# Pharma DA

### Disease

**Pharma profits are up from COVID vaccines, patent waivers threaten this**

**Buchholz, 21**

(Katharina, https://www.statista.com/chart/24829/net-income-profit-pharma-companies/)

The profitability of coronavirus vaccines has been in the spotlight since U.S. President Joe Biden come out in support of temporarily lifting vaccine patents to make the production of the life-saving inoculations more financially feasible for poorer countries. EU leaders meanwhile remain divided over such a move. Company financial reports show that COVID-19 vaccine makers and developers like Johnson & Johnson, Pfizer, Moderna, AstraZeneca and BioNTech have seen their profits increase since the vaccine rollout, at times majorly. In early May, stocks of several companies that benefit from COVID-19 vaccine sales **took a nosedive on the news of Biden’s reversal**. Moderna stocks, for example, were still down more than 6 percent at close on May 5, the day of the announcement. Stocks recovered somewhat as German chancellor Angela Merkel came out against patent waivers the following day. While fluctuations in the stock market price have hurt drug makers in the **short term**, patent waivers would diminish the bottom line of companies involved with the development and production of COVID-19 **vaccines in the long term**. Pharma giants like Johnson & Johnson and Pfizer bring in billions of dollars of income every quarter from diverse sources, so the COVID bump was smaller for them. In the case of Pfizer, which has been a bigger producer than J&J, the year-over-year profit increase was a handsome 44 percent, however. For smaller AstraZeneca, the COVID year meant that its profits doubled. In the case of Moderna, the past year has turned a Q1 loss into a profit. The case is similar for German company BioNTech, which collaborated with Pfizer on its COVID vaccine. While Q1 2021 brought in a profit of $1.1 billion, the company ran a deficit since its founding in 2008 up until Q4 2020, when it posted a profit for the first time. The $446 million earned stood in contrast to losses of almost $428 million accrued in the first nine months of the year.

**Strong IP protection spurs innovation by encouraging risk-taking and incentivizing knowledge sharing -- prefer statistical analysis of multiple studies**

**Ezell and Cory, 19** [Stephen Ezell, vice president & global innovation policy @ ITIF, BS Georgetown School of Foreign Service. Nigel Cory, associate director covering trade policy @ ITIF, MA public policy @ Georgetown. "The Way Forward for Intellectual Property Internationally," Information Technology & Innovation Foundation, 4-25-2019, accessed 8-25-2021, https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally] HWIC

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46 IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.

**Biopharmaceutical innovation is key to prevent future pandemics and bioterror**

**Marjanovic and Feijao, 20** [Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html] HWIC

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term.

**That causes extinction, which outweighs.**

**Millett & Snyder-Beattie, 17** Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity's favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of**state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and mutually assured destruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

# T - Vaccines

#### A. Interpretation: medicine refers to treatments and cures only. Affirmatives must not reduce other medical IP protections.

**B. Violation: the affirmative’s entire case is about vaccines.**

**Vaccines are medical interventions, not medicines**

Elbe, 10

[Stefan Elbe, director of the Centre for Global Health Policy and a professor of international relations at the University of Sussex. "Security and Global Health," ISBN 0745643744, accessed 8-10-2021, https://www.wiley.com/en-ee/Security+and+Global+Health-p-9780745643731] HWIC

Yet here too we must be careful not to overlook other types of medical intervention simultaneously pursued by the 'social' arm of modern medicine at the population level. Vaccines in particular continue to be particularly important medical interventions that repeatedly surface in a variety of different health security delib- erations. Strictly speaking, vaccines are not medicines because they consist of small concentrations of disease-causing microbes (or their derivatives) used to enhance a person's immuno-response to a future infection. As a public health measure, vaccines have therefore also been largely sidelined in the existing medicalization literature. Yet, generally speaking, vaccines too can be considered as medical interventions. That is certainly how the World Health Organization views them, pointing out that 'vaccines are among the most important medical interventions for reducing illness and deaths' available today (WHO 2009a). Whereas pills and other therapies mark the tools of clinical medicine, vaccines play a crucial part in the arsenal of 'social' medicine and public health. Developing and rolling out of new vaccines against a range of current (and future) diseases therefore represents further evidence of how the rise of health security is also encouraging security to be practised through the introduction of new medical interventions in society.

**Vaccines are different from medicines in the context of intellectual property**

Garrison, 04 [Christopher Garrison, Consultant Legal Advisor to WHO. "Intellectual Property Rights and Vaccines in Developing countries," 04-13-2004, accessed 9-2-2021, https://www.who.int/intellectualproperty/events/en/Background\_paper.pdf?ua=1] HWIC

In the last few years, there has been a substantial debate about how intellectual property impacts medicines and in particular how the TRIPS Agreement impacts access to medicines in the developing world. Vaccines are different from medicines in a number of important respects however (at least from the small molecule ‘pill’ medicines if not the newer ‘biotech’ medicines). The issues raised in the access to medicines debate may therefore apply to a greater or lesser extent for vaccines, depending on these differences. This section examines a few of the different forms of intellectual property rights that are relevant in the context of vaccines and outlines the impact of some of the differences between vaccines and medicines.

#### C. Reasons to prefer

#### 1. Limits -- allowing any patented medical intervention includes testing and screening methods, surgery, contact tracing software etc. which takes away generics like innovation bc that applies to pharmaceutical development not distribution of preventative measures which explodes neg prep burden

#### 2. Precision -- we cite the WHO which proves common usage -- they add a whole new caselist based on social medicine which kills predictability -- that's k2 pre-tournament prep and deep clash around the core topic controversy. Reject counter-interps without a positive vision of the topic -- otherwise they can always shift the goalposts

#### D. Paradigm issues

#### 1. Drop the debater -- they skewed the debate from the 1AC and T indicts their advocacy

#### 2. Competing interps -- you can't be reasonably topical and reasonability invites judge intervention

# T - Eliminate

#### Interpretation:

#### Reduce is distinct from eliminate and has a limited application – prefer our evidence for specificity to WTO policy.

LAWASIA Moot Competition, 10

(IN THE INTERNATIONAL COURT OF ARBITRATION NEW DELHI, INDIA, GHC/GHC-MARU Claimant v INTELLECTUAL PROPERTY DEPARTMENT OF THE GOVERNMENT OF MARU Respondent, F3020-R)

The trade objectives support that TRIPS intervene in the national patent regime in order “to reduce distortions and impediments to international trade”. Thus, in cases where there is a distortion in trade, TRIPS should not intervene in the domestic patent regime. Furthermore, the use of the word “reduce”, instead of “eliminate”, means that TRIPS did not intend to intervene in every trade distortion, but only intervene in cases of severe trade distortion. Due to its limited application, the existence of equivalents do not severely disrupt a market, or distort trade49; and therefore, do not warrant any interference by TRIPS, such as obliging members to recognize NLI.

1. **Violation: the affirmative eliminates patents, not reduces them.**
2. **Reasons to prefer:**
   1. **Vote neg for limits – eliminating IP protections is an entirely different literature base and they obfuscate key neg ground like abolition. Extra topicality is a voting issue because it is unpredictable and allows the aff to fiat out of core neg arguments.**
   2. **Precision—my definition is about TRIPS**

# Framework - Util

#### The standard is maximizing expected well-being.

**My Value for the debate is utilitarianism. Util is a moral system where the rightness or wrongness of an action is judged by the outcome it produces.**

**1. Government/global organization actor—nations and trade organizations are not moral individuals so they can’t have Kantian intent.**

**2. Relational wording- Member nations in the resolution is plural, this implies we are debating about how the international community should be shaped and not what an individual’s moral obligations may be.**

#### 3. Weighability – only consequentialism can explain the ethical difference in breaking a promise to take someone to the hospital and breaking a promise to take someone to lunch – that outweighs –

#### 4. Resolvability – there’s no way to weigh between competing offense under their fw which means their fw can’t guide action

#### 5. Extinction is lexically prior and is the biggest impact under all moral frameworks

#### A. Threats eliminate the possibility for people act on moral theories and prevents us from theorizing as well

#### B. Every framework tries to preserve value, which requires us to be alive in the first place

#### C. Multiplying infinity with a small number is still infinite value that the AFF is able to solve

#### Governments must use util since they can’t focus on every individual rights violation

Goodin, 95

Robert, 1995, Philosopher of Political Theory, Public Policy, and Applied Ethics. Utilitarianism as a Public Philosophy, Cambridge University Press, pg. 26-27

The great advantage of utilitarianism as a guide to public conduct is that it avoids gratuitous sacrifices, it ensures as best we are able to ensure in the uncertain world of public policy-making that policies are sensitive to people’s interests or desires or preferences. The great failing of more deontological theories, applied to those realms, is that they fixate upon duties done for the sake of duty rather than for the sake of any good that is done by doing one’s duty. Perhaps it is permissible (perhaps it is even proper) for private individuals in the course of their personal affairs to fetishize duties done for their own sake. It would be a mistake for public officials to do likewise, not least because it is impossible. The fixation on motives makes absolutely no sense in the public realm, and might make precious little sense in the private one even, as Chapter 3 shows. The reason public action is required at all arises from the inability of uncoordinated individual action to achieve certain morally desirable ends. Individuals are rightly excused from pursuing those ends. The inability is real; the excuses, perfectly valid. But libertarians are right in their diagnosis, wrong in their prescription. That is the message of Chapter 2. The same thing that makes those excuses valid at the individual level – the same thing that relieves individuals of responsibility – makes it morally incumbent upon individuals to organize themselves into collective units that are capable of acting where they as isolated individuals are not. When they organize themselves into these collective units, those collective deliberations inevitably take place under very different circumstances and their conclusions inevitably take very different forms. Individuals are morally required to operate in that collective manner, in certain crucial respects. But they are practically circumscribed in how they can operate, in their collective mode. And those special constraints characterizing the public sphere of decision-making give rise to the special circumstances that make utilitarianism peculiarly apt for public policy-making, in ways set out more fully in Chapter 4. Government house utilitarianism thus understood is, I would argue, a uniquely defensible public philosophy.

#### 2. Extinction justifies moral loopholes – therefore, ignoring it is unethical.

Bok, 88

Sissela Bok, Professor of Philosophy, Brandeis, Applied Ethics and Ethical Theory, Ed. David Rosenthal and Fudlou Shehadi, 1988

The same argument can be made for Kant’s other formulations of the Categorical Imperative: “So act as to use humanity, both in your own person and in the person of every other, always at the same time as an end, never simply as a means”; and “So act as if you were always through actions a law-making member in a universal Kingdom of Ends.” No one with a concern for humanity could consistently will to risk eliminating humanity in the person of himself and every other or to risk the death of all members in a universal Kingdom of Ends for the sake of justice. To risk their collective death for the sake of following one’s conscience would be, as Rawls said, “irrational, crazy.” And to say that one did not intend such a catastrophe, but that one merely failed to stop other persons from bringing it about would be beside the point when the end of the world was at stake.For although it is true that we cannot be held responsible for most of the wrongs that others commit, the Latin maxim presents a case where we would have to take such a responsibility seriously—perhaps to the point of deceiving, bribing, even killing an innocent person, in order that the world not perish

**Pref Util over racism fw—**

1. **Extinction is the biggest impact—Bok 88 and my above analytics.**
2. **“Resolving racist oppression” is framed to support the aff and the aff only. Util isn’t biased and is a single fw that works for all debates and topics, emphasizing the topic itself & topic education**
3. **Even low-risk but large-scale extinction impact are important. The point of the debate is to show why you’re right, not assume all extinction impacts are wrong.**

# Case

### Circumvention

#### The plan gets circumvented through prioritization of bilateral trade agreements.

Durand and Milberg, 18

[Cédric, Associate Prof. Political Economy @ U-Geneva, member @ Paris Nord Economics Center; and William, Dean @ The New School for Social Research: “Intellectual Monopoly in Global Value Chains,” published in 2018, https://hal.archives-ouvertes.fr/hal-01850438]//AD

The contention over IPRs exemplified by the dispute between the US and China, reflects the heightened sensitivity of the US and other high-income economies to IPRs in an era where their governments and businesses consider innovation as their main competitive advantage. The US today is the leader of the movement toward stricter international IP norms, in contrast to its position in earlier periods (Peng, Ahlstrom, Carraher, & Shi, 2017). It is the most active complainant at the WTO under the TRIPS agreement but, as illustrated by the recent actions of the Trump administration, TRIPS is not enough (Sell, 2010). The US seeks other ways to extend internationally the standard of IP protection found in U.S. law and in particular to apply existing IP protection to digital media (Akhtar & Ferguson, 2011, p. 25). In order to circumvent the flexibility in the WTO TRIPS Agreement, and the reluctance of developing countries at the WTO to raise WTO standards of IP protection (Helfer, 2004), developed economies have relied increasingly on bilateral and regional preferential trade agreements (PTAs) to accomplish the objective of securing intellectual property related economic advantages (Abbott, 2006; Shadlen, 2008). The international intellectual property policymaking arena has grown ever more complex with overlapping transnational norms. For example, the 33 pages of the chapter dedicated to IPRs in the US-CAFTA agreement details the treaties and conventions that the parties shall ratify, which defines precisely and extensively the scope of IPRs concerned (copyrights, performance, patents, communication, trademarks, plants, microorganisms, industrial design, geographical indication, name domains…). Additionally, it describes enforcement mechanisms to be implemented in national legislation and considers supplementary protection of intellectual property under the investment chapter (CAFTA, 2004). IP provisions included in Japanese and EU international trade agreements are more general but they also provide supplementary coverage and additional obligations (Liberti, 2010). Moreover, investment treaties and chapters dedicated to investment protection in trade agreements open additional routes for IP protection, which can exercise a powerful chilling effect on government actions via the exposure to the risk of costly investor-state arbitration disputes (Ho, 2015, 2016; Kasolowsky & Leikin, 2017). The DESTA database (Dür et al., 2014) allows us to track this qualitative evolution in bilateral and regional trade agreements. IP provisions of trade agreements were nonexistent before the North American Free Trade Agreement (NAFTA) was signed in 1992. They became a standard feature of trade agreements in the 2000s. Figure 6 shows the number of PTAs signed each year and of those, the ones which included IPRs. It also shows the percentage of PTAs with an IP provision. By 2016, every PTA signed included an IP provision.

#### Turn--Bilateral trade agreements are worse than TRIPs – at least TRIPs allows for collective bargaining by the global south.

Kingston, 4

[William, School of Business Studies @ Trinity College (Dublin, Ireland): “Removing Some Harm from the World Trade Organization,” Oxford Development Studies, Vol. 32, No. 2, June 2004. http://www.tara.tcd.ie/bitstream/handle/2262/8696/Removing%20some%20harm.pdf?sequence=1]//AD

Also, now that TRIPS exists, it is better for the poorer countries that it should be maintained in existence, and reformed. This is because as an instrument of international law, it has the potential to enable them to withstand the power of the USTR in bilateral negotiations. As Cancu´ n showed, when a significant group of these countries act together, they can resist being bullied.

#### The aff forces countries to protect IP beyond TRIPs standards – turns case.

Bhala, 7

[Raj, Rice Distinguished Professor @ U- Kansas School of Law, J.D. Harvard, M.Sc. Oxford, M.Sc. London School of Economics, Marshall Scholar, Member @ Council on Foreign Relations, Royal Society for Asian Affairs, and Fellowship of Catholic Scholars, Author of Modern GATT Law (Sweet Maxwell 2005), International Trade Law: Theory and Practice (Lexis 2nd ed. 2000, 3rd ed. forthcoming 2008), and Trade, Development, and Social Justice (Carolina Academic Press 2003): “COMPETITIVE LIBERALIZATION, COMPETITIVE IMPERIALISM, AND INTELLECTUAL PROPERTY,” Liverpool Law Review (2007) 28:77–105. DOI: 10.1007/s10991-007-9017-2]//AD

\*FTA=Free Trade Agreement

Many of America’s newer FTAs, especially accords negotiated after the Uruguay Round, call upon partner countries to go beyond IP protection and enforcement measures set out in the TRIPs Agreement. In part, that reflects America’s bitter experience with lax IP enforcement in major markets like China. US trade negotiators relied, to the detriment of the American IP sector, on promises made by China of future implementation and enforcement during talks for Chinas accession to the WTO, which culminated in a November 1999 US–China bilateral agreement, and accession effective 11 December 2001.30 The subsequent history, from the US vantage point, was one of failure to adhere to the promises. One lesson learned by US trade negotiators was to insist on results – actual implementation and enforcement – before accession. They drilled the point in WTO accession talks with the Kingdom of Saudi Arabia, which culminated with a bilateral accord in the fall of 2005, and accession on 11 December 2005.31 A second lesson from the adverse experience with China was to use FTAs as a vehicle to go beyond the TRIPs Agreement, i.e., to demand TRIPs Plus commitments from a would-be FTA partner. Consider the following examples: In the U.S.–Jordan FTA, Jordan agreed to ratify and implement within two years two IP agreements that are not part of its TRIPs obligations: the World Intellectual Property Organization (WIPO) Copyright Treaty, and the WIPO Performances and Phonograms Treaty. The aim of these agreements, which are known as ‘‘Internet Treaties,’’ is to protect copyrighted works in a digital network environment. Thus, for example, they provide a creator with the exclusive right to make its creative works available online. The same TRIPs Plus provisions, incorporating the most up-to-date international copyright protection standards, exist in the U.S.–Morocco FTA. In the U.S.–Chile FTA and U.S.–Singapore FTA, Chile and Singapore agreed to TRIPs Plus commitments not only for patents, trademarks, and copyrights, but also for trade secrets. The two countries also accepted the obligation of ensuring its legal system contains meaningful penalties for piracy and counterfeiting. In negotiations for a U.S.–Australia FTA, the US had two key objectives concerning IP. First, it sought better IP protection, especially with respect to grey (parallel) market products. The US achieved this objective through provisions in the FTA that not only complement, but also enhance, existing international standards for both protection and enforcement of IP rights. These TRIPs Plus provisions include strong penalties for counterfeiting and piracy. Second, the US opposed the Australian pharmaceutical benefits scheme of pricing. On this point, agreement proved difficult and the end result – though TRIPs Plus – was nebulous. The two countries affirmed their shared objectives of (1) maintaining high quality healthcare and (2) improving public health standards. They agreed on three principles in pursuit of these objectives: (1) the importance of innovative pharmaceuticals, (2) the significance of research and development in the pharmaceutical industry, with appropriate governmental support including IP protection, and (3) the need for timely and affordable access to innovative pharmaceuticals through procedures that value objectively pharmaceuticals based on their therapeutic relevance. The sticking point was the procedures by which a federal health care program lists and prices new pharmaceuticals for reimbursement. Both sides agreed the procedures should demand transparency and accountability. But, how could the US be certain Australia would not discriminate against drugs from US pharmaceutical companies when listing and pricing medicines in its Pharmaceutical Benefits Scheme? From Australias perspective, how could its consumers be assured they would have access to effective US drugs at non-astronomical prices? The FTA establishes a Medicines Working Group to continue the conversation between the two countries on pharmaceutical issues, and creates in Australia an independent review process for listing decisions. The conversation indeed continues on this and other controversies. For example, when approving the FTA, the Australian Parliament added an ‘‘Anti-Evergreening’’ amendment to Australian law.32 This change blocks a pharmaceutical company from evergreening a patent or using the judicial process to preclude introduction of a generic medicine. The US opposes the amendment. In June 2006, NGOs – 416 of them, including the AFL-CIO, Citizens Trade Campaign, Communications Workers of America, Friends of the Earth, National Farmers Union, Sierra Club, and United Steel Workers – signed a letter urging Congress to reject the U.S.–Oman FTA (which Congress ultimately passed that summer.) They argued the accord not only lacked meaningful labor and environmental protections, but also would hurt poor and sick Omanis. The FTA IP provisions benefited large pharmaceutical companies by protecting their ‘‘unprecedented monopoly rights’’ of large pharmaceutical companies, forbidding for extended periods competition from generic products, and limiting access to affordable medicines.33 In the U.S.–Colombia FTA, signed in February 2006, but not implemented as of November 2006, Colombia agreed to join the WTO Information Technology Agreement (ITA).34 The ITA, an outgrowth of the Uruguay Round, lists a large number of computer and computer-related products subject to duty-free, quota-free treatment. However, it is a plurilateral accord, hence joining is required neither by TRIPs nor any other WTO accord. In January 2006, the US and Thailand were engaged in FTA negotiations, which commenced in June 2004. US insistence on TRIPs Plus IP commitments contributed to large-scale protests in Chiang Mai, Thailand, against an FTA, and brought talks to a halt.35 Four specific TRIPs Plus controversies arose:36 (1) The US insisted on 25-year span for patent protection, beyond the TRIPs Agreement norm of 20 years. (2) The US called for compensatory patent extensions by the Thai government to pharmaceutical companies, if the government ‘‘unreasonably’’ delayed either the grant of a drug patent, or approval of a drug for market use. The TRIPs Agreement does not contain this mandate. (3) The US sought a data exclusivity provision not found in the TRIPS Agreement. This provision would preclude manufacturers of generic drugs (which, of course, tended to be Thai companies) from using clinical trial data, or other scientific information, from any other company (e.g., an American pharmaceutical giant), to prove its generic product was safe and effective after the product had entered the market. Thailands Government Pharmaceutical Organization (GPO) objected. The GPO provides ‘‘first line’’ anti-retroviral medicines (i.e., older ones, some of which the patent had lapsed) to 80,000 AIDS patients (as of 2006), and sought to expand this program to 150,000 patients (by 2008). The GPO planned to offer generic ‘‘second line’’ drugs (i.e., newer, more sophisticated medicines still subject to a patent). Data exclusivity would inhibit its ability to do so. Further, data exclusivity would apply even to an unpatented drug, where no patent had been sought because the market for the drug was thought to be too small. (4) The US required tight language that would limit the terms and conditions under which the GPO could effect a compulsory license of a new drug. The US offered a side letter assurance that the language would be consistent with the November 2001 Doha Ministerial Conference Declaration on TRIPs and Public Health. Again, the GPO replied the language would adversely affect its ability to provide drugs to Thai AIDS patients. Thousands of Thai health care workers, AIDS victims, and activists – fearful of high-priced medicines should their government ‘‘cave’’ to the demands, demonstrated noisily, but peacefully (in front of the Sheraton Chiang Mai!) for about two days. Farmers, who were upset at US demands concerning agricultural trade (e.g., that Thailand reduce rice tariff barriers), joined them. The US team left the Sheraton as inconspicuously as possible, through a side door behind the concierge desk, into an unmarked van, and down a side street. The USTR blamed the ensuing stall in negotiations on Thai political unrest.37 Not surprisingly, some international trade law scholars offer persuasive arguments for the proposition that ‘‘TRIPs Plus’’ is ‘‘TRIPs Minus’’ for poor countries. For example, Dr Mohammed El-Said of the University of Central Lancashire cogently argues TRIPs Plus commitments in deals like the U.S.–Jordan and U.S.–Bahrain FTA end up doing greater harm than good to the US partners, hence rendering those countries worse off than under WTO disciplines.38 This line of argumentation would appear to be consistent with the competitive imperialism paradigm. In that paradigm, major trading powers race against one another to get the best possible deal for themselves. They neither intend to, nor hope to see, the IP provisions in their FTA and CU deals multilateralized. Obviously, if their provisions become WTO law, then their benefits no longer are specially tailored. All WTO Members, consisting of a not inconsiderable number of free riders (from the American or European perspective, at least), would enjoy whatever benefits they can realize for whatever IP industry they have.

### Vaccines won’t be made.

**No solvency and reject "empirical" claims -- vaccines require complex infrastructure to manufacture, not just patents**

**Hotez, 21**

[Peter J. Hotez, Maria Elena Bottazzi, and Prashant Yadav. "Producing a Vaccine Requires More Than a Patent," Foreign Affairs, 5-10-2021, accessed 8-8-2021, https://www.foreignaffairs.com/articles/united-states/2021-05-10/producing-vaccine-requires-more-patent] HWIC

On May 5, President Joe Biden announced that the United States would support an international bid to waive intellectual property rights to vaccines for the duration of the coronavirus pandemic, thereby ostensibly allowing other countries to ramp up production even of the sophisticated technology behind the Pfizer-BioNTech and Moderna vaccines against COVID-19. Many in the global health community and developing world welcomed the decision as a victory for greater equity in vaccine distribution, in which middle- and low-income countries are lagging far behind wealthy ones. But the jubilation may be premature. The drive for intellectual property waivers originates in part from the world’s experience fighting the last war, against HIV/AIDS. Patent pools, intellectual property waivers, and other liberalizing mechanisms were urgent in assuring equity of access to lifesaving drugs during that epidemic. But these tools are better suited to medicines and other pharmaceuticals than to vaccines. Producing vaccines—particularly those as technologically complex as the messenger RNA (mRNA) inoculations against COVID-19—requires not only patents but an entire infrastructure that cannot be transferred overnight. The sharing of patents is an important and welcome development for the long term, but it may not even be the most pressing first step. JUST OPEN THE SPIGOT At the turn of the millennium, multinational pharmaceutical companies were charging $10,000 per patient for a daily drug regimen that could keep those infected with HIV/AIDS alive. Those in low- and middle-income countries in Africa and elsewhere could access this cocktail only under limited circumstances. Then, in 2001, the Indian drug manufacturer Cipla Limited began producing versions of a triple antiretroviral drug cocktail for a mere $350. Cipla, in collaboration with Médecins Sans Frontières (Doctors Without Borders), helped usher in a new era of global access to essential medicines—one that justified relaxing or even ignoring international patents and other property rights to produce and distribute an important and lifesaving drug as a generic. Since that time, global health advocacy organizations have found increasingly sophisticated ways to work with multinationals in ensuring access to essential medicines for low- and middle-income countries. In the 2010s, the global health initiative Unitaid helped create a Medicines Patent Pool, in which pharmaceutical companies from all over the world offered antiretroviral drug licenses, thereby creating a path for developing generic versions so long as the patent holders received royalties. The mechanism supplied voluntary licenses to new producers even while protecting the legal rights of the drugs’ original manufacturers. Companies such as Gilead, for example, have supplied voluntary licenses for their antivirals directly to generic manufacturers, allowing for tiered pricing across countries. Barely any COVID-19 vaccines have been administered in the African continent or in low- or middle-income countries in Asia and Latin America. Global health professionals have understandably sought to ascertain whether a similar approach could help make the distribution of COVID-19 vaccines less lopsided. More than one billion vaccine doses have now been administered—but overwhelmingly to people living in just a few countries. More than half have been administered in the United States (250 million) and China (290 million) alone, followed by India (160 million), the United Kingdom (51 million), and Germany (32 million). In contrast, for all practical purposes, barely any COVID-19 vaccines have been [administered](https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html) in the African continent or in low- or middle-income countries in Asia and Latin America. Global health advocates have responded to this inequity by seeking to apply the lessons they learned from antiretroviral drugs and demanding patent pools or other intellectual property waivers for COVID-19 vaccines. In March 2021, Médecins Sans Frontières organized protests at the World Trade Organization (WTO) headquarters in Geneva, unfurling a banner that read, “No COVID Monopolies—Wealthy Countries Stop Blocking TRIPS Waiver,” referring to the organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights. The assumption underlying such demands is that intellectual property is a crucial barrier blocking vaccine developers, especially in low- and middle-income countries, from producing COVID-19 vaccines to scale—particularly the high-performing mRNA vaccines that Pfizer-BioNTech and Moderna currently produce. These vaccines elicit more than 90 percent protective immunity against both symptomatic illness and documented infection, including asymptomatic infection, with COVID-19. They are successfully driving the recovery of the United States, Israel, and other nations. But so far, mRNA vaccines are mostly invisible to Africa, Latin America, and low- and middle-income countries in other regions. The hope of those pushing for TRIPS waivers and patent pools is that these will unleash the technology to make the recovery global. IT TAKES A WHOLE ECOSYSTEM Intellectual property sharing may be helpful in the long term. But producing complicated biologics, especially innovative ones such as mRNA or adenovirus-vectored vaccines, is not solely a matter of patent access. Small-molecule antiviral drugs are comparatively straightforward: the multistep chemical processes through which they are synthesized are often fully detailed in published patents or scientific papers. Chemists and formulation experts can often synthesize and scale up production just from knowing the drug structure. But vaccines are different. Producing and manufacturing lipid-encased mRNA molecules, recombinant adenoviruses, or even the proteins or whole inactivated viruses used in older-generation vaccines requires a far higher level of sophistication than is needed for producing small-molecule drugs. Moreover, vaccine production must meet stringent requirements for quality control, quality assurance, and regulatory oversight. The **effective transfer of such complex technology requires a receiving ecosystem that can take years, sometimes decades, to build**. Countries seeking to ramp up vaccine production will need to train staff scientists and technicians. They will also need scientific administrators versed not only in basic research and development but also in detailed record keeping, including specific documentation practices such as batch production records. Moreover, they will need strong quality control systems and regulatory guardrails. Building such an infrastructure requires intensive training and often considerable financial investment and risk. It also takes time—by some estimates, vaccine development requires at least 11 years, and even then the probability that such efforts will result in bringing a vaccine to market is less than ten percent. Consider that the COVID-19 vaccines were themselves the outcome of decades of research and development. Few nations are prepared to take such risks. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. The most notable and largest is India, which currently makes the adenovirus-vectored vaccines developed by Janssen and by Oxford and AstraZeneca, as well as an older-technology recombinant protein vaccine and a whole inactivated virus vaccine. Manufacturers in Brazil, Cuba, and some Southeast Asian countries have experience producing childhood vaccines and may be able to develop the capacity to make COVID-19 vaccines as well. Other possibilities may develop elsewhere, including in the Middle East and Africa. But in the near term, such manufacturers will require financing, access to very large amounts of raw materials and supplies (possibly including relaxation of export controls), and some technical expertise in manufacturing and quality control if they are to produce the existing vaccines against COVID-19. Vaccinating India alone will require almost two billion doses, and more than 12 billion doses will be required to vaccinate the world. The emergence of new variants and the need for booster doses may increase demand even further. Whether mRNA vaccine technology can be scaled to produce billions of doses in 2021, or even by early 2022, remains entirely unknown, but the goal is worth pursuing. To this end, some kind of patent relaxation may be necessary, but far from sufficient. Would-be producers will need technical know-how, regulatory controls, and components that are currently in very short supply, such as nucleotides and lipids.

#### Tech transfer is key and not included under IP

Smith, 21

(Laura Smith-Spark; Newsdesk Editor, CNN Digital; (05-05-21) Rich nations urged to share vaccine knowledge while WTO debates waiving patents; CNN; <https://www.cnn.com/2021/05/05/world/covid-19-vaccine-patents-wto-intl/index.html>; CKD)

Thomas Bollyky, director of the Global Health Program at the Council on Foreign Relations, told CNN on Friday that what's really needed to scale up global manufacturing of vaccines is technology transfer. "It's not just a matter of intellectual property. It's also the transfer of know-how," he said. "I don't think there's clear evidence that a waiver of an intellectual property is going to be the best way for that technology transfer to occur." Waiving patents will not work in the same way for vaccines as it has for drugs, Bollyky said. For HIV drugs, for example, manufacturers were more or less able to reverse engineer them without much help from the original developer. "It's very different for vaccines, where it's really a biological process as much as a product. It's hard to scale up manufacturing in this process for the original company, let alone another manufacturer trying to figure this out without assistance," he said. "It requires a lot of knowledge that's not part of the IP." The deal between AstraZeneca and the Serum Institute of India is a successful example of such technology transfer, Bollyky said, where the licensing of IP happened voluntarily. "The question is what can we do to facilitate more deals like the one between AstraZeneca and the Serum Institute of India to have this transfer," he said. Michael Head, senior research fellow in global health at the University of Southampton, in England, told CNN that increasing regional manufacturing capacity, particularly in the global south, was key -- and should be a focus between pandemics. "Sharing intellectual property during the pandemic is something that should happen but that doesn't resolve the issues," he said. "Manufacturing vaccines is hard. It's hard to rapidly set up a new site with all the equipment, infrastructure, all the vaccine ingredients, with suitable staff to produce a large number of high quality vaccine products." Philanthropist Bill Gates, a major supporter of [global Covid-19 vaccine equity](https://www.cnn.com/2021/02/05/world/covax-explainer-intl/index.html) through the Bill & Melinda Gates Foundation, also [told Sky News](https://news.sky.com/story/covid-19-bill-gates-hopeful-world-completely-back-to-normal-by-end-of-2022-and-vaccine-sharing-to-ramp-up-12285840) last month that he did not believe overriding IP rules was the answer. "There's only so many vaccine factories in the world and people are very serious about the safety of vaccines," he said. "The thing that's holding things back in this case is not intellectual property. There's not, like, some idle vaccine factory with regulatory approval that makes magically safe vaccines. You've got to do the trials on these things and every manufacturing process has to be looked at in a very careful way."