# 1N

## 1 – Cap

#### The aff’s international approach to the patent system is the essence of the capitalist empire. It seeks to deprive local power while bolstering the influence of the global market over them, securing its position of dominance in the world. Knezevic 07,

Intellectual Property or Intellectual Poverty? Between Colonialism and Empire in the Context of AIDS and Public Health Crises

Boris Knezevic, UCL Faculty of Laws Medicine, Ethics and Law  
February 2007

**The corporate-industrialized world nexus project in pushing the global IP agenda with a view to adopt a “common standard”85 or “one size fits all”86 model for patents regardless of the field of technology (in this case medicine) or socio-economic circumstances in question (AIDS epidemic in Africa) is not only hypocritical but dangerous,** and not just to immediate public health concerns. **It constitutes an attempt to sever the juridical notion of patent from its material historical source** – to deprive us of the language to articulate the un-ethics of the situation. **It seeks to monopolize the very language and thought-processes that permit us to ethically and effectively question the ‘rational’ decision-making of world leaders and corporations**. **This is what Hardt and Negri refer to (in a reading of Foucault) as a ‘biopolitics’ of control, which permeates below the level of consciousness to the bios in order to manipulate** 87 [T]he problem of the new juridical apparatus is presented to us in its most immediate figure: a global order, a justice, and a right that are still virtual but nonetheless apply to us...**our internal moral disposition...tends to be determined by the ethical, political, and juridical categories of Empire...The means of the private and individual apprehension of values are dissolved**: with the appearance of Empire, we are confronted no longer with the local 89 This latter tension represents most faithfully the precise tension between the position of developing nations and that of industrialized nations in relation to pharmaceutical patents. **It is the tension between an adaptive conception that is modified as it is historically and socio-economically contextualized or ‘locally mediated’ – and on the other hand a conception that is in juristic terms rigid and by claiming for itself ‘concrete universality’ extinguishes all contextualized conceptions**. This tendency of the very limits of what we are capable of thinking. The sentiment is echoed in the comment cited above by Spiegel regarding the ‘Cuba taboo’ – a conspicuous silence which reflects an “inclination to narrow the boundaries of what are deemed to be possible approaches”88 to public health. Out of this universalized silence, the global order of ‘Empire’ unfolds [my italics]: [T]he problem of the new juridical apparatus is presented to us in its most immediate figure: a global order, a justice, and a right that are still virtual but nonetheless apply to us...our internal moral disposition...tends to be determined by the ethical, political, and juridical categories of Empire...The means of the private and individual apprehension of values are dissolved: with the appearance of Empire, we are confronted no longer with the local mediations of the universal but with a concrete universal itself. Empire to extinguish and erase context and ‘local mediation’ is not directed merely at the Other – **the industrialized world which here is the agent of empire seeks to expunge its own context and history from the record, too, so long as the order that is universalized is the one it dominates at present**. The characteristic of Empire is that it is “formed not on the basis of force but on the basis of the capacity to present force as being in the service of right and peace.”90 **The only truly effective means to resist this process of Empire then is to deny it its ethical foundation by insisting on history**, both that of the developed and developing world, and in particular the complicity of the former in the plight of the latter, for example: Besides introducing new diseases, European colonial incursions created devastating ecological changes in Africa. Mining, plantation agriculture, irrigation schemes, and drainage ditches created good habitats for malaria- bearing mosquitoes. As Africans died from smallpox and famine, cultivated areas returned to bush, promoting the spread of tsetse flies... That, in short, is the sort of thing European ‘transfer of technology’ to Africa achieved in the 19th and early 20th century. Hunter goes on to note some further examples, among them this: it took until the 1960s to rid the Serengeti plain of the rinderpest virus brought there by the British and Italians in the 1880s, by which time most of the native domestic cattle and wild ungulates on which the Masai population depended were dead. From 1880 to 1933 the population of the Belgian Congo declined from around 40 million to 9.25 million. In another French colony it went from 20 million to 2.5 million in the space of 20 years, 1911-1931. On the heels of these ravages, “Western medicine matured at just the right time to be used as a ‘tool of empire’.”92 This configuration, it seems, persists today in what Hardt and Negri call the new ‘imperial paradigm’, which has migrated from “disciplinary society to a society of control.”93 It is the latter that operates at the level of bios, which rather than merely employing physical coercion, attempts to regulate from afar our very thought processes “to narrow the boundaries of what are deemed to be possible approaches.”94 **What is taking place here is the transition to an order wherein the agents of Empire need not instruct colonial subjects what to do or coerce them to it, but are able to ensure that goals are carried out merely by limiting the horizons of thought.** **It is clear that industrialized countries have taken every opportunity to adapt their patent systems and evolve them according to their immediate socio-economic or public health needs in different epochs**. **Developing countries should be allowed to do the same, especially given the historical complicity of developed countries in their demise and in the retardation of their development**. **The global model imposed by industrialized countries cannot serve the immediate public health needs of the developing world**. In this process and particularly in dealing with existing public health crises such as the AIDS epidemic, Cuba provides the best existing model for developing countries to learn from, given both its success and the country’s socio- economic identity with other developing countries, and there is no reason why this model could not be implemented without replicating its political environment. Over this entire complex, however, looms the hegemonic global order of Empire, with the industrialized world as agent, seeking to universalize its own conception. **In order to resist this universalizing process, developing countries should insist as a matter of right on managing their own public health networks matched by suitable patent regimes crafted to their immediate needs (i.e. compulsory licenses, import of generics) – rather than accepting the universalising imposition in return for ad hoc donations and other aid as a matter of charity or good will**. **Developing nations** should, in other words, **reject ad hoc utilitarian approaches of enforcing patents unconditionally at the service of the industrialized world designed to alleviate their suffering** but never allow them to stand on their own two feet, **leaving them always a step behind and at the mercy of corporate and international donors**. They should continue to assert their moral rights in the face of the global pharmaceutical lobby and insist on their unfettered discretion to determine the existence of health crises on their territories and design patent regimes appropriate to their immediate needs. They should implement “social and organizational priorities” shown to produce results toward the “social production of health” simultaneously investing (socially and financially) in their public health networks and in publicly financed institutions to conduct R&D programs crafted to their concerns, guided by public health needs and motives and not profit possibilities**. The attainment of public health goals is financially well within their reach merely by the implementation of appropriate policies**, as discussed above. This of course raises a number of issues relating to the willingness of African officials and governments to deal with the AIDS crisis in an effective way, and the various cultural and political 96 obstacles to this, however that this only makes the compendium of obstacles to the resolution of the AIDS crisis more complex;97 by removing the global obstacles (stringent pharmaceutical patent protection) and reducing the crisis to the level of national politics, the immediate technical responsibility is placed on the shoulders of leaders who in most cases are in one way or another politically accountable to the very populace afflicted by the epidemic, rather than on the shoulders of corporate executives thousands of miles away who answer primarily to shareholders. Thus if there is unwillingness among African politicians and elites to engage effectively with the epidemic (as some writers suggest), a more systematically ethical and less profit- oriented approach to patent enforcement by industrialized countries would be much more likely to expose this unwillingness and eliminate such politicians. **So long as industrialized countries insist on a ‘common standard’, they will remain the main scapegoat.** If they believe it to be in their interest to produce a greater confluence of norms relating to intellectual property, they should work from the opposite end to where they are now – by investing in the public health networks of developing countries with a view to making them sustainable and self-sufficient both in providing for immediate health needs and conducting R&D in the long term; that is, by working toward a ‘common standard’ in public health rather than in patent protection, for the former would in turn produce greater confluence in patent systems.

#### Slight adjustments to the current IP system inevitably fail while allowing global regimes to expand their power. The aff specifically kills the opportunity to critique the current system allowed for by the pandemic. Krikorian and Torreele 6-23,

Krikorian, Gaëlle, and Els Torreele. "We Cannot Win the Access to Medicines Struggle Using the Same Thinking That Causes the Chronic Access Crisis." *Health and Human Rights* 23.1 (2021): 119.

**Supply gaps and market failures are also increasing for health products considered not profitable enough to continue production. The availability of medicines and diagnostics required in small volumes is being increasingly threatened, as is the case for many neglected diseases such as tuberculosis, sleeping sickness, leishmaniasis, and diphtheria**. We are also seeing shortages of old and inexpensive yet essential medicines, such as penicillin and cotrimoxazole.[23](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r23) **In the context of the COVID-19 pandemic, we have witnessed global shortages of key antibiotics** (such as amoxicillin and doxycycline), **morphine, and basic reagents for diagnostics**.[24](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r24) At various points since the start of the pandemic, even if one wanted to buy these, they are simply not available or have already been sold to the highest bidder. **This has led to calls for considering essential medicines strategic products that every country or region should be self-sufficient in and for creating nonprofit- and government-controlled production to ensure this**.[25](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r25) These **emerging tensions are questioning the efficiency, cost-effectiveness, and fairness of the dominant system**. Another extraordinary example of unjustified control by pharmaceutical companies that affects patients worldwide is the rising prices of previously cheap—yet lifesaving—medicines, such as insulin, where a few corporations control the market for their mutual benefit and are able to increase prices year after year to the detriment of many people with diabetes who can no longer afford the treatment.[26](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r26) Seeking to challenge this status quo, **a group of scientists is exploring small-scale community-based open source production of insulin**.[27](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r27) In a similar move to increase access to overly expensive medicines and circumvent monopolies, doctors and pharmacists are looking into bedside magistral production as a way to provide personalized medicine.[28](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r28) **The COVID-19 crisis has added to the growing understanding that the scarcity of many essential medicines, vaccines, and raw materials is not inevitable but rather the consequence of policies** and decisions from the industry and governments. On the one hand, pharmaceutical companies have wielded unrivaled power to determine the scope and direction of medical innovation and to decide who gets access and under which conditions. On the other hand, **states, relinquishing their power to exert their health sovereignty, agree to rely on the private sector for the provision of these essential health tools**. **They thus became dependent on a handful of producers and a globalized supply that cannot fulfill all existing needs**, chose to adopt economic and industrial policies that **prioritized business interests over the needs of their populations and health systems**.[29](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r29) Business-as-usual is not an option; we must break the deadlock Wishing to replicate past successes, **health advocates have pushed for broadening the scope of existing solutions** to encompass additional diseases and health technologies and to expand the set of “eligible” countries for the exceptions created in earlier years. **This has been welcomed by some of the organizations embodying those solutions, as they see it as an opportunity to expand their mandate and scope of activities across disease areas or to new territories and be able to tap into additional funding sources for sustainability**. This applies for instance to Gavi, the Coalition for Epidemic Preparedness Innovations, the Global Fund, the Foundation for Innovative Diagnostics, and Unitaid, which positioned themselves as key players in the design, setup, and functioning of ACT-A together with the Gates Foundation and Wellcome. The same players are now advocating for ACT-A’s evolution into a permanent epidemic response infrastructure.[30](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r30) **But the replication and routinization of ad hoc and donor-driven solutions, bringing more and more public health areas under the control of self-declared global health institutions that focus on narrowly defined biomedical solutions, does not necessarily suit all current and future health challenges or take into account existing shortfalls or pitfalls of these mechanisms**. **It also does not address the governance gaps that exist in many international organizations that function more like untransparent public-private partnerships than institutions whose policies are dictated by public interest**. **Because countries’ ability to set priorities and develop an integrated health policy are often hampered and skewed by donor subsidies and their priorities, there are growing voices from “beneficiary” countries calling for increased agency and participation, if not leadership and autonomy, in designing the solutions they deem most fit to promote the health and well-being of their populations**—a movement that also includes #DecolonizeGlobalHealth.[31](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r31) **For the ongoing COVID-19 pandemic, it is clear that the established global health architecture is unable—and ill suited—to work out relevant and equitable solutions for the developing world,** as exemplified by ACT-A and its well-intended but so far ineffective COVAX facility, held hostage to supply restrictions by companies and the vaccine nationalism from those who created it in the first place.[32](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r32) **Voluntary proposals that keep developing nations captive to the willingness of corporations and wealthy countries to access lifesaving public health tools are being increasingly criticized**.[**33**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r33) **The political tensions on an IP waiver on COVID-19-related technologies at the World Trade Organization are reopening an old battle that raged during the HIV epidemic 20 years ago between developing countries challenging monopolies on medical technologies and the wealthy countries defending the pharmaceutical corporations** located in their countries.[34](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r34) However, the COVID-19 vaccine scarcity affects people everywhere, rendering the flaws of the monopoly-based yet highly subsidized pharmaceutical economy visible to more people, and making it obvious that **limited exceptions to the IP regimes** (for a few patents, for one virus, for a few months, and so forth) **will not fix the problems.** The COVID-19 crisis illustrates the critical role of public contributions in the research, development, production, and deployment of medical innovations for global public health.[35](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8233016/#r35) The inequities in vaccine access that we are seeing due to the fact that control over such innovations was left in the hands of a few private companies highlights the colossal unbalance that exists between the public health interest and private profits. They illustrate how public resources are used without adequate checks and balances to ensure public value, and fail to prevent growing inequalities in access, even in the wealthiest countries. **Tinkering in the margins of the status quo is unlikely to be successful**. The market-based health, pharmaceutical, and medical innovation policies that our governments designed are unable to generate the relevant health technologies and make them available—at an affordable price—to all who need them. Therefore, **we need transparent R&D and access policies and governance that are no longer captive to the current, Western-driven global health order**. The design of needs-driven research and production of pharmaceuticals could be organized to deliver health commons, not market commodities, making the best of public capacities and setting up transparent and fair collaboration with the private sector for the public interest.

#### Global capitalism and industrialization cause climate change and extinction. McDuff 19,

McDuff, Phil. "Ending climate change requires the end of capitalism. Have we got the stomach for it." *The Guardian* 18 (2019).

Climate change activism is increasingly the domain of the young, such as 16-year-old Greta Thunberg, the unlikely face of the school strike for climate movement, which has seen many thousands of children walk out of school to demand that their parents’ generation takes responsibility for leaving them a planet to live on. In comparison, the existing political establishment looks more and more like an impediment to change. **The consequences of global warming have moved from the merely theoretical and predicted to observable reality over the past few years, but this has not been matched by an uptick in urgency. The need to keep the wheels of capitalism well-oiled takes precedence even against a backdrop of fires, floods and hurricanes**. Today’s children, as they become more politically aware, will be much more radical than their parents, simply because there will be no other choice for them. This emergent radicalism is already taking people by surprise. **The Green New Deal (GND**), a term presently most associated with 29-year-old US representative Alexandria Ocasio-Cortez, **has provoked a wildly** **unhinged backlash from the “pro free market” wing**, who argue that it’s a Trojan horse, nothing more than an attempt to piggyback Marxism onto the back of climate legislation. Think we should be at school? Today’s climate strike is the biggest lesson of all Greta Thunberg, Anna Taylor and others Greta Thunberg Read more **The criticism feels ridiculous. Partly because the GND is far from truly radical** and already represents a compromise solution**, but mainly because** the radical economics isn’t a hidden clause, but a headline feature. **Climate change is the result of our current economic and industrial system.** GND-style proposals marry sweeping environmental policy changes with broader socialist reforms because the level of disruption required to keep us at a temperature anywhere below “absolutely catastrophic” is fundamentally, on a deep structural level, incompatible with the status quo. **Right now we can, with a massive investment of effort by 2030, just about keep the warming level below 1.5C. This is “bad, but manageable” territory. Failing to put that effort in sees the world crossing more severe temperature barriers that would lead to outcomes like ecosystem collapse, ocean acidification, mass desertification, and coastal cities being flooded into inhabitability. We will simply have to throw the kitchen sink at this. Policy tweaks such as a carbon tax won’t do it. We need to fundamentally re-evaluate our relationship to ownership, work and capital. The impact of a dramatic reconfiguration of the industrial economy require similarly large changes to the welfare state. Basic incomes, large-scale public works programmes, everything has to be on the table to ensure that the oncoming system shocks do not leave vast swathes of the global population starving and destitute. Perhaps even more fundamentally, we cannot continue to treat the welfare system as a tool for disciplining the supposedly idle underclasses. Our system must be reformed with a more humane view of worklessness, poverty and migration than we have now.** Unfortunately for our children, the people they have to convince of all this are the people who have done very well out of this system, and are powerfully incentivised to deny that it is all that bad. Already, Joke Schauvliege, a Belgian environment minister, has been forced to resign after falsely claiming that she had been told by Belgian state security services that “ghosts” behind the scenes were behind demonstrations in Belgium. This conspiracism of the elite, these claims that genuine mass movement can’t possibly really exist and must be in some way being guided by agents provocateurs, is just one of the ways in which those currently running things have resorted to a kind of political gaslighting in an attempt to maintain their grip on power. 3:18 Dianne Feinstein rebuffs young climate activists' calls for Green New Deal – video **Gaslighting is a term I don’t use lightly, because it describes a genuine form of emotional abuse, where an abuser will deny reality in an attempt to get their victim to literally doubt their own sanity, and this should not be diluted by overuse. Yet I struggle to think of another word that adequately sums up the way in which “sensible” adults are doubling down on their tactic of manufacturing a political reality which bears no relationship to the world we see around us. It’s the Marxism of Groucho rather than Karl: “Who are you going to believe? The serious political professionals or your own lying eyes?”** US Senator Dianne Feinstein’s meeting with schoolchildren petitioning her to take action over the issue went viral because of the way she condescended to them for, basically, asking her to leave them a planet behind to live on. “I’ve been doing this for 30 years,” she said, “I know what I’m doing.” The obvious response is, of course, that messing something up for 30 years is quite long enough, thanks. Long tenure without results is not the same thing as expertise. This is a tough and bitter pill to swallow for the political professionals whose feet are firmly under the table. It is increasingly obvious that all their tactics have done almost nothing except run down the clock, but still they insist that it’s the young who just don’t get it and that things aren’t that simple. They’re the living embodiment of the famous New Yorker cartoon, with a suited man sat in a post-apocalyptic landscape telling his young audience “Yes, the planet got destroyed. But for a beautiful moment in time we created a lot of value for shareholders.” Capitalism can crack climate change. But only if it takes risks Larry Elliott Larry Elliott Read more **This is reality v the vested interests of the powerful. Any meaningful policy has to upset the established power base and the political donor class. Any policy that doesn’t upset these people will be useless. To pretend that we can compromise our way through this while we wait for a magical, technological bullet that will keep temperatures down without costing us anything is beyond wilful ignorance now. It is a question of basic morality.** Many of today’s climate strikers won’t even be 30 by the time the 1.5C deadline comes around in 2030. They are asking us to consider a simple question: is their future worth more than preserving our reputations? What will our response to them be?

#### And warming causes extinction

#### Xu 17

Yangyang Xu 17, Assistant Professor of Atmospheric Sciences at Texas A&M University; and Veerabhadran Ramanathan, Distinguished Professor of Atmospheric and Climate Sciences at the Scripps Institution of Oceanography, University of California, San Diego, 9/26/17, “Well below 2 °C: Mitigation strategies for avoiding dangerous to catastrophic climate changes,” Proceedings of the National Academy of Sciences of the United States of America, Vol. 114, No. 39, p. 10315-10323

We are proposing the following extension to the DAI risk categorization: warming greater than 1.5 °C as “dangerous”; warming greater than 3 °C as “catastrophic?”; and warming in excess of 5 °C as “unknown??,” with the understanding that changes of this magnitude, not experienced in the last 20+ million years, pose **existential threats** to a majority of the population. The question mark denotes the subjective nature of our deduction and the fact that catastrophe can strike at even lower warming levels. The justifications for the proposed extension to risk categorization are given below. From the IPCC burning embers diagram and from the language of the Paris Agreement, we infer that the DAI begins at warming greater than 1.5 °C. Our criteria for extending the risk category beyond DAI include the potential risks of climate change to the physical climate system, the ecosystem, human health, and **species extinction**. Let us first consider the category of catastrophic (3 to 5 °C warming). The first major concern is the issue of **tipping points**. Several studies (48, 49) have concluded that 3 to 5 °C global warming is likely to be the threshold for tipping points such as the collapse of the western Antarctic ice sheet, shutdown of deep water circulation in the North Atlantic, dieback of Amazon rainforests as well as boreal forests, and collapse of the West African monsoon, among others. While natural scientists refer to these as **abrupt and irreversible climate changes**, economists refer to them as catastrophic events (49). Warming of such magnitudes also has **catastrophic human health effects**. Many recent studies (50, 51) have focused on the direct influence of extreme events such as heat waves on public health by evaluating exposure to heat stress and hyperthermia. It has been estimated that the likelihood of extreme events (defined as 3-sigma events), including heat waves, has increased 10-fold in the recent decades (52). Human beings are extremely sensitive to heat stress. For example, the 2013 European heat wave led to about 70,000 premature mortalities (53). The major finding of a recent study (51) is that, currently, about 13.6% of land area with a population of 30.6% is exposed to deadly heat. The authors of that study defined deadly heat as exceeding a threshold of temperature as well as humidity. The thresholds were determined from numerous heat wave events and data for mortalities attributed to heat waves. According to this study, a 2 °C warming would double the land area subject to deadly heat and expose 48% of the population. A 4 °C warming by 2100 would subject 47% of the land area and almost 74% of the world population to deadly heat, which could pose **existential risks to humans** and mammals alike unless massive adaptation measures are implemented, such as providing air conditioning to the entire population or a massive relocation of most of the population to safer climates. Climate risks can vary markedly depending on the socioeconomic status and culture of the population, and so we must take up the question of “dangerous to whom?” (54). Our discussion in this study is focused more on people and not on the ecosystem, and even with this limited scope, there are multitudes of categories of people. We will focus on the poorest 3 billion people living mostly in tropical rural areas, who are still relying on 18th-century technologies for meeting basic needs such as cooking and heating. Their contribution to CO2 pollution is roughly 5% compared with the 50% contribution by the wealthiest 1 billion (55). This bottom 3 billion population comprises mostly subsistent farmers, whose livelihood will be severely impacted, if not destroyed, with a one- to five-year megadrought, heat waves, or heavy floods; for those among the bottom 3 billion of the world’s population who are living in coastal areas, a 1- to 2-m rise in sea level (likely with a warming in excess of 3 °C) poses **existential threat** if they do not relocate or migrate. It has been estimated that several hundred million people would be subject to famine with warming in excess of 4 °C (54). However, there has essentially been no discussion on warming beyond 5 °C. Climate change-induced species extinction is one major concern with warming of such large magnitudes (>5 °C). The current rate of loss of species is ∼1,000-fold the historical rate, due largely to habitat destruction. At this rate, about 25% of species are in danger of extinction in the coming decades (56). Global warming of 6 °C or more (accompanied by increase in ocean acidity due to increased CO2) can act as a major force multiplier and **expose** as much as **90% of species to** the dangers of **extinction** (57). The bodily harms combined with climate change-forced species destruction, biodiversity loss, and threats to water and food security, as summarized recently (58), motivated us to categorize warming beyond 5 °C as unknown??, implying the possibility of **existential threats**. Fig. 2 displays these three risk categorizations (vertical dashed lines).

#### The alternative is earth democracy. It prioritizes local values and production over globalization, dismantling global capitalist power while maintaining the ability to produce at large scales and ensure wellbeing of citizens, but it is incompatible with the aff’s view on global trade and the WTO. Fukuda 10,

Fukuda, Yasuo. "WTO regime as a new stage of imperialism: Decaying capitalism and its alternative." *World Review of Political Economy* 1.3 (2010): 485.

There is considerable ongoing debate between “globaphobes” and “globaphiles.” **The decaying nature of modern capitalism shows that free trade is not a panacea for citizen welfare**. The task of this section is not however to recount the arguments between globaphobes and globaphiles. Rather, **the aim is to outline an alternative system**. **The matter at hand is how to restore viability, independence, and sustainability to local communities**. But before arguing how this may be achieved, it is worthwhile to clarify the social conditions necessary for realizing such an outcome. **V. Shiva (2005: Ch. 2) advocates “earth democracy” as an alternative to corporate globalization**. **Earth democracy is composed of four basic principles of sustainable society**. **The first is “ecological sustainability.”** That is, **the recognition that all species have intrinsic worth and that their life-cycles are interdependent of one another.** **The second is “community control of the commons.”** **Resources vital to sustenance, including public services and infrastructure, should not be privately owned; public resources must remain in the commons**. The **third is “security of livelihoods.”** That is, the idea that **all people have the right to basic needs, such as food, water, housing, and jobs**. **The fourth is “local sovereignty,” which amounts to community self-governance in regards to local economic affairs.** **Localization of the economy does not mean a closed economy; rather, it is the idea that local production should have priority over trade**. These four principles are necessary conditions for sound and sustainable community life. The second principle, community control of the commons, and the fourth, local sovereignty, are necessary conditions for the third, security of livelihoods. The first principle, ecological sustainability, guarantees preservation of the environment, thereby protecting sustainability of livelihoods as well. **These principles are not just the necessary conditions for sustainable society (Cavanach and Mander 2004), they are also the policy guidelines for realizing it** (Korten 2001). **It is a requirement of earth democracy that corporate globalization be dismantled**. This is because **corporate globalization denies all of the principles of earth democracy**. Therefore, the **power structure of corporate globalization must be broken up**. **First, the Anti-Trust Act must be reformed so that governments can mitigate the power of large firms in the global marketplace**. Large companies that have no technical reason for maintaining such large organizations should be broken up into more governable segments. **Second, market rules such as WTO agreements, should be rewritten**. **Introduced in the name of deregulation and trade liberalization, the aim of these rules has been nothing other than to allow large companies to use monopolistic power to control the global marketplace**. **Local governments must take back the right to formulate policy on matters affecting their own communities, reclaiming the policy space which has been hijacked by the WTO, the IMF, and the World Bank**. **Third, the ability of corporate power to design market systems must be checked**. The political power of big business is principally based on cozy relationships with government. Therefore, **political contributions from corporations must be prohibited**, **lobbying tied to political money should not be allowed**, **and revolving doors between big business and government must be closed** (Marx et al. 2007). Finally, **corporations should be deprived of the entitlement to express their political opinions through media, think tanks, etc**. Simultaneous to the dismantling of the excesses of corporate power, **it is also necessary that communities regain their independence on matters of economic policy**. The arguments presented below are intended to itemize the policy tasks needed for the rebuilding of community-based society. The **first task is to strengthen the foundations of the local economy**. Here, **the policy matter is how to secure productive investment in local communities**. **Local governments need to protect and support their home firms by adopting policies such as local contents regulations, and reinvestment rules in regards to profits gained locally.** The **second task is to support and nurture local businesses, such as small to medium-sized firms, the self-employed, family farming, and so forth**, as these represent core elements of the local economy. The **priority of industrial policies must be to shift power from big business to these local actors**. The objective of such a policy shift should be to strengthen reproductive circulation within the local economy. Local actors are interdependent on one another through the internal circulations which occur at the local level. Therefore, **the strengthening of local actors leads to the independence of the local economy**. But this policy does not amount to locally closed economies (autarky). To the contrary, **it is essential that local industries establish linkages with external markets to ensure viability of the local economy**. **What is important here is for local actors to take the initiative in establishing these linkages**. Therefore, large firms need to be regulated so as to prevent them from damaging the interests of local economic actors. **Large companies should be made to support local actors rather than inhibit them**. The **third task is for local communities to regain control of the commons.** The commons, including **natural resources** (water, soil, seeds, gene information), **public services and utilities** (municipal water supplies, electric power sources, educational services, medical care), **are indispensable to peoples’ lives**. **It is thus a prerequisite to the establishment of economic independence that local communities retain their policy space on issues which concern the commons**. Even in cases of private ownership, **local communities should have the final say with respect to governance of the commons**. In addition, it should be strongly encouraged for citizens to develop a stake in the local economy through, for example, promotion of the co-ownership of cooperatives and the establishment of municipal holding companies. Localization is a way for people to realize democracy on a higher level. Upon this new dimension of democracy, local citizens can make strides toward more healthy and sustainable lives.

#### The role of the ballot is to contest the ontological structure of capitalism. Global capitalism relies on a structurally divided form of society which allows it to commodify all logic which accepts the given structure. This is used to cover the unsustainability of its current form. However, the lines of such divisions can be contested from outside the commodification by pursuing valuation of ecology, reproduction, and polity above capital. FRASER

[Fraser, Nancy. “Beyond Marx’s Hidden Abode: For an Expanded Conception of Capitalism.” *Critical Theory in Critical Times*. Pg 142-159]

Likewise, the picture I have sketched differs from the view of capitalism as a reified form of ethical life, characterized by pervasive commodification and monetization. In **that view**, as articulated in Georg Luka.cs's celebrated essay on "Reification and the Consciousness **of** the Proletariat," **the commodity form colonizes all of life**, stamping its mark on such diverse phenomena as law, science, morality, art, and culture.11 In my view**, commodification is far from universal in capitalist society**. On the contrary**, where it is present, it depends for its very existence on zones of noncommodification**. **Social, ecological, and political**, these **noncommodified zones do not simply mirror the commodity logic but embody distinctive normative and ontological grammars of their own**. For example, **social practices oriented to reproduction (as opposed to production) tend to engender ideals of care, mutual responsibility, and solidarity, however hierarchical and parochial these may be**.12 Likewise, **practices oriented to polity, as opposed to economy, often refer to principles of democracy, public autonomy, and collective self-determination, however restricted or exclusionary these may be**. Finally, **practices associated with capitalism's background conditions in nonhuman nature tend to foster such values as ecological stewardship, nondomination of nature, and justice among generations, however romantic and sectarian these may be**. Of course, **my point is not to idealize these "noneconomic" normativities** **but** **to register their divergence from the values associated with capitalism**'s foreground-above all, growth, efficiency, equal exchange, individual choice, negative liberty, and meritocratic advancement This divergence makes all the difference to how we conceptualize capitalism. **Far from generating a single, all-pervasive logic of reification, capitalist society is normatively differentiated, encompassing a determinate plurality of distinct but interrelated social ontologies.** What happens when these collide remains to be seen. But the structure that underpins them is already clear: capitalism's distinctive normative topography arises from the foreground-background relations we have identified**. If we aim to develop a critical theory of it, we must replace the view of capitalism as a reified form of ethical life with a more differentiated, structural view.** If capitalism is neither an economic system nor a reified form of ethical life, then what is it? My answer is that **it is best conceived as an institutionalized social order, on a par with, for example, feudalism**. **Understanding capitalism in this way underscores its structural divisions, especially the institutional separations that I have identified**. **Constitutive of capitalism, we have seen, is the institutional separation of "economic production" from "social reproduction,"** a gendered separation that grounds specifically capitalist forms of male domination even as it also enables capitalist exploitation of labor power and, through that, its officially sanctioned mode of accumulation. **Also definitive of capitalism is the institutional separation of "economy" from "polity," a separation that expels matters defined as "economic" from the political agenda of territorial states, freeing capital to roam in a transnational no-man's-land, where it reaps the benefits of hegemonic ordering while escaping political control**. Equally **fundamental to capitalism**, finally, **is the ontological division, preexisting but massively intensified, between its (nonhuman) "natural" background and its (apparently nonnatural) "human" foreground**. Therefore, to speak of capitalism as an institutionalized social order, premised on such separations, is to suggest its nonaccidental, structural imbrication with gender oppression, political domination-both national and transnational, colonial and postcolonial-and ecological degradation, in conjunction, of course, with its equally structural, nonaccidental foreground dynamic of labor exploitation. This is not to suggest, however, that capitalism's institutional divisions are simply given once and for all. On the contrary, as we saw**, precisely where and how capitalist societies draw the line between production and reproduction, economy and polity, human and nonhuman nature varies historically, according to the regime of accumulation**. In fact, we can con­ ceptualize competitive laissez-faire capitalism, state-managed monopoly capitalism, and globalizing neoliberal capitalism in precisely these terms, as three historically specific ways of demarcating economy from polity, production from reproduction, and human from nonhuman nature. Equally important, **the precise configuration of the capitalist order at any place and time depends on politic**s-on the balance of social power and on the outcome of social struggles. **Far from being simply given, capitalism's institutional divisions often become foci of conflict, as actors mobilize to challenge or defend the established boundaries separating economy from polity, production from reproduction, human from nonhuman nature.** **Insofar as they aim to relocate contested processes on capitalism's institutional map, capitalism's subjects draw on the normative perspective**s associated with the various zones that we have identified.We can see this happening today. For example**, some opponents of neoliberalism draw on ideals of car**e, solidarity, and mutual responsibility, associated with reproduction, in order **to oppose efforts to commodify education**. **Others** **summon notions of stewardship of nature** and justice among generations, **associated with ecology, to militate for a shift to renewable energy**. Still others invoke ideals of public autonomy, associated with polity, to advocate international capital controls and to extend democratic accountability beyond the state. **Such claims, along with the counterclaims they inevitably incite, are the very stuff of social struggle in capitalist societies-as fundamental as the class struggles over control of commodity production and distribution of surplus value that Marx privileged**. **These boundary struggles**, as I shall call them, **decisively shape the structure of capitalist societies**.13 They play a constitutive role in the view of capitalism as an institutionalized social order.The focus on boundary struggles should forestall any misimpression that the view I have been sketching is functionalist. Granted, I began by characterizing reproduction, **ecology**, and political power **as necessary background conditions for capitalism's economic front story, stressing their functionality for commodity production, labor exploitation, and capital accumulation. But this structural moment does not capture the full story of capitalism's foreground-background relations. It coexists, rather, with another "moment," already hinted at, which is equally central and which emerges from the characterization of the social, political, and ecological as reservoirs of"noneconomic" normativity. This implies that, even as these "noneconomic" orders make commodity production possible, they are not reducible to that enabling function. Far from being wholly exhausted by, or entirely subservient to, the dynamics of accumulation, each of these hidden abodes harbors distinctive ontologies of so­ cial practice and normative ideals.** Moreover, **these "noneconomic" ideals are pregnant with critical­political possibili**ty**. Especially in times of crisis, they can be turned against core economic practices associated with capital accumulation**. In such times, the structural divisions that normally serve to segregate the various normativities within their own institutional spheres tend to weaken. When the separations fail to hold, capitalism's subjects-who live, after all, in more than one sphere-experience normative conflict. **Far from bringing in ideas from the "outside," they draw on capitalism's own complex normativity to criticize it, mobilizing against the grain the multiplicity of ideals** that coexist, at times uneasily, in an institutionalized social order premised on foreground-background divisions. Thus, the view of capitalism as an institutionalized social order helps us understand how a critique of capitalism is possible from within it. Yet this view also suggests that it would be wrong to construe society, polity, and nature romantically, as "outside" capitalism and as inherently opposed to it. That romantic view is held today by a fair number of anticapitalist thinkers and left-wing activists, including cultural femi­ nists, deep ecologists, and neo-anarchists, as well as by many proponents of "plural," "postgrowth," "solidary," and "popular" economies. Too often, these currents treat "care;' "nature;' "direct action," or "commoning" as intrinsically anticapitalist. As a result, they overlook the fact that their favorite practices not only are sources of critique but also are inte­ gral parts of the capitalist order. Rather, the argument here is that society, polity, and nature arose con­ currently with economy and developed in symbiosis with it. They are effectively the latter's "others" and only acquire their specific character in contrast to it. Thus, reproduction and production make a pair, with each term co-defined by way of the other. Neither makes any sense apart from the other. The same is true of polity/economy and nature/human. Part and parcel of the capitalist order, none of the "noneconomic" realms af­ fords a wholly external standpoint that could underwrite an absolutely pure and fully radical form of critique. On the contrary, political projects that appeal to what they imagine to be capitalism's "outside" usually end up recycling capitalist stereotypes, as they counterpose female nurtur­ ance to male aggression, spontaneous cooperation to economic calcula­ tion, nature's holistic organicism to anthropocentric individualism. To premise one's struggles on these oppositions is not to challenge but to un­ wittingly reflect the institutionalized social order of capitalist society. It follows from this that a proper account of capitalism's foreground­ background relations must hold together three distinct ideas. **First, capitalism's "noneconomic" realms serve as enabling background conditions for its economy; the economy depends for its very existence on values and inputs from the "noneconomic." Second, however, capitalism's "noneco­ nomic" realms have a weight and character of their own, which can, under certain circumstances, provide resources for anticapitalist struggle.** Nevertheless, and this is the third point, these realms are part and parcel of capitalist society, historically coconstituted in tandem with its economy and marked by their symbiosis with it. There is also a fourth idea, which returns us to the problem of crisis with which I began. Capitalism's foreground-background relations harbor built-in sources of social instability. As we have seen**, capitalist production is not self-sustaining; it free rides on social reproduction, nature, and political power. Yet its orientation to endless accumulation threatens to destabilize these very conditions of its possibility**. **In the case of its ecological conditions, what is at risk are the natural processes that sustain life and provide the material inputs for social provisioning.** In the case of its social-reproduction conditions, what is imperiled are the sociocultural processes that supply the solidary relations, affective dis­ positions, and value horizons that underpin social cooperation while also furnishing the appropriately socialized and skilled human beings who con­ stitute "labor." In the case of its political conditions, what is compromised are the public powers, both national and transnational, that guarantee property rights, enforce contracts, adjudicate disputes, quell anticapital­ ist rebellions, and maintain the money supply.

## 2 – T

#### Interpretation: Affirmative debaters must not advocate for actions outside of the resolution – to clarify, no extra T.

#### Violation – The India/South Africa plan is extra-T – the TRIPs waiver includes things other than medicines, like manufacturing or protective equipment.

<https://www.crowell.com/NewsEvents/AlertsNewsletters/all/Three-Takeaways-From-the-May-21-Revised-TRIPS-Waiver-Proposal>

***Second***, **paragraph 1 of the revised proposal, in contrast to same paragraph in the original proposal, provides additional clarity as to the scope of the proposed waiver.** Specifically, the scope **encompasses “health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19**.” As in the original proposal, the scope of the revised waiver likewise **applies to the implementation, application, and enforcement of TRIPS provisions regarding copyright and related rights** (Part II, section 1), industrial designs (section 4), patents (section 5), and the protection of undisclosed information (section 7). The scope of potential “health products and technologies” remains unclear, not least because the specified list does not appear to be exhaustive. What is certain, however, is that **the scope of the revised proposal remains broad including, among others, COVID-19 vaccines and diagnostic tests, as well as underlying manufacturing technologies, and covering various types of intellectual property**. Whether, during subsequent negotiations, the scope of the waiver is reduced, such as limiting the health products and technologies or applicable TRIPS provisions, will be critical for stakeholders. Notably, Ambassador Tai’s statement earlier this month specifically reflects the Biden-Harris Administration’s support for a temporary waiver for COVID-19 vaccines only, not other health products or technologies.

#### AND Merriam Webster -- medicines are

https://www.merriam-webster.com/dictionary/medicine

**a substance or preparation used in treating disease**

#### Now negate –

#### [1] Semantics first –

#### A] stasis point – the topic is the only reasonable focal point for debate – anything else destroys the possibility of debate because we will be two ships passing

#### B] internal link turn – violating semantics justifies the aff talking about whatever with zero neg prep or prediction which is the most unfair and uneducational

#### C] Jurisdiction – you can’t vote for them because the ballot and the tournament invitation say to vote for the better debater in the context of the resolution

#### [2] Limits – you explode them since you’re extra topical – you can remove IP protections for medicines and anything else, making it impossible for the negative to create strong enough links. Two impacts:

#### A] Cherry-picking – you can select a trivially true aff that makes it impossible to negate

#### B] prep skew – you can always leverage your extra T aff to back generic neg prep or weigh the extra T impacts, which makes the neg prep burdens impossible to meet

#### C] Predictability – can’t predict what permutation of IP protections in addition to medicines they’ll ban.

#### [3] Topic Ed – we won’t get any education if they choose to write an aff that skirts the topic and functions outside of it – there are plenty of topical affs to choose that enable us to solely focus on the topic.

#### TVA – Read any aff that only reduces IP protections for medicines – like trips plus.

#### Fairness is a voter

#### a] they concede the authority of fairness by agreeing to tournament procedures and speech times

#### b] fairness is a procedural constraint—if they had 10 minutes to say fairness bad and I only had 1 minute to defend it, they would win because it was structurally unfair to begin with.

#### Drop the debater (a) deter future abuse – empirically confirmed with aprioris and (b) dropping the arg on T is incoherent because it is dropping the aff advocacy so its functionally the same.

#### No RVI’s – (a)

#### chilling effect – aff is dangerous on theory because they get to prep a long counterinterp in the 1ar and then get the 2ar to collapse, weigh, and contextualize - negs would always be disincentives from reading theory against good theory debaters which leads to infinite abuse so it outweighs time skew and

#### (b) they’re illogical - “I’m fair vote for me” doesn’t make any sense - logic comes first on theory since all args need to make sense in order to be evaluable.

#### Competing interpretations – a] reasonability is arbitrary since it relies upon judge opinion which outweighs since it’s terminally unfair – it relies on something completely out of control and b] reasonability collapses into competing interpretations since you need to justify why your brightline is better than competing ones.

T over 1ar theory –

## Case

### Lbl

#### Covid Impact –

### Solvency/Turns

#### [1] The proposed waiver won’t solve because of how complicated it would be to mandate disclosure and transfer of trade secrets—the plan is insufficient to trigger the advantages, Donahoe

<https://www.natlawreview.com/article/waiver-ip-protections-covid-19-vaccines-still-under-consideration-wto>, 24 Aug 2021, Donahoe, Casey D.

While the proposed waiver extends to several areas of IP, most agree that patents and undisclosed information, in particular, form the crux of the debate. Katherine Tai, the U.S. Trade Representative, has not publicly committed to any position beyond waiving patent protections in particular. [Karpan 2021-07-01] Moderna has temporarily waived its COVID-19 vaccine patent rights, but the vaccine is still protected, at least in the U.S. and EU by regulatory marketing exclusivity. [Collins 2021-06-11] **With respect to patents, existing TRIPS flexibilities already allow for countries to issue compulsory licenses for domestic production in the face of public health crises and, under additional criteria, compulsory licenses for export.** But proponents of the waiver argue that the existing processes, which can require country-by-country and case-by-case negotiations and litigation with the vaccine developers and may be limited to public uses, are too time-consuming and inconvenient to mount an effective response, particularly where thickets of IP protection cover single vaccines. [Labonte 2021-01-09, The Conversation]; [Public Citizen, tradewatch.org] In fact, compulsory licensing to exporting manufacturers under Article 31b is has only been successfully used once in the past twenty years, [Public Citizen, tradewatch.org] when Canada issued a compulsory license authorizing the manufacture and export of an AIDS medication to Rwanda. [WTO 2007-10-04] Additionally, multiple countries may be involved in the pipeline for manufacturing a single packaged vaccine to be distributed in a country in need. Further, one key advantage to a unanimously agreed-upon waiver over attempting to utilize existing TRIPS flexibilities, would be that countries could more comfortably exploit the waiver without the threat of trade complaints or sanctions from other nations. [Lopez 2021-05-07] Proponents of the waiver point to alleged U.S. and European retaliatory trade measures against nations that have attempted to use existing TRIPS flexibilities to skirt IP protections. [Public Citizen, tradewatch.org] While the proposed waiver extends to several areas of IP, most agree that patents and undisclosed information, in particular, form the crux of the debate. **However, even if patent protection were not an issue, manufacturing and distribution of the vaccines would remain a substantial obstacle to achieving global immunity.** [Paton 2021-05-07 Bloomberg] **Aspects of vaccine manufacturing and regulation raise further issues of what TRIPS calls “undisclosed information,” encompassing trade secrets and know-how. Such undisclosed information may be particularly crucial in scaling up manufacture in a commercially viable fashion**. [Garrison 2020-12-16]. Article 39 of TRIPS requires members to protect the confidentiality of undisclosed information, including data submitted to regulatory agencies for marketing approval of pharmaceuticals. **As related to vaccines, undisclosed information could include clinical data** (e.g., related to effectivity, including negative results), **manufacturing processes, medical formulas, cell lines, genomic information, technical designs and specifications, instruction manuals, process controls and monitoring, quality control procedures, technical training, working practices, etc.** [Garrison 2020-12-16]; [Levine 2020-07-10]; [Eakin 2021-05-25 Law360] **The Pfizer and Moderna vaccines,** in particular, are expected to be **extremely difficult to replicate** given **they rely on new mRNA technology.** The WTO touts the COVID-19 Clinical Research Coalition, which aims to provide a platform for voluntary data-sharing, and the WHO-backed COVID-19 Technology Access Pool (C-TAP), which provides a platform for technology developers to bundle intellectual property rights, knowledge, and data into non-exclusive licenses with each other and with multiple quality-assured manufacturers, as examples of voluntary efforts to fill-in the know-how gap. [WTO Report 2020-10-15] In general, the voluntary transfer of know-how between two parties is highly contractually stipulated, usually allowing the licensor strict control over the dissemination of its know-how and protecting rights to improvements and developments that may derive from the collaboration, some of which might be patentable in themselves. [Bracho 2021-05-24 Bloomberg]. **The proposed waiver**, though, **wades into relatively unchartered territory of compulsory transfers of undisclosed information. Likely the biggest threat felt by vaccine manufacturers is that the compulsory transfer of undisclosed information will not simply diminish their return on investments in COVID19 vaccines, but would jeopardize entire proprietary technological platforms that support a wide range of potential products.** Such giveaways would likely impact small-to-medium sized enterprises especially, which account for approximately 75% of US COVID-19 treatments, and particularly small university spin-outs, which are highly depend on IP for valuation. [Balfour 2021-06-30] As details of a waiver have not yet been hammered out, it remains unclear exactly who might have access to such undisclosed information (e.g., the general public or only generic manufacturers) and the mechanisms by which such transfers would be achieved. Even with a waiver in place, individual countries would likely need to enact legislation or emergency executive actions to execute the transfer of information. [Labonte 2021-01-09, The Conversation**] The most obvious means would be for regulatory agencies to disclose data and manufacturing protocols submitted by vaccine manufacturers that they are ordinarily required to keep confidential.** In fact, the issue of data confidentiality has already been raised in the U.S. as an obstacle to developing a competitive generic biologics market, with some pointing to the Federal Pesticide Act (FPA) as a successful model which allows more free dissipation of regulatory data by the EPA. [Heled 2019] There are some exemptions to confidentiality of data supplied to regulatory drug agencies implemented in the U.S. and Europe, particularly where public funding helped finance the underlying research. For example, for research funded by the U.S. government, the Bayh-Dole Act provides some additional licensing provisions to the government which could potentially extend to some know-how; however, these provisions are largely untested and may be contractually restricted. [Collins 2021-06-11]. **But there is no precedent for compulsory transfer of confidential information in general**. [Levine 2020-07-10] **Even with a waiver in place, individual countries would likely need to enact legislation or emergency executive actions to execute the transfer of information. Additionally, knowledge holders may be located outside the jurisdiction of a member state desiring to compel transfer,** [Garrison 2020-12-16] **and waiving an obligation for member states to protect undisclosed information does not necessarily compel other member states to do so.  Notably, India, one of the waiver proponents that actually has substantial pharmaceutical manufacturing capacity, does not even presently require submission of test data for marketing approval.**  [Haugen 2020-12-01]  **Compulsory disclosure of undisclosed information is further complicated by the fact that the knowledge holders for manufacturing a single vaccine may be dispersed across multiple entities and/or even multiple jurisdictions, particularly where a supply chain of highly technical components is utilized or certain processes are outsourced to contractor entities.**  [Garrison 2020-12-16]  **The legislative levers that might be needed to fully enforce compulsory disclosure of undisclosed information or that could be pulled to halt executive branch action, as well as the lawsuits that might be filed would seem likely to stall any grand gestures of governmental action related to undisclosed information.** [Eakin 2021-05-25 Law360]  **For instance, compulsory disclosures would likely spurn allegations of violating the Takings Clause of the Fifth Amendment**, although the Supreme Court had found previously in *Ruckelshaus v. Monsanto Co*. that the FPA had not done so [Heled 2019].  Still, compulsory disclosure facilitated by regulatory agencies may not be sufficient to fill the knowledge gap for the successful manufacture of the vaccines, leaving room for countries to consider other creative avenues.  Brazil, for instance, has proposed one of a kind legislation which would tie patent rights to the compulsory disclosure of all information needed to make COVID-19 vaccines.  [Eakin 2021-05-25 Law360] Opponents argue that **bottlenecks in manufacturing capacity and supplies would stymie the effect of the waiver, despite the transfer of undisclosed information, and that even with full technology transfer, it would take months or years for factories to come up to speed on vaccine production.**  [Leonard 2021-05-06, Bloomberg]; [Paton 2021-05-07 Bloomberg]  **Manufacturing capacity is particularly limited for mRNA-based vaccines and there’s not even necessarily a sufficient population of people with expertise capable of manufacturing them.**  [Karpan 2021-05-11 Law360]  **Some also warn that redistributing crucial supplies to manufacturers without existing capabilities to manufacture the high-quality vaccines with regulatory approval would actually hinder vaccine distribution efforts.**  [Karpan 2021-05-11 Law360]; [Lima 2021-05-08 Bloomberg]; [Paton 2021-05-07 Bloomberg]  Even manufacturing facilities with access to all IP rights are experiencing production delays from regulatory reviews.  [Baschuck 2021-05-06]  Opponents also resound that such efforts to undermine IP rights will only discourage future innovation, including research that targets new variants of the coronavirus.  [Bacchus 2020-12-16 Cato Institute];  [Paton 2021-05-07 Bloomberg] The large divide between fervid proponents of the waiver and even those who have expressed some mild support suggests any significant compromise may be some time coming.  Many view the waiver controversy any way as less of a problem-driven exercise and more of an opportunity for the usual players to debate both the power of big pharma in the U.S.  [Collins 2021-06-11] and the stifling effects IP protections can have on the least developed nations around the world.  Also, the angst amongst some proponents of the waiver, some believe, may stem more from policies of vaccine nationalism than of TRIP impediments. [Clarke 2021-04-22 Lexology] Regardless, the decisions reached at the WTO during this crisis are likely to shape future policy discussions for years to come.

#### [2] Waivers won’t solve the actual problem. Supply will be a non-issue by years end. The TRIPS waiver is a theatrical gesture aiming to let rich economies off the hook for actually solving the problem, Adler

<https://foreignpolicy.com/2021/07/20/wto-trips-waiver-vaccine-equity-distribution-covid-pandemic/>, July 20, 2021

These rollout problems found in the United States are amplified many times when it comes to global rollout. The Biden administration discovered this first hand when it attempted to donate 80 million doses from domestic U.S. supply to the rest of the world in June but fell well short of this target. **White House press secretary Jen Psaki** [**said**](https://www.whitehouse.gov/briefing-room/press-briefings/2021/06/21/press-briefing-by-press-secretary-jen-psaki-june-21-2021/)**, “what we found to be the biggest challenge is not actually the supply—we have plenty of doses to share with the world—but this is a herculean logistical challenge.** And we’ve seen that as we’ve begun to implement.” She pointed to the distributional challenges associated with storing vaccines at the proper temperature as well as the need for needles and syringes. **The TRIPS waiver can be seen as essentially a political or even theatrical gesture.** As Psaki’s comments show, there is more to vaccinating the world than just increasing supply. **Even if there are vaccine shortages at this moment, limited vaccine supply may not be a binding constraint by year end**. Serum Institute of India, the world’s largest vaccine manufacturer, has announced **it will begin** [**exporting later this year**](https://www.reuters.com/world/india/indias-serum-institute-start-export-covid-19-vaccine-by-year-end-2021-05-18/)**, implying India should have adequate vaccine supply by then.** **Pfizer/BioNTech has** [**pledged to deliver**](https://www.voanews.com/covid-19-pandemic/pfizer-biontech-pledge-2-billion-vaccine-doses-poor-nations) **2 billion doses to low- and middle-income countries**. **AstraZeneca is continuing to scale up production.** Nonetheless, the Biden administration’s signature international COVID-19 policy, the [**TRIPS waiver**](https://crsreports.congress.gov/product/pdf/IN/IN11662)**, is a supply side move—but one unlikely to lead to any actual increase in supply**. This waves intellectual property protections for COVID-19 vaccines to further foreign production. The [U.K.](https://www.gov.uk/government/news/wto-trips-council-june-2021-uk-statements) and [German](https://www.dw.com/en/germany-rejects-us-push-to-waive-covid-vaccine-patents/a-57453453) governments have viewed it skeptically and can block it. Also, as has been widely noted, manufacturing involves trade secrets and supply chain issues that go well beyond intellectual property (IP) rights. Less widely noted is the fact that the Johnson & Johnson, AstraZeneca, and Novavax vaccines have already been [licensed to Indian manufacturers](https://www.statnews.com/2021/05/05/india-vaccine-heist-shoddy-regulatory-oversight-imperil-global-vaccine-access/), so it is not clear to what degree IP rights are really hindering additional foreign production. Therefore, the TRIPS waiver can be seen as essentially a political or even theatrical gesture, well removed from the messy world of vaccine distribution and administration. It appealed to a domestic audience hostile to Big Pharma and an international audience of countries like India and South Africa whose industrial policies have long called for limitations on IP rights. The Biden administration’s policies keep [evolving](https://foreignpolicy.com/2021/07/16/biden-africa-covid-19-ship-millions-vaccines/), and newer proposals are likely to show more immediate results. The United States has [pledged](https://www.whitehouse.gov/briefing-room/statements-releases/2021/06/10/fact-sheet-president-biden-announces-historic-vaccine-donation-half-a-billion-pfizer-vaccines-to-the-worlds-lowest-income-nations/) to buy 500 million U.S. produced doses of the Pfizer/BioNTech vaccine over the next year and donate them to low-income countries. Many [financing initiatives](https://www.npr.org/2021/02/18/969145224/biden-to-announce-4-billion-for-global-covid-19-vaccine-effort) have been announced. But U.S. plans of how to tackle the critical last mile and get the vaccines into people’s arms have not been as clearly fleshed out, with the United States mostly taking a hands-off approach. Administering vaccines requires a global rollout plan. After all, as the truism goes, a global pandemic demands a global response. However, this phrase is open to interpretation, with vaccine nationalism typically cloaked in globalist rhetoric. Many in the United States are deeply uncomfortable with a U.S.-led pandemic effort and hear the statement to mean that globalist institutions should take the lead. In other countries, the phrase can mean something very different. For instance, when European Commission President Ursula von der Leyen floated the idea of a “[vaccine export transparency mechanism](https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_221)” to block vaccine exports from the EU to the U.K., she said it was for the “global common good.” These various meanings are somehow aligned in discouraging any U.S. unilateralism and pose challenges to a more active U.S. involvement in a global rollout. The primary global initiative to ensure all countries have access to COVID-19 vaccines is [COVAX](https://www.gavi.org/covax-facility?gclid=Cj0KCQjwub-HBhCyARIsAPctr7wD6lbQwpflk8lliN12KxEUIUL9NkbdH7NgZ3UTkYqdsLWgG380utMaAqtvEALw_wcB), co-convened by the Coalition for Epidemic Preparedness Innovations, the vaccine alliance Gavi, and the World Health Organization. Gavi oversees procurement but does not have an [on-the-ground presence](https://www.gavi.org/our-alliance/operating-model) for administering vaccines. This is left up to the health ministries of developing countries and other partners. The coalition’s key partner responsible for delivering vaccines is UNICEF. UNICEF is a [children’s agency](https://www.unicef.org/) whose mission is helping every child thrive all over the world. However, it is the elderly who are most at risk for COVID-19. Ultimately, COVAX has rollout capabilities but limited bandwidth and resources when it comes to vaccine administration. The United States has these resources, including deep expertise in both vaccine distribution and administration. Operation Warp Speed showed the Defense Department can manage the complex ultra-cold logistics required for mRNA vaccine distribution. The Centers for Disease Control and Prevention (CDC) and the U.S. Agency for International Development (USAID) have knowledge of vaccine administration—although addressing a global pandemic would be a “stretch goal.” The United States could use its personnel and expertise to help solve the global rollout problem, either on its own or in a partnership with multilateral institutions, such as COVAX. This is not to imply the United States, with its declining life expectancy, necessarily has a better health system than other afflicted countries—only that it has rollout knowledge it learned the hard way. The key lesson is the last mile is the hardest part to roll out. Rather than having vaccine supplies arrive and only then start training, it is better to have mass vaccination sites up and running and already fully staffed. The United States could offer technical guidance and materials necessary for rollouts, including refrigeration, ancillary kits, and having enough needles on hand. USAID could offer advice on how a country could improve its vaccine readiness plan. Addressing vaccine hesitancy is also critical to a successful rollout. The reasons behind vaccine hesitancy are complex and vary by country and population. Hence, responses need to be country specific but will typically require a massive communications effort. Where is the global effort? Where is the global planning for this effort? Tackling these global, last-mile challenges faces huge domestic roadblocks in the United States. It would require making global rollout a top U.S. foreign-policy priority, necessitating the planning, financing, and personnel of something akin to the Marshall Plan. It would be expensive. It involves industrial planning, which still has negative overtones in the United States. Which agency in the U.S. government should coordinate such a plan? The State Department? The Defense Department? The National Institute of Health? The CDC? The White House COVID-19 Response Team? Perhaps the most divisive question is if the United States should lead such an effort or follow the WHO’s directives. But none of this is relevant because there is no domestic political pressure for pursuing such an approach, unlike the TRIPS waiver. This is because nonprofit activism is still primarily focused on [supply](https://www.amnesty.org/en/latest/news/2021/06/g7-support-for-pharma-monopolies-putting-millions-of-lives-at-risk/) and [eliminating vaccine hoarding](https://www.oxfamamerica.org/press/cnn-rich-countries-are-hoarding-covid-19-vaccines-and-leaving-developing-world-behind-peoples-vaccine-alliance-warns/) by rich countries. True global vaccine equity requires a broader definition and effort beyond just manufacturing more supply, namely creating a global rollout plan and deploying the health resources necessary to get shots into people’s arms. The end result is the United States is hesitant to find more concrete ways to get involved with a global rollout beyond just pledging more vaccine supplies or money. It is hesitant to directly intervene to help the worst afflicted poor countries distribute and administer vaccines. And vaccine hesitancy, in whichever form it takes, can be deadly.

#### Turns case – enables rich countries to politically justify not putting additional effort into int. COVID vaccinations.

#### [3] Turn- Waiving patents can’t resolve drug access issues but instead create a more dangerous scenario for developing countries – Garde 21

Damian Garde (national biotech reporter for STAT), Helen Branswell (senior writer at STAT covering infectious diseases and global health; former CDC Knight Fellow and Nieman Global Health Fellow at Harvard; recipient of the 2020 George Polk Award for coverage of the Covid pandemic), and Matthew Herper (senior writer at STAT covering medicine). “Waiver of patent rights on Covid‐19 vaccines, in near term, may be more symbolic than substantive.” Stat News. 6 May 2021. JDN. https://www.statnews.com/2021/05/06/waiver‐of‐patent‐rights‐on‐covid‐19‐vaccines‐ in‐near‐term‐may‐be‐more‐symbolic‐than‐substantive/

In October, **Moderna vowed not to enforce its Covid‐19‐related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines**. “There are currently no generic vaccines primarily because there are hundreds of pro‐ cess steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, **but the transfer of skills is not that simple,” said Norman Baylor,** who formerly **headed the F**ood and **D**rug **A**dministration**’s Office of Vaccines Research and Review**, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — **using messenger RNA technology** — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. **There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instanc**e, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in‐demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry‐wide ... looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly **all of the peo‐ ple who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing**.”  As Michelle McMurry‐Heath, CEO of the trade group BIO, put it in a statement, “**hand‐ ing needy countries a recipe book without the ingredients, safeguards, and sizable work‐ force needed will not help people waiting for the vaccine.”**

#### [4] A vaccine waiver greenlights counterfeit medicine – independently turns Case.

**Conrad 5-18** John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

#### [5] Lack of access is not a result of IP – rather IP is key to ensure high quality vaccines that pass regulatory hurdles, which means the plan actually reduces access

**Stevens**, Philip, **and** Mark **Schultz 1/14**. “Why Intellectual Property Rights Matter for COVID-19 - Geneva Network - Intellectual Property Rights and Covid-19.” Geneva Network, 14 Jan. 2021, geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/. Philip Stevens in the Founder and Executive Director of Geneva Network. He is also a Senior Fellow at the Institute for Democracy and Economic Affairs, Malaysia.; Professor Mark F. Schultz is the Goodyear Tire & Rubber Company Endowed Chair in Intellectual Property Law, the Director of the Intellectual Property and Technology Law Program at the University of Akron School of Law. He was a professor at Southern Illinois University School of Law for 16 years and was co-founder and a leader of the Center for Protection of Intellectual Property (CPIP) at George Mason University in Washington, D.C., where he remains a non-resident Senior Scholar. He also serves as a Senior Fellow of the Geneva Network. //sid

IP has underpinned the research and development that has led to the arrival of several game-changing vaccines. But the challenge does not end there. Perhaps the biggest hurdle is manufacturing billions of doses or new antibody treatments while maintaining the highest quality standards.

There’s more to it than starting a global manufacturing free for all by overriding or ignoring patents. A spokesperson for Regeneron, a manufacturer of a novel COVID-19 antibody treatment explained to [The Lancet](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext): “Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months, as well as significant resources and skill. Unfortunately, it is not as simple as putting a recipe on the internet and committing to not sue other companies during the pandemic”.

[John-Arne Røttingen](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext), chair of the WHO COVID-19 Solidarity trial, explains that technology transfer will be crucial to scaling up production, but voluntary mechanisms are better: “If you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological samples, cell lines, or bacteria” to be able to document to regulatory agencies that you have an identical product, he explains.