Ballaine & Ford

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

I. THE NEED FOR CHANGE

A. The Current Lack of Access

Eighty percent of people in low- and middle-income countries that need antiretroviral therapy (“ART”) to treat HIV/AIDS do not have access to it.27 Eighty-three percent of sub-Saharan Africans and ninety-five percent of northern Africans and Middle Easterners do not receive needed medicines.28 In East, South, and Southeast Asia, eighty-four percent of those requiring ART do not receive it. In low- and middle-income countries in Europe and Central Asia, eighty-seven percent do not receive ART.29 In Latin America and the Caribbean, ART coverage is better but still inadequate at sixty-eight percent.30

While these statistics represent the situation in a substantial part of the world, they do not represent what the standard of care can be, especially considering that ART coverage in high-income countries, such as the United States, the United Kingdom, and France reaches above seventyfive percent.31 Also disconcerting is the fact that access to treatment is uneven between similarly situated countries. For example, Thailand’s coverage reaches up to sixty percent32 while in India, ART is accessible to a mere seven percent of those that need it.33 Botswana and Uganda have over fifty percent coverage while coverage in other sub-Saharan countries is well below ten percent.34

One reason why essential medicines are not reaching all who need them is their high price.35 Though prices have dropped over the last few years in some low-income countries, they remain “unacceptably high in some countries” and have remained “almost stable” in middle-income countries.36 Additionally, drugs that have decreased in price represent mostly first-line treatment37 while second-line treatment (used after patients develop immunities to first-line drugs 38) costs are “prohibitive” in most countries 39 and vary greatly amongst countries of similar income level.40

Brazil, where ART coverage is at eighty-three percent,41 presents a prime example of the dramatic effect drug prices have on access to treatment. Brazil was the first developing nation to provide universal free AIDS treatment and has “the best anti-AIDS program of any developing country.”42 It has been able to afford this by manufacturing generic versions of brand name drugs, thus reducing costs by up to almost half.43

Generic manufacturers have been identified favorably as contributing to the price drops that have occurred within the last few years.44 Moreover, in addition to making cheaper and therefore more accessible drugs, generic manufacturers are better able to serve the treatment needs of individuals in middle- and low-income countries because they provide drugs in therapy combinations not supplied by brand-name manufacturers.45

B. The Right to Health: Legal Ramifications of Inadequate Access

That treatments for HIV/AIDS are available yet so many cannot access them is a great social tragedy. However, it is also a legal dilemma. On December 12, 1948, the General Assembly of the United Nations adopted the Universal Declaration of Human Rights (“UDHR”).46 From this list of principles emerged two binding treaties: the International Covenant on Civil and Political Rights (“ICCPR”)47 and the International Covenant on Economic, Social and Cultural Rights (“ICESCR”).48 These three documents together constitute the International Bill of Human Rights and have enabled the modern day human rights movement.49 They also officially established every individual’s right to health, thus making access to treatment for medical illness a human rights and international law issue.

Article 25.1 of the UDHR proclaims that “[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.”50 This concept is comprehensively enshrined in and given binding effect by article 12 of the ICESCR. Section 1 of the article defines the right and section 2 lays out the correlative governmental obligations to protect the right by providing an “illustrative, nonexhaustive” list of examples.51 Article 12 reads in relevant part:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

. . .

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions, which would assure to all medical service and medical attention in the event of sickness.52

The right to health is also recognized in various other international and regional agreements.53 None of these documents explicitly grant a right of “access to pharmaceuticals,” however, the language of the provisions clearly contemplates access to essential medicines and article 25 has been interpreted to include such a right.54 Moreover, other rights also imply a right of access to pharmaceuticals. The UDHR states that everyone has the right to “share in scientific advancement and its benefits.”55 The ICESCR confers on everyone “the right to enjoy the benefits of scientific progress and its applications.”56 There is also the right to life itself,57 to which the right to health is regarded as “closely related” and “dependent upon.”58

Finally, access to essential medicines is acknowledged as a legitimate and important concern in non-human rights contexts as well. The WTO has most prominently addressed the issue.59 The World Bank has issued statements recognizing its importance.60 Even the World Intellectual Property Organization (“WIPO”),61 which downplays both the impact of patent protection on drug prices and the impact of drug prices on access to drugs, acknowledges the importance of striking a balance between health concerns such as access to medicine and the benefits of a robust patent regime.62

Despite the fact that the concept has been a part of the human rights movement for quite some time and is recognized in a number of instruments, the right to health does not enjoy the same legal force as rights that are considered “fundamental,” such as rights protecting against torture and genocide. There are a number of reasons for this. First, the right to health suffers from a degree of “conceptual unclarity.”63 Although certain core concepts, including access to essential medicine, have emerged over the years,64 “[i]t is difficult to pinpoint exactly what the right to health contains. Health is a very broad and subjective concept . . . [and] there exists a certain normative overlap with other human rights . . . .”65

Second, the right to health is different from other human rights in that it is subject to progressive realization over time.66 However, “[r]ecognition of core content underlines the fact that some elements are not subject to progressive realization and should be realized immediately, a notion which makes the right to health more tangible.”67 Additionally, the right to health does impose an immediate obligation to take meaningful steps towards its fulfillment.68 Finally, there is a presumption that the right prohibits states from taking steps that would undermine progress towards its realization69 as well as an obligation to “refrain from interfering directly or indirectly with the enjoyment” of it.70

Another challenge is that the right to health is not universally binding. One hundred fifty-seven countries have ratified the ICESCR.71 Thus, five countries, including the United States, are not bound to its expression of the right to health.72 Moreover, the right to health does not enjoy the status of customary international law,73 which would be binding on the United States in certain contexts despite the absence of a formal recognition of the right.74 Additionally, unlike the ICCPR, there currently is no formal system in place for adjudicating violations of the ICESCR.75 Fi-nally, many governments are ambivalent or hostile to economic and social rights generally in part because they believe civil and political rights are more basic and urgent and should be prioritized.76

The fact that the right to health is a progressive right, lacks binding force, and struggles along with other economic and social rights to be taken seriously leaves individuals hoping to assert it with no venue to challenge general violations. However, as will be argued in Part II of this Note, the access to essential medicines component of the right to health is now ripe for elevation to customary international law. Assigning such status to the access issue is a step towards judicial enforcement.

C. The Legal Dilemma: The Conflict between Intellectual Property Rights and Health Rights

Another issue that complicates the realization of the right to health is that, like all rights, it competes and conflicts with other rights. Often, these other rights are more widely accepted and are supported by a much more robust jurisprudence consisting of generations of statutes, treaties, and case law.77 It is, in a sense, an uneven fight. Consequently, right to health issues are not prioritized.78 The right to access to essential medicines, in particular, is in direct competition most significantly with patent rights.

Unlike the right to health, patent rights are longstanding79 and universally accepted.80 They are a component of intellectual property rights81 and give inventors the ability to legally exclude others from profiting from their innovations.82 The theory of patent rights is based on the premise that inventions are “public goods that are costly to make and that are difficult to control once they are released into the world.”83 Thus, patent rights provide the economic incentive necessary to spur invention by giving inventors the ability to take legal action against those that attempt to profit from the their invention, whether by stealing it, reverse engineering it, or discovering it independently.84

Patent protection directly conflicts with access to essential medicine because it prevents the production and sale of generic versions of patented drugs.85 Generic drugs significantly increase the accessibility of medicine because they are cheaper than the patented brand name versions. “It is well documented that drug prices drop when countries promote the use of generics, abolish patents, or impose direct price controls.”86

At the international level, the production of generic drugs was primarily impeded by TRIPS, an agreement passed in 1994 by the WTO.87 The agreement “brings together . . . a broad range of intellectual property rights (“IRPs”) previously protected by subject-specific agreements”88 and is “the first significant multilateral agreement requiring member countries to provide certain minimum levels of protection to owners of intellectual property.”89 It also contains an enforcement mechanism. A state party alleging violations of the agreement by another state party may have its claim adjudicated by WTO dispute settlement procedures.90 Member states that fail to comply with the provisions of the agreement may be subject to trade sanctions.91 Additionally, TRIPS requires member states to maintain both civil and criminal enforcement procedures within their own borders to protect individual rights holders.92 Currently, 151 countries are members of the WTO and TRIPS.93

Part II, section 5 of TRIPS governs patents. It sets the minimum substantive protections that all member governments must provide to eligible innovations and provides criteria that tightly control the circumstances under which derogation of patent rights is permitted.94 Under article 27, pharmaceutical drugs are generally eligible for patent protection.95 However, products must be new and innovative in order to receive protection.96 Article 28 defines the patent holder’s rights. These include the right to exclude third parties from making, using, selling, or importing the patented product or process without consent97 as well as the right to assign, transfer, and license the patent.98 Under article 33, the patent holder has the right to exercise these rights for a term of twenty years.99 Article 30 allows the government of a member state to limit a patent holder’s right to exclude other generic manufacturers “provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”100

Under article 27, a member government is permitted to deny a patent to an otherwise eligible invention if preventing the commercialization of the invention “is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment . . . .”101 This provision is known as the public health exception.102 Article 31 establishes parameters under which a member government may exercise the public health exception by breaking a pharmaceutical drug patent, also known as compulsory licensing.103 The decision to break a patent in this manner must be made on a case-bycase basis.104 Additionally, the patent can only be broken for a limited scope and duration.105 The majority of the goods produced as a result of the patent break must be used domestically106 and thus they cannot be exported to another country.107 The member government must also pay the patent holder remunerations if it breaks the patent.108

These mechanisms that allow member governments to loosen patent protection in cases of national emergencies are commonly referred to as “flexibilities.”109 The flexibilities make TRIPS compatible with an international patent system that adequately balances patent interests with the need for access to essential medicines. The system was able to address the concerns of the pharmaceutical industry 110 while allowing member governments the ability to modify their patent rules where necessary to secure the citizens’ right to health.

Unfortunately, these flexibilities proved unsuccessful. Despite the inclusion of a public health exception in TRIPS, patent protection still prevented access to essential medicine. The TRIPS flexibilities were underutilized because they were unclear and developing nations feared retaliation from other countries if they invoked them.111 For example, when South Africa attempted to invoke the flexibilities for patented AIDS drugs, forty-two pharmaceutical companies filed suit alleging violation of TRIPS and the United States Trade Representative (“USTR”)112 pressured the South African government to maintain normal patent protection.113

Another problem with the public health exception was the “Paragraph 6 Problem,” a reference to TRIPS article 31(f) (the sixth paragraph of article 31).114 As discussed above, article 31(f) requires that goods produced pursuant to compulsory licensing115 be used “predominantly for the domestic market.”116 The problem with this provision is that many countries able to efficiently to produce generic drugs117 could not export them to countries that needed cheaper versions but lacked the infrastructure and industry to produce them domestically.118 “Thus, for a state lacking a drug manufacturing base, the ability to issue a compulsory license [was] largely academic.”119 Others have argued that the language of TRIPS itself does not impede access as much as the power disparity between developed and developing nations.120

#### TRIPS currently allows for countries to put profit over the lives of their citizens. Oh ‘00

[Oh C. TRIPS and pharmaceuticals: A Case of Corporate Profits Over Public Health. Editorial. Third World Network]kitkat

A **key factor in determining the cost of a particular drug is the patent on it.** Of the 50% of the patients in developing countries who lack access to essential drugs, many die because the drugs are patented and therefore too expensive. **These patented drugs include treatment for tuberculosis and AIDS as well as the Hepatitis-B vaccine**. Public health activists and consumer groups warn that the World Health Organisation (WHO) estimates - **one third of the world's population lacks access to essential drugs** - will further **increase**. They are concerned that World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (which developing countries have to implement as of 1 January 2000) will give rise to factors that will put access to essential drugs and healthcare out of the reach of millions of people in developing countries. The problem with TRIPS 'We went to Geneva where we presented (our) document to the staff of the GATT Secretariat. What I have described to you is absolutely unprecedented in GATT. Industry has identified a major problem in international trade. It crafted a solution, reduced it to a concrete proposal and sold it to our own and other governments ... The industries and traders of world commerce have played simultaneously the role of patient, the diagnostician and the prescribing physician.'(b) The above is a quote from an industry representative, describing the role of industry in formulating the TRIPS Agreement. It is therefore not surprising that **commentators describe the negotiation of the TRIPS Agreement as one that was forced by the developed countries against objections from many developing countries.** The aim was to universalise the standards of intellectual Property Rights (IPRs) protection that developed countries had already incorporated within their legal systems.(c) Thus, the TRIPS Agreement now requires all WTO members to adapt their laws to the minimum standards of IPRs protection. During the 1980s, the gradual erosion of the developed countries' supremacy in manufacturing and technology, due to the rise of the Asian countries as competitors, was a cause for concern. The industrial lobbies convinced developed-country governments on the need to link trade with IPRs, in order to prevent imitation and to increase returns on research and development. Monopoly rights granted by IPRs were regarded as crucial to prevent the developing countries from further undergoing the 'catching-up' process towards industrialisation based on imitating and copying technologies, as the developed countries themselves had done. In other words, IPR protection was a tool to guarantee the comparative advantage that had so far ensured the developed countries' technological supremacy.(d) Problems for developing countries Prior to the negotiation of the TRIPS Agreement, over 50 countries (including developed countries) did not confer patent protection on pharmaceuticals.(e) Many developing countries regarded the absence of protection as necessary to promote access to drugs at competitive prices. Therefore, conforming to TRIPS provisions by recognising and strengthening protection of IPRs on pharmaceutical products and processes will cause problems for developing countries. Implementation of the TRIPS Agreement may lead to high drug prices, low access and a weakening of national pharmaceutical industries(f), due to factors described below. Twenty-year protection: The minimum term of 20-year patent protection required by the TRIPS Agreement effectively allows a pharmaceutical company a monopoly over its patented drug. Free from competition, the company will be able to keep the price of the drug high during the protection period. By virtue of TRIPS protection, no generic equivalent can come into the market until expiry of the 20 years, **denying patients cheaper alternatives.** Product and process patents: The TRIPS Agreement extends the scope of patent protection to both products and processes. Product patents provide for absolute protection of the product, whereas process patents provide protection in respect of the technology and method of manufacture. A process patent system promotes a more competitive environment and a check on prices, as compared to the monopoly system created through product patents. With the TRIPS requirement for both product and process patents, it will therefore be possible to apply for patent rights over a product for 20 years, and thereafter, further periods of protection could be applied for the processes by which the product is produced.(g) Some experts also caution that the 20-year protection can be (ab)used to extend the monopoly through process patents as well as patents on usage form, dosage form and combination form. In the US, for example, patents have been taken on new combinations of drugs even when the product patent on the basic drug - the active ingredient - has long expired.(h) Monopoly protection would be extended through minor changes to the existing medicines where the product patents have expired. Threat to domestic pharmaceutical industry: Developing-country pharmaceutical producers will find themselves pushed out of the market, having to compete with the large transnational corporations (TNCs). For the smaller producers in the developing world which specialise in and depend on manufacturing cheaper generic alternatives, this would no longer be possible (until the expiry of the 20-year period). The TRIPS Agreement further requires patents to be granted regardless whether the products are imported or locally produced.(i) This means that patent holders can merely import their product, without having to work the patent in the country granting the right. This will mean that a TNC can supply global markets under the patent monopoly, exporting the finished product instead of transferring technology or making foreign direct investment.(j) This rubbishes TRIPS supporters' argument that strict patent regimes will increase the flow of technology and investment into developing countries. Overriding patent rights Notwithstanding the above, some provisions in the TRIPS Agreement do provide certain exceptions to patent protection of pharmaceuticals. Parallel imports: Parallel importing is a means by which developing countries could lower drug prices. Where there are price differences for the same product in different markets, it is possible to import the product from the cheaper market for resale. The principle of IPR exhaustion allows any interested party from country A to purchase a product legally sold in country B for resale in Country A, without the consent of the patent holder. Compulsory licensing: The use of compulsory licences is not prohibited by the TRIPS Agreement, although it is not specifically referred to in the agreement. The government or court of law may grant a licence to a third party to use a patent, without the patent holder's consent, under specified conditions, such as in cases of national emergency or extreme urgency, or to remedy anti-competitive practices.(k) **Experts consider compulsory licensing a crucial element in increasing the affordability and availability of drugs, while ensuring that the patent holder is compensated for the use of the patent.** Battle lines drawn ... But **some developing countries have been reluctant to use these options for fear of trade sanctions by the developed countries.** A report from Medecins sans Frontieres (MSF) details the US government's pressure on Thailand to restrict its use of parallel imports and compulsory licences. The Thai government passed a law banning parallel imports in 1992, under the threat from the US to limit textile imports (parallel imports are allowed again after amendments to the patent law which came into force in 1999).(l) Although patent law in Thailand provides for compulsory licensing, MSF reports that the Thai government - this time under threat of high tariffs on imports of wood products and jewellery - passed ministerial regulations in 1998 to restrict the use of compulsory licences.(m) **Without the life-prolonging AIDS drugs, hundreds of thousands of people in Thailand will die. Already 300,000 have died.** AIDS activists and health experts have criticised the pharmaceutical companies for the lack of action on their previous pledge to reduce drug prices. They insist that one crucial method of improving access to drugs is compulsory licensing, and have condemned the US government's policy of protecting big business over people's lives. When the South African government sought to enact the Medicines and Related Substances Control Bill, the US government accused it of failing to adequately protect American drug patents. The US objection was directed at provisions in the law which would allow for compulsory licences and parallel importing. Despite the considerable pressure exerted on the government and Parliament of South Africa, the bill was passed in 1997.(n) The pharmaceutical industry in South Africa, backed by the TNCs and the pharmaceutical lobby in the US, filed a legal challenge to the new law. The US government, taking its cue from its pharmaceutical lobby, began a process of negotiations and threats to get the South African government to change its stance. It was only after intense campaigning by AIDS and health activists - successfully embarrassing Presidential candidate Al Gore and marring his campaign efforts - that the US retreated from its position and eventually reached a resolution of the matter. From reports, it is understood that South Africa has made clear its intention to use compulsory licensing and parallel importing in a TRIPS-compliant manner, and that the offending provisions in the act remain.(o) These incidents of unilateral pressure have provoked outrage from many developing countries. Commentators also point to the irony of the situation. The US, like most developed countries, provides for compulsory licensing in its national laws. The US also grants perhaps the largest number of compulsory licences (more than a hundred such licences have been granted) to address anti-competitive practices and for government uses. It would appear that in the battle between the right to health and the right to monopolies and profits, the battle lines have been drawn between countries of the South on one side, and the Northern governments and their industrial lobbies on the other. ... at the World Summit for Social Development The North-South battle lines were clearly drawn during the recent UN World Summit for Social Development, held in Geneva.(p) The G77 group of developing countries had proposed to exclude essential and life-saving medicines from patentability, in order to ensure access to such medicines. The developed countries - including the US, the EU, Canada and Japan - vehemently rejected this proposal, citing the need for patents to stimulate research and development. In response to Canada's call to delete the proposal, the South African delegate had said: 'When you are going to lose 25% of your productive work force due to HIV/AIDS, you cannot be so blasé with your comments'.(q) The final agreed text does not include the G77 proposal to exclude essential medicines from patentability, but affirms countries' right to 'freely exercise' their legal options in an unrestricted manner. This was a reference to the pressure exerted by the US and its pharmaceutical lobby on developing countries not to exercise their option to take measures (such as compulsory licensing and parallel imports) already available to them under the TRIPS Agreement to ensure access to essential medicines. Although some experts are of the opinion that this does not represent any change in terms of the developing countries' obligations to implement the WTO agreements, others believe that it is a point well worth making. It represents a moral victory for the developing countries, and it should also be seen as the first step to the real battle in the WTO. ... and at the WTO The exclusion of essential drugs from patenting is expected to be discussed in the WTO, in the context of 'implementation issues'. During preparations for the WTO's Third Ministerial Conference, which took place in Seattle on 30 November - 3 December 1999, many developing countries raised the issue of the imbalances and inequities inherent in the WTO agreements. The developing countries had expressed dismay that having seen little of the benefits of the Uruguay Round (of trade negotiations which resulted in the establishment of the WTO), they were now being pressured to bear the considerable burden of implementing their onerous obligations. With respect to the TRIPS Agreement, developing countries were concerned over the costs and the socio-economic and developmental implications of establishing the strict IPR regimes required. In this connection, developing countries had tabled proposals for the reform of the TRIPS Agreement. Of relevance is a joint submission from the Like-Minded Group of developing countries (comprising Cuba, the Dominican Republic, Egypt, El Salvador, Honduras, India, Indonesia, Malaysia, Nigeria, Pakistan, Sri Lanka and Uganda), which proposed that 'the list of exceptions to patentability in Article 27.3(b) of the TRIPS Agreement shall include the list of essential drugs of the World Health Organisation'. This proposal has yet to be considered, given the failure of the Seattle Ministerial Conference to conclude with any decisions. In the meanwhile, the WTO General Council, in a Special Session, has agreed on a work programme to address the 'implementation issues' raised. During the first Special Session (23 June and 3 July 2000), some of the implementation issues and proposals raised by the developing countries were discussed, including the proposal for exclusion of essential drugs from patentability. The Special Session is scheduled to meet again in October 2000.

#### **IPR enables big pharma to keep medicine inaccessible.**

Chaudhry '20 (Faisal Chaudhry; Professor of Law, University of Dayton; 1-28-2020; "A secret reason Rx drugs cost so much: A global web of patent laws protects Big Pharma"; https://theconversation.com/a-secret-reason-rx-drugs-cost-so-much-a-global-web-of-patent-laws-protects-big-pharma-122028, Conversation, accessed 7-30-2021; JPark)

Scientists working in Canada’s public sector discovered insulin nearly a century ago. The first techniques for synthesizing the compound, which should have more readily allowed for the production of generic versions, emerged some four decades ago. Yet today insulin remains unavailable in any significant generic version. Political analysis, without partisanship One of the three companies that control 90% of the world insulin market, Eli Lilly, recently did bow to public pressure by announcing a forthcoming “authorized generic” version called Lispro. But that could still run some people $140 per prescription. U.S. consumers are not alone in facing high prices of insulin and other life-saving drugs. For the last two decades, intense controversy has raged around multinational pharmaceutical giants being able to monopolize access to vital medicines the world over. A key means of doing so is through the legal power of patents, and the monopoly-like profits – or what some experts call unearned economic rents – they guarantee. Think of rent as a windfall gained for making little effort of one’s own. Being “unearned,” rents are thus usually distinguished from ordinary business profits. In this way, they are comparable to the fees a medieval lord would charge for access to cropland on a vast estate. To fully explain the problem of economic rents and access to medicines, however, we need to look still further: to the controversies that have swirled around pharmaceutical patents in countries far less wealthy than the U.S. A worldwide problem, but hidden from sight **For more than 20 years, in various parts of Africa, Asia and Latin America, countries have been battling a global system of rent-taking, or “rentierism” for short, that disproportionately benefits Big Pharma.** This state of affairs could not exist without the government officials whom Big Pharma has lobbied successfully in wealthy countries. **Patents and other intellectual property rights allow the multinationals to capture rent by evading competition for years on end. This global battle around pharmaceutical patents began in earnest with the founding of the World Trade Organization(WTO) in 1994.** This included an annex agreement on intellectual property rights known as the Trade-Related Aspects of Intellectual Property Rights. Many countries already allowed for patents before 1994, but only on “processes” of manufacture or synthesis. After 1994, WTO member countries were required to extend patents to the vital end products of such processes as well. For inhabitants of developing countries, whose greatest public health problems at the time derived from diseases like malaria, tuberculosis and HIV-AIDS, this crystallized various questions of great import. **Should the agreements enable Big Pharma’s monopoly-like patent rights to trump the ability of the sick and dying to obtain generic versions of life savings medicines?** And if so, to what extent? By 2001, all WTO member states officially had conceded the rights of developing countries to take measures to increase access to lifesaving medicines. But Big Pharma and its allies have never relented in pressing for more, not less, stringent intellectual property protections around the world.

### Plan

#### The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by defining the term “essential medication” in TRIPS as medicines that are needed in countries around the world to save lives and removing intellectual property protections for essential medications.

#### Defining the term essential medications solves, decreases the human rights violations around the globe, and does not decrease innovation. Subhan ‘06

[Subhan, Junaid. “Scrutinized: the TRIPS agreement and public health.” McGill journal of medicine : MJM : an international forum for the advancement of medical sciences by students vol. 9,2 (2006): 152-9.]kitkat

Patents can be applied to a wide variety of technologies; from the most complex and sophisticated piece of computer software to the most mundane hinge, nut or bolt. Even within the pharmaceutical industry, products under patent vary greatly. With this immense variance, should a patent on a drug for AIDS be treated in the same way as a patent on a drug for erectile dysfunction or high cholesterol? A **wide array of drugs are developed and manufactured by pharmaceutical companies and the TRIPS agreement must differentiate between patents for Viagra and patents for Efavirenz.** It is reasonable to demand full 20-year intellectual property protection for “chemical toys” (17) but when it comes to life-saving essential medications certain concessions in favour of the promotion of public health must be made. **The term “essential medication” should be defined under the TRIPS agreement, not in reference to a list of diseases, as has been proposed in the past (18), but rather as a general description of what constitutes the difference between an essential and a non-essential drug.** Possible criteria for inclusion into such a category would be: availability of alternative treatment, severity of the disease the medication is aimed at treating, and the capacity of the patent-holder to adequately supply markets that demand the patented product. For separate definitions to be beneficial though, separate provisions should be made where appropriate. Ideally, two separate sets of patent legislation would exist in parallel; one applying to medications deemed essential and another applying to non-essential medications. By creating separate categories of drugs, the TRIPS Agreement can more properly balance intellectual property protection of drugs with their purpose of healing as many of the ill as possible. Such a system can encourage innovation by increasing the potential rewards of a successful discovery of a non-essential medication. Simultaneously, access to essential medications by patients in developing areas can be improved by placing fewer protections on the intellectual property behind these medications. There is, however, **one glaring problem with this recommendation; creating a two-tiered system of intellectual property protection, where one set of drugs is given stronger protection than the other, will likely drive research investment into the more strongly protected class of drugs. The solution to this is surprisingly simple: because two classes of drugs are established, additional rewards that do not interfere with access can be implemented in the class of drugs that is less protected.** For example, patents on essential medications could be restricted to process patents alone; in exchange, duration on a process patent could be extended beyond twenty years. Because two separate categories of drugs are defined, product patents would be maintained on all patentable goods other than essential medications, including non-essential drugs. In effect, **creating separate categories of intellectual property protection for disparate classes of drugs allows for customized protection that can both promote innovation and uphold the fundamental human rights of those in need of essential medications**.

#### We are topical, reduce from Merriam-Webster (https://www.merriam-webster.com/dictionary/reduce)

to diminish in size, amount, extent, or number

### Underview

#### 1. 1ar theory since the neg can do bad things and I can’t check. It’s drop the debater since the 1ar is too short to win both layers. No RVI since they’d dump on it for 6 minutes. CI since reasonability is arbitrary and bites intervention. Evaluate the debate after the 1AC – key to preventing the 1N from spreading us out. Responses presume the debate hasn't already been evaluated.

#### 2. RVI on NC theory – you can read arguments such as T that are exclusively neg so I need them to compensate

#### 3. Fairness first a) every argument concedes the importance of fairness since you assume arguments would be evaluated fairly b) fairness isn’t just debater vs debater – unfairness means the judge can hack against scholarships c) many debaters would quit if the game was unfair which guts inclusion.

### Theory

#### Interpretation: negative debaters must disclose any past 2NRs and with at least 30 minutes before round

#### Violation: they don’t – even after I disclosed. They were also neg before already

Graphical user interface, text, application, email

Description automatically generated

Graphical user interface, text, application

Description automatically generated

Application

Description automatically generated with medium confidence

#### Standards:

#### 1] Strat Skew - disclosure lets us plan ahead of time which leads to better debates And reciprocity bc I meet the interp u know my strat – skews strat even more and controls fairness bc I cant compensate for other forms of abuse wo a strategy

#### 2] Norms – Disclosure is a norm on the circuit if everyones starts breaking disclosure rules that means that debates will functionally become less and less engageable 🡪 kills deb8 in the long run

#### CI, fairness—competitive activity, needs both deb8ers to have the same playing ground

#### Education – only reason why schools fund deb8

#### DTD – the only deterrent possible