## Util

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

#### 1] Only pleasure and pain are intrinsically valuable – all other frameworks collapse.

Moen 16 [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] TDI

Let us start by observing, empirically, that a widely shared judgment about intrinsic value and disvalue is that **pleasure is intrinsically valuable and pain is intrinsically disvaluable**. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for **there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels**, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 **The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values.** If you tell me that you are heading for the convenience store, I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the **pleasure is not good for anything further**; it is simply that for which going to the convenience store and buying the soda is good.3 As Aristotle observes: “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that **pleasure and pain are both places where we reach the end of the line in matters of value.**

#### 2] Extinction first --- moral uncertainty.

**Bostrom 12** [(Nick Bostrom, Faculty of Philosophy & Oxford Martin School University of Oxford) “Existential Risk Prevention as Global Priority.” Global Policy, 2012] TDI

These reflections on moral uncertainty suggest an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate. **Our** present **understanding** of axiology **might** well **be confused**. We may not now know — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet be able to imagine the best ends of our journey. **If we are** indeed profoundly **uncertain about our** ultimate aims, **then we should** recognize that there is a great option **value** in preserving — and ideally improving — **our ability to** recognize value and to **steer the future accordingly. Ensuring** that there will be **a future** version **of humanity** with great powers and a propensity to use them wisely is plausibly the best way available to us to increase the probability that the future will contain a lot of value. To do this, **we must prevent any existential catastrophe**.

#### 3] Actor specificity: A] Governments must aggregate since every policy benefit some and harms others, which also means side constraints freeze action. B] States lack wills or intentions since policies are collective actions. C] Actor-specificity comes first since different agents have different ethical standings.

#### 4] Only consequentialism explains degrees of wrongness—if I break a promise to meet up for lunch, that is not as bad as breaking a promise to take a dying person to the hospital. Only the consequences of breaking the promise explain why the second one is much worse than the first.

## BioTech

#### **U.S dominance over biotech now BUT Misguided policy cedes control to China.**

Gupta 6/11 [“As Washington Ties Pharma's Hands, China Is Leaping Ahead.”, Gaurav Gupta, *Opinion | America Risks Ceding Its Biotech Dominance to China | Barron's*, Barrons, 11 June 2021, www.barrons.com/articles/as-washington-ties-pharmas-hands-china-is-leaping-ahead-51623438808., *Gaurav Gupta, a physician, is the founder of the biotechnology investment firm Ascendant BioCapital.]//Lex AKu*

There should be no doubt that we are living at the dawn of a golden age of biomedical innovation. The American scientific engine that produced Covid-19 vaccines in record time was fueled by a convergence of advances in genomics, biomarkers, data science, and manufacturing years in the making. The first Food and Drug Administration approvals of a host of new product formats—oligonucleotide, bispecific, oncolytic virus, CAR-T, and lentivirus/AAV—all took place within the last decade. These represent an unprecedented expansion of the armamentarium that physicians have at their disposal to treat and cure disease. In the last few years, 47% of all new medicines were invented by U.S. biopharma companies, with homegrown startups driving the majority of innovation. The bulk of the remainder were developed by foreign companies specifically for the U.S. market. An indirect benefit of these trends is that most novel therapeutics undergo clinical development and early commercial launch here in the U.S. The rest of the world understands that the American patient has earlier and broader access to groundbreaking therapies via these mechanisms. Indeed, the past decade is filled with examples of medical “firsts” for American patients: the first cure for Hepatitis C, the first gene therapy for blindness, the first immunotherapy for cancer. Future rewards will be greater still if we preserve our current system of incentivizing and protecting The remarkable innovation capacity of our biopharmaceutical industry ought to be a source of national pride. Yet while “Made in America” is the global standard for medicines in development today, misguided policy risks ceding our scientific prowess to other countries in the future. This is particularly true in the case of China, where biotechnology has become a strategic pillar for the health of its people and economy. From 2016 to 2020, the market capitalization of all Chinese biopharma companies increased exponentially from $1 billion to over $200 billion. China saw over $28 billion invested in its life sciences sector in 2020, double the previous year’s amount. Returns on China’s investment are already arriving. The FDA approved a drug developed in China for the first time ever in 2019. While China’s innovation capacity currently remains behind America’s, my experiences as a biopharma professional make it clear they are doing everything they can to catch up and catch up fast. In fact, when I speak to Chinese biotechnology executives, they boast that they can run clinical trials faster than their U.S. counterparts. The danger of misguided policies that disincentivize pharmaceutical innovation in the U.S. is effectively driving that same innovation to China. If we close off the market in the U.S. at the same time that China is opening its market to innovative new products, then we will see companies choose to first launch impactful novel medicines in China, based on clinical trials conducted in China. Because the FDA rarely accepts data generated entirely outside the U.S., this relocation of research capacity will negatively affect Americans’ access to cutting-edge therapies. The biotechnology field is advancing rapidly. Promising technologies such as targeted protein degradation and gene editing are perhaps not far from being developed into impactful medicines, and the U.S. risks these technologies being mastered by Chinese companies.

#### pThe plan chills American biomed innovation and cedes control to China.

Paulsen 7/9 [ERIK PAULSEN: We can save the world with our vaccines — without surrendering our IP to China," Bakersfield Californian, https://www.bakersfield.com/opinion/erik-paulsen-we-can-save-the-world-with-our-vaccines-without-surrendering-our-ip-to/article\_b0b87692-df61-11eb-9a13-d7fa02eefaee.html]//Lex AKu

The Biden administration gave Beijing a gift when it endorsed a petition before the World Trade Organization to force the American developers of Covid-19 vaccines and therapeutics to relinquish their intellectual property rights to these medicines. The Chinese government seeks to take over in biotech, a sector where U.S. innovators lead. Biotech is included in its “Made in China 2025” plan, which lists 10 sectors that China aims to dominate. The government intends to force anyone doing business in China in those spheres to hand over know-how. Surrendering IP protections on biomedical technology has dire consequences. Foremost, it guts the foundation of biomedical innovation, which takes huge investments spanning many years to bear fruit. IP protections assure innovators that they can recover those investments and make a profit. Losing IP protection would have a chilling effect on investments in the sector. Equally injurious to America, the IP waiver would allow China to become a biotech powerhouse by piggybacking on American innovation. A waiver on IP for Covid-19 vaccines would accelerate the timeline for “Made in China 2025.” The mRNA technology, which undergirds the Pfizer-BioNTech and Moderna vaccines has uses beyond this pandemic. It has the potential to take on cancers and other diseases. With the waiver, China and others will be emboldened to use the once-proprietary mRNA know-how for broader research and applications. Is this in America’s interest? Mark Cohen, an expert on Chinese IP theft, recently told the Washington Post that the waiver would deliver “a competitive advantage to countries that are increasingly viewed as our adversaries, at taxpayer expense.” Beyond the damage that an mRNA giveaway will inflict on US R&D investments, the waiver sends a signal that America could agree to force American innovators to part with trade secrets every time there’s a global crisis. That attitude will arrest biopharmaceutical innovation. Small biotech firms spearhead 70 percent of the R&D pipeline, relying heavily on private investors to fund that work. If investors know that innovators may have to give away their discoveries in a global crisis, they’ll deploy their money elsewhere. That’ll make it even harder to draw the R&D investments needed to address infectious diseases, including drug-resistant infections and viruses. America is benefitting greatly from the early access to COVID-19 treatments and vaccines, saving lives and speeding economic recovery. Preserving U.S. leadership in biomedical innovation includes preserving the incentives that helped make it the world’s leader. A final downside of the waiver is the ability for American firms to find a cure for the next pandemic. Among the greatest threats is bacteria resistant to our current arsenal of antibiotics that becomes a pandemic-inducing superbug. Already, the market for new antimicrobials is broken. Only a handful of biotechs have them in development, and many have gone bankrupt trying to commercialize one. “A lot of people have rightly said we need to start thinking about preparing for the next pandemic now,” noted Craig Garthwaite, a healthcare-business professor at Northwestern University. “Suspending IP for vaccine manufacturers would send exactly the wrong signal for the future.” For the sake of patients everywhere, American IP rights must stay protected. It’s the only way to keep China at bay and American innovators at work.

#### Biotech leadership key to future military primacy.

Moore 21 [(Scott Moore is a political scientist and administrator at the University of Pennsylvania and the author of a forthcoming book, “How China Shapes the Future,” on China’s role in public goods and emerging technologies.) 8-8-2021, "In Biotech, the Industry of the Future, the U.S. Is Way Ahead of China," Lawfare, https://www.lawfareblog.com/biotech-industry-future-us-way-ahead-china]//Lex AKu

A continuing refrain from Washington in recent years has been that the United States is falling behind China in the development of critical emerging technologies. In some fields, this may be true. But not in biotechnology. To be sure, China’s biotech sector is growing at a torrid pace, and some of its firms are becoming leaders in certain areas, such as cancer treatment. Yet the U.S. retains a dominant position in research, development and commercialization, accounting for almost half of all biotech patents filed from 1999 to 2013. The triumph of its biotechnology industry during the coronavirus pandemic, producing two highly effective vaccines using an entirely new approach based on messenger RNA, and in record time, shows that the U.S.’s competitive edge in biotechnology remains largely intact. And that has important implications as Washington gears up for a sustained period of geopolitical competition with Beijing. Biotech is such a critical area for technological competition between the U.S. and China because it is transforming fields from medicine to military power. The great advances of the 19th century, like chemical fertilizers, resulted from mastering chemistry. In the 20th century, mastery of physics led to nuclear energy—and, more ominously, nuclear weapons. In the 21st century, biology offers a similar mix of peril and promise. This was illustrated dramatically by the award of the 2020 Nobel Prize for the discovery of an enzyme system known as CRISPR-Cas9, which allows an organism’s genomes to be edited with high precision. It is a transformational breakthrough. But while CRISPR shows great promise in the development of new cures for long-untreatable diseases, it could also lead to a whole new generation of deadly bioweapons. That’s a prospect that increasingly alarms U.S. intelligence officials. In 2016, then-Director of National Intelligence James Clapper warned Congress that “[r]esearch in genome editing conducted by countries with different regulatory or ethical standards than those of western countries probably increases the risk of the creation of potentially harmful biological agents or products.” Although Clapper didn’t name specific countries, it soon became clear that he was referring mainly to China. Four years later, his successor, John Ratcliffe, issued a far more pointed warning that “China has even conducted human testing on members of the People’s Liberation Army in hope of developing soldiers with biologically enhanced capabilities. There are no ethical boundaries to Beijing’s pursuit of power.” Such capabilities are almost certainly only speculative—but they underscore why biotech leadership is so important for national security as well as economic competitiveness. Beijing has long envied the United States’s dominant position in biotechnology and spent heavily to overtake it. Biotech has been a priority sector for state investment since the 1980s, and by one estimate Beijing had poured some $100 billion into the sector by 2018. Nowhere did it lavish more attention or invest more of its propaganda power than in developing a coronavirus vaccine. State media have spent months crowing that “China is working around the clock for breakthroughs in COVID-19 vaccines.” Yet despite this push, China’s vaccine program quickly took on a Potemkin air. In February 2020, barely two months after the onset of the pandemic and after a supposedly crash vaccine effort, a military doctor stood in front of a Chinese flag to receive what was billed as an experimental vaccine dose but was widely suspected to be a staged photo op. Now, having spent months talking up its two primary vaccine candidates to developing countries like Brazil and Indonesia, both of which have entered into purchase agreements with Chinese biotech firms, Chinese officials face severe mistrust among their nation’s overseas partners. For China’s leaders, the disappointing returns on their big bet on biotechnology look likely to cause them more headaches at home as well as abroad—there are already signs that affluent Chinese place more trust in foreign-developed coronavirus vaccines than the homegrown ones produced at such great expense. For U.S. officials, though, China’s relative underperformance in vaccine development presents an opportunity to reassert the United States’s leadership in biotechnology and public health and bolster the nation’s depleted soft power in the process. The Biden administration has already signaled it will reengage in multilateral bodies such as the World Health Organization. Yet the U.S. shouldn’t stop there. Washington should begin thinking now about how to emulate the success of the President’s Emergency Plan for AIDS Relief (PEPFAR)—which, though imperfect, is widely regarded as one of the most successful single public health interventions in history—to address growing disparities in access to coronavirus vaccines between countries. At the moment, vaccine supplies are controlled largely by rich countries, creating the risk of moral and public health failure if the gap persists. While COVID-19, the respiratory disease caused by the novel coronavirus, differs in many respects from AIDS, PEPFAR combined research, prevention, and access to therapeutics. Developing a comparable institutional structure to close the coronavirus vaccine access gap is the right thing to do—but it would also go a long way to restoring America’s battered global reputation. At the same time, the United States can’t afford to rest on its laurels in biotechnology, or any other field. Aside from China, other nations like Singapore and Israel have also invested heavily to develop their biotechnology sectors, with Israel in particular giving rise to a thriving biotech industry. U.S. public investment in basic scientific research and development has meanwhile been on the decline for decades, and there are worrying signs that America’s once world-beating innovation ecosystem is less productive, and less entrepreneurial, than it once was. Despite strengths in translational research, moreover, the frontiers of biology increasingly sit at the intersection with other disciplines like computer science, meaning that funding agencies, universities and other organizations need to break down disciplinary silos. Boosting support for biotechnology research, while reforming how that money is used, will go a long way toward shoring up the United States’s leading position in the global biotech sector. The U.S. biotechnology sector also faces other threats, not least growing espionage and intellectual property theft by foreign actors, especially those linked to China. Several high-profile cases brought by the U.S. Department of Justice’s China Initiative have involved biotechnology researchers, and American biotech firms have been top targets for cyber theft and intrusion. Sustained outreach to researchers and research institutions is critical to preventing such theft. But efforts to clamp down on the threats posed by espionage and intellectual property theft can easily go too far and must preserve the researcher mobility and data-sharing that is essential to doing cutting-edge science. Beyond its shores, the United States should work with its partners and allies to enhance export controls on dual-use biotechnology—used for both peaceful and military gain—especially DNA templates. Many forms of genetic material and synthetic biology products are already subject to U.S. export controls, but gaps remain, and screening for genetic sequence orders relies primarily on voluntary regulation by biotech firms. Better coordinating export controls among major economies and U.S. allies can dramatically reduce the risk of sophisticated bioweapons development in the decades to come.

#### hHeg solves arms races, land grabs, rogue states, and great power war.

Brands 18 [Hal, Henry Kissinger Distinguished Professor at Johns Hopkins University's School of Advanced International Studies and a senior fellow at the Center for Strategic and Budgetary Assessments." American Grand Strategy in the Age of Trump." Page 129-133]

Since World War II, the United States has had a military second to none. Since the Cold War, America has committed to having overwhelming military primacy. The idea, as George W. Bush declared in 2002, that America must possess “strengths beyond challenge” has featured in every major U.S. strategy document for a quarter century; it has also been reflected in concrete terms.6 From the early 1990s, for example, the United States consistently accounted for around 35 to 45 percent of world defense spending and maintained peerless global power-projection capabilities.7 Perhaps more important, U.S. primacy was also unrivaled in key overseas strategic regions—Europe, East Asia, the Middle East. From thrashing Saddam Hussein’s million-man Iraqi military during Operation Desert Storm, to deploying—with impunity—two carrier strike groups off Taiwan during the China-Taiwan crisis of 1995– 96, Washington has been able to project military power superior to anything a regional rival could employ even on its own geopolitical doorstep. This military dominance has constituted the hard-power backbone of an ambitious global strategy. After the Cold War, U.S. policymakers committed to averting a return to the unstable multipolarity of earlier eras, and to perpetuating the more favorable unipolar order. They committed to building on the successes of the postwar era by further advancing liberal political values and an open international economy, and to suppressing international scourges such as rogue states, nuclear proliferation, and catastrophic terrorism. And because they recognized that military force remained the ultima ratio regum, they understood the centrality of military preponderance. Washington would need the military power necessary to underwrite worldwide alliance commitments. It would have to preserve substantial overmatch versus any potential great-power rival. It must be able to answer the sharpest challenges to the international system, such as Saddam’s invasion of Kuwait in 1990 or jihadist extremism after 9/11. Finally, because prevailing global norms generally reflect hard-power realities, America would need the superiority to assure that its own values remained ascendant. It was impolitic to say that U.S. strategy and the international order required “strengths beyond challenge,” but it was not at all inaccurate. American primacy, moreover, was eminently affordable. At the height of the Cold War, the United States spent over 12 percent of GDP on defense. Since the mid-1990s, the number has usually been between 3 and 4 percent.8 In a historically favorable international environment, Washington could enjoy primacy—and its geopolitical fruits—on the cheap. Yet U.S. strategy also heeded, at least until recently, the fact that there was a limit to how cheaply that primacy could be had. The American military did shrink significantly during the 1990s, but U.S. officials understood that if Washington cut back too far, its primacy would erode to a point where it ceased to deliver its geopolitical benefits. Alliances would lose credibility; the stability of key regions would be eroded; rivals would be emboldened; international crises would go unaddressed. American primacy was thus like a reasonably priced insurance policy. It required nontrivial expenditures, but protected against far costlier outcomes.9 Washington paid its insurance premiums for two decades after the Cold War. But more recently American primacy and strategic solvency have been imperiled. THE DARKENING HORIZON For most of the post–Cold War era, the international system was— by historical standards—remarkably benign. Dangers existed, and as the terrorist attacks of September 11, 2001, demonstrated, they could manifest with horrific effect. But for two decades after the Soviet collapse, the world was characterized by remarkably low levels of great-power competition, high levels of security in key theaters such as Europe and East Asia, and the comparative weakness of those “rogue” actors—Iran, Iraq, North Korea, al-Qaeda—who most aggressively challenged American power. During the 1990s, some observers even spoke of a “strategic pause,” the idea being that the end of the Cold War had afforded the United States a respite from normal levels of geopolitical danger and competition. Now, however, the strategic horizon is darkening, due to four factors. First, great-power military competition is back. The world’s two leading authoritarian powers—China and Russia—are seeking regional hegemony, contesting global norms such as nonaggression and freedom of navigation, and developing the military punch to underwrite these ambitions. Notwithstanding severe economic and demographic problems, Russia has conducted a major military modernization emphasizing nuclear weapons, high-end conventional capabilities, and rapid-deployment and special operations forces— and utilized many of these capabilities in conflicts in Ukraine and Syria.10 China, meanwhile, has carried out a buildup of historic proportions, with constant-dollar defense outlays rising from US$26 billion in 1995 to US$226 billion in 2016.11 Ominously, these expenditures have funded development of power-projection and antiaccess/area denial (A2/AD) tools necessary to threaten China’s neighbors and complicate U.S. intervention on their behalf. Washington has grown accustomed to having a generational military lead; Russian and Chinese modernization efforts are now creating a far more competitive environment. Second, the international outlaws are no longer so weak. North Korea’s conventional forces have atrophied, but it has amassed a growing nuclear arsenal and is developing an intercontinental delivery capability that will soon allow it to threaten not just America’s regional allies but also the continental United States.12 Iran remains a nuclear threshold state, one that continues to develop ballistic missiles and A2/AD capabilities while employing sectarian and proxy forces across the Middle East. The Islamic State, for its part, is headed for defeat, but has displayed military capabilities unprecedented for any terrorist group, and shown that counterterrorism will continue to place significant operational demands on U.S. forces whether in this context or in others. Rogue actors have long preoccupied American planners, but the rogues are now more capable than at any time in decades. Third, the democratization of technology has allowed more actors to contest American superiority in dangerous ways. The spread of antisatellite and cyberwarfare capabilities; the proliferation of man-portable air defense systems and ballistic missiles; the increasing availability of key elements of the precision-strike complex— these phenomena have had a military leveling effect by giving weaker actors capabilities which were formerly unique to technologically advanced states. As such technologies “proliferate worldwide,” Air Force Chief of Staff General David Goldfein commented in 2016, “the technology and capability gaps between America and our adversaries are closing dangerously fast.”13 Indeed, as these capabilities spread, fourth-generation systems (such as F-15s and F-16s) may provide decreasing utility against even non-great-power competitors, and far more fifth-generation capabilities may be needed to perpetuate American overmatch. Finally, the number of challenges has multiplied. During the 1990s and early 2000s, Washington faced rogue states and jihadist extremism—but not intense great-power rivalry. America faced conflicts in the Middle East—but East Asia and Europe were comparatively secure. Now, the old threats still exist—but the more permissive conditions have vanished. The United States confronts rogue states, lethal jihadist organizations, and great-power competition; there are severe challenges in all three Eurasian theaters. “I don’t recall a time when we have been confronted with a more diverse array of threats, whether it’s the nation state threats posed by Russia and China and particularly their substantial nuclear capabilities, or non-nation states of the likes of ISIL, Al Qaida, etc.,” Director of National Intelligence James Clapper commented in 2016. Trends in the strategic landscape constituted a veritable “litany of doom.”14 The United States thus faces not just more significant, but also more numerous, challenges to its military dominance than it has for at least a quarter century.

## I Law

#### Intellectual property rights cannot be discriminated on the basis of field, or place of invention

WTO <https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm>, Article 27.1, Section 5 on patents, World trade Organization, WTO, Part II — Standards concerning the availability, scope and use of Intellectual Property Rights

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [(5)](https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#fnt-5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

#### The WTO’s appellate body no longer exists to mediate disputes, without immediate buy in by states, and no mechanism to make disobedient states obey, the system collapses

Horton, 08/3, Lessons from Trump’s assault on the World Trade Organization, https://www.chathamhouse.org/2021/08/lessons-trumps-assault-world-trade-organization, Chatham House – International Affairs Think Tank, Communications Manager; Project Lead, Common Futures Conversations

The WTO is unique amongst international institutions because it has a powerful enforcement mechanism – the dispute settlement system. However, the fundamental vulnerability is that if powerful states like the US and others won’t participate in the system and be bound by its rules, they quickly risk becoming irrelevant. And that’s the situation we’re in right now with the appellate body crisis, where, without a functioning mechanism to ensure that WTO rules are enforced, the entire system of global trade rules risk collapsing. Ironically, the United States has been the leader of the liberal trading order for the past 70 years, but since Trump, it has become its leading saboteur.

#### A major country operating outside WTO consensus wrecks global trade norms

Bacchus 20 [James Bacchus, member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida, 12-16-2020, "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," Cato Institute, [https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines]/Kankee](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines%5d/Kankee)

In a sign of their increasing frustration with global efforts to ensure that all people everywhere will have access to COVID-19 vaccines, several developing countries have asked other members of the World Trade Organization (WTO) to join them in a sweeping waiver of the intellectual property (IP) rights relating to those vaccines. Their waiver request raises anew the recurring debate within the WTO over the right balance between the protection of IP rights and access in poorer countries to urgently needed medicines. But the last thing the WTO needs is another debate over perceived trade obstacles to public health. Unless WTO members reach a consensus, the multilateral trading system may be further complicated by a delay like that in resolving the two‐​decades‐​old dispute between developed and developing countries over the compulsory licensing and generic distribution of HIV/AIDS drugs. A new and contentious “North‐​South” political struggle definitely would not be in the interest of the developed countries, the developing countries, the pharmaceutical companies, or the WTO. Certainly it would not be in the interest of the victims and potential victims of COVID-19. Background In early October 2020, India and South Africa asked the members of the WTO to waive protections in WTO rules for patents, copyrights, industrial designs, and undisclosed information (trade secrets) in relation to the “prevention, containment or treatment of COVID-19 … until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.”1 India and South Africa want to give all WTO members freedom to refuse to grant or enforce patents and other IP rights relating to COVID-19 vaccines, drugs, diagnostics, and other technologies for the duration of the pandemic. In requesting the waiver, India and South Africa have argued that “an effective response to the COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.” They have said that “as new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable prices to meet global demand.”2 Later in October, the members of the WTO failed to muster the required consensus to move forward with the proposed waiver. The European Union, the United States, the United Kingdom, and other developed countries opposed the waiver request.3 One WTO delegate, from the United Kingdom, described it as “an extreme measure to address an unproven problem.”4 A spokesperson for the European Union explained, “There is no evidence that intellectual property rights are a genuine barrier for accessibility of COVID‐​19‐​related medicines and technologies.”5 In the absence of a consensus, WTO members have decided to postpone further discussion of the proposed waiver until early 2021. Balancing IP Rights and Access to Medicines Not New to WTO This waiver controversy comes nearly two decades after the end of the long battle in the multilateral trading system over access to HIV/AIDS drugs. At the height of the HIV/AIDS crisis at the turn of the century, numerous countries, including especially those from sub‐​Saharan Africa, could not afford the high‐​priced HIV/AIDS drugs patented by pharmaceutical companies in developed countries. Having spent billions of dollars on developing the drugs, the patent holders resisted lowering their prices. The credibility of the companies, the countries that supported them, and the WTO itself were all damaged by an extended controversy over whether patent rights should take precedence over providing affordable medicines for people afflicted by a lethal disease. Article 8 of the WTO Agreement on the Trade‐​Related Aspects of Intellectual Property Rights (the TRIPS Agreement) provides that WTO members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement.” In similar vein, Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights” shall be “in a manner conducive to social and economic welfare.”6 It can be maintained that these two WTO IP rules are significantly capacious to include any reasonable health measures that a WTO member may take during a health emergency, such as a pandemic. Yet there was doubt among the members during the HIV/AIDS crisis about the precise reach of these provisions. As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”7 But, in public health emergencies, it may be impossible to obtain a license. In such cases, “compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders.8

#### Without all states buy in, we risk WW3 but with nukes

Hopewell and Horton 08-03 [Kristen Hopewell Associate Professor and Canada Research Chair in Global Policy at the University of British Columbia, and Ben Horton, Communications Manager; Project Lead, Common Futures Conversations, 08-03-2021, "Lessons from Trump’s assault on the World Trade Organization," Chatham House – International Affairs Think Tank, https://www.chathamhouse.org/2021/08/lessons-trumps-assault-world-trade-organization]/Kankee

What has this episode revealed about the strength of multilateral institutions such as the WTO, in the face of spoiling tactics from major powers? The WTO is unique amongst international institutions because it has a powerful enforcement mechanism – the dispute settlement system. However, the fundamental vulnerability is that if powerful states like the US and others won’t participate in the system and be bound by its rules, they quickly risk becoming irrelevant. And that’s the situation we’re in right now with the appellate body crisis, where, without a functioning mechanism to ensure that WTO rules are enforced, the entire system of global trade rules risk collapsing. Ironically, the United States has been the leader of the liberal trading order for the past 70 years, but since Trump, it has become its leading saboteur. What are the implications of a permanent collapse of the international trading system? The very real danger from such a breakdown is a return to what we saw in the 1930s. In response to the outbreak of the Great Depression, you had countries imposing trade barriers, blocking imports from other state, and a general escalation of tit-for-tat protectionism. This response wound up not only exacerbating the effects of the depression itself but has also been credited by some as paving the way for the outbreak of the second world war. The reason why institutions like the WTO were created in the first place was to prevent a recurrence of the 1930s protectionist trade spiral. The danger now – if those rules become meaningless and unenforceable – is the institutional foundations of postwar economic prosperity could unravel, throwing us back into economic chaos and potentially political disorder. What does the WTO’s future look like under new director-general Dr Okonjo-Iweala?

## 1NC – Production CP

#### The United States federal government should:

#### -   reduce intellectual property protections for medicines except for vaccines.

**- substantially increase production and global distribution of the COVID-19 Vaccine,**

**- cooperate with allies to achieve increased production and global distribution of the COVID-19 Vaccine.**

**That comparatively solves better – IP rights don’t hinder vaccine cooperation, but manufacturing capacity is the current constraint.**

Hans **Sauer 6-17** [(Deputy General Counsel, Biotechnology Industry Organization.) “Web event — Confronting Joe Biden’s proposed TRIPS waiver for COVID-19 vaccines and treatments” https://www.aei.org/wp-content/uploads/2021/06/210617-Confronting-Joe-Bidens-proposed-TRIPS-waiver.pdf?x91208&x91208] TDI

But contrary to what Lori said, **there are genuine real problems in the supply chain** that are **not caused by patents**, that are simply caused by the unavailability and the constraints on existing capacity. There is in this world such a thing as maxed-out capacity that just can’t be increased on a dime. It’s not all due to intellectual property. This is true for existing vaccines as well as for vaccine raw materials. There are trade barriers. There are export restrictions that we should all be aware of and that we need to work on. And there are very real political, I think, interests in finding an explanation for how we got to this place that absolve governments around the world from their own policy decisions that they made in the past. In the United States, again, it was the declared policy of the previous administration, as well as this one, that we would vaccinate healthy college kids and go all down the line and offer a vaccine to everybody who wants it before we start sharing any with grandmothers in Burkina Faso. That was the policy. You can agree with it or disagree with it, but that was policy. We had export restrictions in place before a lot of other countries did. And that, too, contributed to unequal access of vaccines around the world. Another thing that was predictable was that politicians and governments around the world who want to be seen as proactive, on the ball, in control, for a long time were actually very indecisive, very unsure about how to address the COVID problem, which has so many dimensions. Vaccines are only one of those. But with respect to vaccines, not many governments took decisive action, put money on the table, put bets on multiple horses, before we knew whether these vaccines would work, would be approved. And it was governments in middle-income countries who now, I think, justifiably are concerned that they’re not getting fast enough access, who didn’t have the means and who didn’t have the decision-making structure to place the same bets on multiple horses, if you will, that were placed in the relatively more wealthy, global North and global West. But there is, I think, a really good and, with hindsight, predictable explanation of how we got to this place, and I think it teaches us something about how to fix the problem going forward. **So why will the waiver not work**? Well, first of all, with complex technology like vaccines, Lori touched on it, reverse engineering, like you would for a small molecule drug, is much more difficult if not impossible. But it depends very much more than small molecule drugs on cooperation, on voluntary transfer of technology, and on mutual assistance. We have seen as part of the pandemic response an unprecedented level of collaborations and cooperation and no indication that IP has stood in the way of the pandemic response. **The waiver proponents have found zero credible examples of where IP has actually been an obstacle,** where somebody has tried to block somebody else from developing a COVID vaccine or other COVID countermeasure, right? It’s not there. **Second, the myth of this vast global capacity to manufacture COVID vaccines that somehow exists** **out there is unsubstantiated** and frankly, in my opinion, untrue. But there is no such thing as vast untapped, idle capacity that could be turned around on a dime to start making COVID vaccines within weeks or even months. This capacity needs to be built; it needs to be established. And at a time when time is of the essence to beat this pandemic, starting capacity-building discussions is helpful, but it won’t be the answer to beat this pandemic. It will be the answer if we do everything right to beating the next pandemic. And if we learn any lesson of this, and then I will stop, is that the COVID waiver as well as the situation in which we find ourselves — if anything, it’s a reminder that we definitely have to take global capacity-building more seriously than we did in the past. That is true for the global North, as well as for middle-income countries — all of whom have to dedicate themselves much more determinedly to pandemic preparedness. And there’s a need to invest both in preparedness and in public health systems that hasn’t happened in the wake of past pandemic threats. This is what we will need to do. We will need to reduce export restrictions, and we will need to rededicate ourselves to preparing for the next pandemic. As far as this pandemic goes, **there are 11 vaccines around the world that are already being shot into arms, only four of which come from the global North. How many more vaccines do we want?** I don’t know, maybe 11 is enough if we start making more of them. But there are manufacturers around the world who know how to do this — including in China, including in India, and including in Russia. All developed their homegrown vaccines, apparently without interference by IP rights, right? **So let’s make more of those. I think that’s going to be the more practical and realistic answer to solving the problem**. And we need to lean on governments to stop export controls and to dedicate themselves to more global equity.

## E Spec

#### Interpretation: Debaters must delineate how they enforce reduction of IPP in the 1AC.

#### Violation: They dont

#### 1] Resolvability – enforcement is the core to aff solvency. Yu 14

Peter K. Yu, 12-2014, "Why Are the TRIPS Enforcement Provisions Ineffective?," Texas A&amp;M Law Scholarship, <https://scholarship.law.tamu.edu/facscholar/1022/> AT

Shortly after the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), commentators widely praised the Agreement for transforming the international intellectual property system. While some considered the extension of the mandatory dispute settlement process of the World Trade Organization (WTO) to intellectual property disputes a crowning achievement of the Uruguay Round of Multilateral Trade Negotiations (Uruguay Round), others extolled the unprecedented benefits of having a set of multilateral enforcement norms built into the international intellectual property system. With twenty-one provisions on obligations that range from border measures to criminal sanctions, the TRIPS Agreement, for the first time, provides comprehensive international minimum standards on the enforcement of intellectual property rights. Notwithstanding these quick praises, some commentators provided more measured assessments. For example, in a prescient, and still highly relevant, article published shortly after the adoption of the TRIPS Agreement, Jerome Reichman and David Lange described the Agreement’s enforcement provisions as its ‘Achilles’ heel’. As they observed: The enforcement provisions are crafted as broad legal standards, rather than as narrow rules, and their inherent ambiguity will make it harder for mediators or dispute-settlement panels to pin down clear-cut violations of international law … . We predict that the level of enforcement under the TRIPS Agreement will greatly disappoint rightsholders in the developed countries, and that recourse to coercive measures will not appreciably improve the situation in the short and medium terms.

#### That’s a voter since judges need to decide debates and takes out regress since its key to topic debates.

#### 2] Stable advocacy – 1AR clarification delinks neg positions that prove why enforcement in a certain instance is bad by saying it isn't their method of enforcement – wrecks neg ballot access and kills in depth clash – CX doesn't check since it kills 1NC construction pre-round since I don't know advocacy till in round, and judges do not flow cross ex so its not verifiable.

#### 3] Prep skew – I don't know what they will be willing to clarify until CX which means I could go 6 minutes planning to read a disad and then get screwed over in CX when they spec something else.

#### Fairness- consittutive of comp activites, args presume

#### Edu- funded ny schools

#### DTD- dta illogical, time skew

#### No RVI’s- illogical, baiting

#### CI- intervention, race to bottom, collapses, yours vs best

# Case

#### IP developed COVID vaccines rapidly and produced collaboration – turns case

Stevens and Schultz 21 [Philip Stevens and Mark Schultz, “WHY INTELLECTUAL PROPERTY RIGHTS MATTER FOR COVID-19”. Geneva Network, January, 2021. https://geneva-network.com/wp-content/uploads/2021/01/Why-IP-matters-for-Covid-19.pdf]

Some asserted that intellectual property would inevitably hold up urgent research. They theorised that the “winner-takes-all” nature of intellectual property rights, especially patents, would prevent scientists from rapidly disclosing research results, and discourage the sharing of unpatentable insights that may potentially lead to patentable treatments with further work. Members of Congress warned that IP would “put public health at risk”, while NGO Médecins Sans Frontières (MSF) called for “no patents or profiteering” on yet to be developed health technologies. A coalition of over 500 NGOs claimed that IP rights were a “hindrance” to efforts to tackle the pandemic, calling for all COVID-19-related IP to be rescinded. As events demonstrated, critics of IP were wrong by a wide margin. In January 2020 very little was known about COVID-19. By January 2021, three safe and highly efficacious vaccines had been authorised for use by stringent regulatory authorities, with several others poised to follow. As of 21st December 2o20, there were 1052 COVID-19-19 vaccines, therapeutics and diagnostic tools under development or approved globally, of which 219 are vaccines. This major achievement is a testament to how well the IP system has worked during the pandemic. Calls to override intellectual property rights in the early stages of the pandemic were seductive and were backed by respected global humanitarian NGOs and prominent political figures. But it is to the credit of the majority of governments that they held their nerve and ignored such calls, despite the growing urgency of the situation over 2020. V BUILDING ON EXISTING IP IP is the bedrock upon which today’s COVID-19 vaccines have been built. The technologies they are based on did not come out of thin air at the beginning of the pandemic, but had been under development for decades, with substantial research in academic labs followed by years of risky investment by commercial start-ups. Consider the messenger RNA (mRNA) technology that is the basis for two of the first vaccines approved in Western countries. Scientists discovered in 1961 that mRNA could be used to “reprogram” cells to battle disease. It took decades of lab research and private sector-funded development by startups BioNTech and Moderna to overcome major difficulties and turn the technology into an effective vaccine that can be safely given to patients. Both companies and their investors have spent billions of dollars on mRNA research prior to the pandemic. While academic research is fundamental, the end result would not have been possible without the private sector, which depends on intellectual property rights. Shortly before the pandemic started, we spoke to Dr. Derrick Rossi, the academic founder of Moderna. When asked whether the treatments could be brought from the academic lab to patients without the help of the private sector, Dr. Rossi’s reply was categorical: “Not a chance. Academics are good at academia and fundamental science. They are not good at developing drugs for patients.” Dr. Rossi explains that bringing a drug to market takes many professionals, sharing their labour and diverse expertise. “This industry of professionals is out there... The more people that are involved in the chain, post-academic discovery, the more you have pros involved — all the way from IP filings to VCs to due diligence to assembling a team,” the more likely you are to develop a viable treatment. Developing a practical application for a great academic insight takes vast sums, and investors need some prospect of a return on that investment. As Dr. Rossi explains, “you can be working on the coolest thing, but investors need to know that there is some protection for their investment, plain and simple.” V IP HELPS NOT HINDERS R&D COLLABORATION The other claim frequently heard at the beginning of the pandemic was that IP poses a barrier to collaboration and knowledge sharing, so in a time of emergency any related IP should be open licensed or pooled. In reality, the IP system encouraged the rapid establishment of dozens of partnerships around COVID-19-19, with even commercial rivals prepared to cooperate and share capital and proprietary intellectual resources such as compound libraries. Examples of consortia between the private sector and research centres include the COVID-19-19 Therapeutics Accelerator to evaluate new and repurposed drugs and biologics, the EU-backed Swift COronavirus therapeutics REsponse, Corona Accelerated R&D in Europe (CARE) as well as dozens of bilateral agreements between companies. Indeed, the Pfizer vaccine is the result of its collaboration with BioNtech, where partners shared and combined knowhow and proprietary knowledge to create the first vaccine authorized in the U.S. Far from being a barrier to such collaborations, IP is fundamental. Because patent rights require public disclosure, they enable drug developers to identify partners with the right intellectual assets such as knowhow, platforms, compounds and technical expertise. Without patents most of this valuable proprietary knowledge would be kept hidden as trade secrets, making it impossible for researchers to know what is out there. Second, the existence of laws protecting intellectual property helps rights-holders make the decision to collaborate in the first place. By allaying concerns about confidentiality, IP enables companies to open up their compound libraries, and to share platform technology and know-how without worrying they are going to sacrifice their wider business objectives or lose control of their valuable assets. For instance, rights holders might contribute IP that is useful for entirely different diseases to COVID-19 collaborations. IP rights and licensing ensure those rights can only be used for the agreed reason, preventing competitors freeriding to gain an unfair advantage in other areas. As the former Director General of WIPO noted in June 2020, the main challenge at the time was “not access to vaccines, treatments or cures for COVID-19-19, but the absence of any approved vaccines, treatments or cures to have access to. The policy focus of governments at this stage should therefore be on supporting science and innovation”. During this initial phase of the pandemic, the majority of governments followed this advice, especially by not threatening to remove IP of products yet to be invented. No government from a country with a significant life-science R&D industry, for instance, backed the WHO’s “Solidarity Call to Action” in which companies were asked to unilaterally cede IP and data related to COVID-19 to its new technology and IP pool, C-TAP. The WHO embarked on this initiative with no evidence that IP would stand in the way of R&D and access efforts, distracting efforts away from more practical initiatives that stood greater chance of success. V WHAT ABOUT THE PRICE OF PATENTED VACCINES AND THERAPEUTICS? Nevertheless, the emergence of several competing vaccines has shifted the debate. There are increasingly loud calls to suspend IP rights in order to promote affordable prices for low and middle-income countries, and to mandate forced transfer of know-how and technology in order to scale up global manufacturing . These calls have culminated in proposals at the WTO to implement a temporary suspension of certain provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), including obligations regarding patent rights and the protection of undisclosed information on all COVID-19-related technologies Such extreme proposals are based on muddled thinking. Specifically, the political campaigns that underpin them mischaracterise IP rights as “monopolies” that allow companies to charge unaffordable prices. One eminent scholar of patents, Prof. Edmund Kitch described the application of the term “monopoly” to patents as one of the “elementary and persistent errors in the economic analysis of Intellectual Property”. In reality, IP rights drive the emergence of competing products in the same category, putting a lid on the ability of manufacturers to charge premium prices. Owning IP rarely gives control over a market and IP markets are often intensely competitive. In medicines, for instance, there are usually many substitutes and alternatives. For example, a patient needing a cholesterol drug has a host of statins from which to choose, both patented and generic. Similarly, patients with osteoporosis and their doctors can choose from Fosamax®, Actonel®, or Boniva®. Recent years have seen the emergence of competing shingle vaccines, increased competition in the lung cancer therapeutic space, and a slew of promising clinical trials and new drug launches in the under-served area of lung disease. Each of the owners of patents in these products has a temporary exclusive right to their product; none of them has a monopoly over the market for this type of treatment. The most spectacular demonstration of this point is the recent emergence of multiple competing hepatitis C cures, which have opened up a wide range of treatment options and placed downward pressure on prices. As Geoffrey Dusheiko and Charles Gore wrote in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.” Every step of the development of this new market in hepatitis C cures was accompanied by calls to override their IP by civil society and certain intergovernmental organizations. Had those calls been heeded, it is doubtful such a competitive market would exist today. A similar story is unfolding in the COVID-19 vaccine space. Pharmaceutical market analysts predict competition will hold COVID-19 vaccine prices down even in the unlikely scenario of rights holders declining to license their IP to other manufacturers. “In two years’ time, there could be 20 vaccines on the market,” Emily Field, head of European pharmaceutical research at Barclays told the BBC. “It’s going to be difficult to charge a premium price.” V THE REAL CHALLENGES 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: “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, 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. The TRIPS waiver, he says, is the “wrong approach” because COVID-19 therapeutics and vaccines are complex biological products in which the main barriers are production facilities, infrastructure, and know-how. “IP is the least of the barriers”, he says. Then there is the problem of distributing the vaccines to billions of people in every country. Even with plentiful supplies, a range of issues need to be considered such as regulatory bottlenecks; supply chain, transport and storage; maintenance of the cold chain; adequately trained staff; data tracking; and vaccine hesitancy amongst the population. The costs of the vaccine itself is only a small component of the total cost of delivering doses to millions of people. The UK, for example, has spent around £2.9bn on procuring vaccines, far less than the official estimate of £8.8bn to be spent on distributing and delivering them. Comparable costs will exist for all other countries, even if they are subsidised by Overseas Development Assistance. Even then, the combined costs of vaccination are dwarved by the other economic costs of the pandemic. V IP IS PART OF THE SOLUTION Far from being a problem, IP has repeatedly proven itself to be part of the solution in fighting disease. It allows innovators to manage production scale-up by selecting and licensing technology to partners who have the skills and capacity to reliably manufacture large quantities of high-quality products, which they distribute at scale in low and middle-income countries. It would make no sense for IP owners to use it to withhold access, when they can profit from supplying all demand. IP licensing is the way this is done. This is the model unfolding for COVID-19, with new manufacturing licensing deals such as those between AstraZeneca and the Serum Institute in India (1bn doses), China’s BioKangtai (200m doses), Brazil’s FioCruz, Russia’s R-Pharm and South Korea’s SK Bioscience. Collectively, such deals will see the manufacture of 2 billion doses by the end of 2021. The Serum Institute has also entered into manufacturing licenses with a number of developers of yet to be approved COVID-19 vaccines, as have several other Indian vaccine manufacturers. Many of these doses will be procured on a non-profit basis by new collective procurement bodies such as COVAX, for distribution to low and middleincome countries. IP is important because it allows the innovator to control which partners manufacture the product, ensuring the quality of supplies, while maximising low-cost access for low and middle-income countries. It also allows the innovator to preserve its ability to recoup costs from richer markets, meaning the preservation of incentives for future R&D investment. Voluntary licensing has worked well in the past, particularly for low and middle-income countries. A recent academic analysis of hepatitis C voluntary licenses published by The Lancet Global Health concluded that they have increased access to medicines at a considerably faster pace than alternative access models, by avoiding the need for lengthy patent disputes and bringing to bear intercompany competition and economies of scale. But again, these licenses model were criticised by public health NGOs and other stakeholders, who called for the confiscation of IP rights via compulsory licensing. Time has shown such calls to be mistaken. As of January 2021, there are three vaccines approved by stringent regulatory authorities with several more likely to follow in the coming months. Prices of COVID-19 vaccines vary between more expensive but complex to manufacture, and cheaper ones based on existing technologies. Companies are offering their vaccines at cost, with pooled procurement mechanisms such as COVAX ready to leverage their enormous purchasing power to drive economies of scale and bring prices down further for developing countries, many of which will have the cost of vaccination subsidised by Overseas Development Assistance. Meanwhile, the existence of multiple vaccines means there is no COVID-19 vaccine “monopoly”, and minimal risk of premium pricing. In fact, there is a competitive marketplace in which manufacturers are incentivised to refine and improve their vaccines – vital given the new strains of the virus which constantly emerge. Providing COVID-19 vaccines rapidly at scale is a pressing challenge for all countries but there is no evidence that overriding intellectual property rights will achieve more than the licensing agreements currently being forged between innovators and reputable vaccine manufacturers in countries like India and Brazil. Manufacturing of COVID-19 vaccines is continuing at speed, and mechanisms are gearing up to ensure a rapid global role out. Forceable tech transfer and other forms of IP abrogation such as those proposed by India and South Africa at the WTO TRIPS Council would throw manufacturing supply chain planning, financing and distribution systems into chaos for little upside. Instead of sowing division and creating major distractions at venues such as the WTO, opponents of IP should stop the rhetoric. The IP system has put us in a position to end the pandemic. We should allow it to continue doing its job.

#### IP Protections are key to the pharma sector – strong innovation solves future pandemics.

**Wilbur 20** [Tom Wilbur, Tom Wilbur is Director of Public Affairs at PhRMA focusing on message development and opinion research. Prior to joining PhRMA in 2019, Tom worked on Capitol Hill and on political campaigns for nearly a decade, most recently responsible for communications, campaigns and strategy for U.S. Rep. Fred Upton and the House Energy and Commerce Committee. 5-4-2020, accessed on 8-3-2021, Catalyst.phrma.org, "What they are saying: Intellectual property protections are critical as we work to defeat COVID-19", <https://catalyst.phrma.org/what-they-are-saying-intellectual-property-protections-are-critical-as-we-work-to-defeat-covid-19>] Adam

The U.S. biopharmaceutical industry depends on reliable intellectual property (IP) protections to promote the development of new breakthrough treatments and cures for patients. Strong IP protections are especially important while biopharmaceutical companies work around the clock to develop solutions to help prevent infection and treat those with COVID-19, a disease cause by the novel strain of coronavirus. In fact, many of the existing medicines and investigational medicines being tested for COVID-19 exist today because of IP and other incentives that drove their research and development. Here is a closer look at recent comments spotlighting how strong IP protections help fuel discovery efforts for COVID-19 treatments and vaccines: “The world has placed its profound confidence in the free enterprise of the leading scientists and innovators to reach as many solutions as possible in the shortest amount of time. It is obviously a heavy weight for researchers to bear, but not a burden…Removing the ability of these first responders to own their work while they are in the process, or after completion, undermines their efforts. Keeping these rights intact not only allows more knowledge-sharing in the fight against COVID-19 but also ensures long-term research to ready the fight against the next pandemic, as well.” – Philip Thomas, policy analyst at the Property Rights Alliance, in [Morning Consult](https://morningconsult.com/opinions/fighting-covid-19-doesnt-require-selling-out-our-innovation-ecosystem/) “Good patent policy incentivizes inventors to find solutions, not merely for today’s, but for tomorrow’s problems… America’s biomedical innovators have assumed the risk of costly dead ends along the long, bumpy road to developing a successful drug, device or test that addresses COVID-19. They’ve shouldered this burden in good faith in a no-holds-barred race on all fronts — diagnostics, ventilators, personal protective equipment, therapeutics and vaccines. For many, the IP exclusivity over the terms of their patents will help offset R&D costs eaten now.” – James Edwards, IP consultant and Gene Quinn, President and CEO of IP Watchdog Inc., in [IP Watchdog](https://www.ipwatchdog.com/2020/04/08/facilitating-innovation-to-fight-coronavirus-act-legislation-mixed-bag/id=120483/) “The Bayh-Dole Act represents one of the bedrock policies that has helped make the U.S. biomedical innovation system the envy of the world and a key place the world is now turning to in the search for an accessible coronavirus vaccine or treatment. Those who would misguidedly interpret Bayh-Dole march-in-rights as a price-control provision that could be leveraged in the coronavirus case or other circumstances advocate for an approach that threatens to seriously deter biomedical innovation and undermine a key pillar of America’s biomedical innovation system.” – Stephen Ezell, vice president for global innovation policy at the Information Technology and Innovation Foundation, in [Morning Consult](https://morningconsult.com/opinions/how-bayh-dole-act-facilitates-development-coronavirus-therapies/) “The appropriate intellectual property framework is enabling the rapid R&D response. Many potential treatments are based on decades of prior R&D and investment or originally were pioneered to treat other conditions. These breakthroughs were enabled by a robust innovation eco-system underpinned by effective IP.” – Oscar Guinea, senior economist at the European Centre for International Political Economy and Koen Berden, executive director of international trade at the European Federation of Pharmaceutical Industries and Associations in [EFPIA News](https://www.efpia.eu/news-events/the-efpia-view/blog-articles/trade-policy-and-covid-19-openness-and-cooperation-in-times-of-a-pandemic/) “From the birth of the modern pharmaceutical industry in the early 20th century, the U.S. patent system incentivized R&D in new drugs and medical treatments. Our scientists have led the world in creating breakthrough medical treatments. The vaccines and drug treatments they created improved the quality of life and extended lifespans for billions of people around the world. Instead of imposing more price controls and regulatory burdens, lawmakers should be bolstering legal protection for innovations in life-saving [COVID-19] treatments and cures. They should reform the patent laws to ensure investments continue in creating new cures.” – Adam Mossoff, patent law expert at Antonin Scalia Law School at George Mason University and senior fellow at the Hudson Institute, in [The Washington Times](https://www.washingtontimes.com/news/2020/mar/12/patent-term-extensions-will-help-speed-up-developm/) “The right of exclusivity that IP, particularly patents, provides innovators is critical to developing and commercializing cutting-edge inventions in biopharma… American IP, including the right to exclude competitors during the limited duration of a patent term, is essential to our solving the current global medical crisis, continually introducing new cures and better therapies and sustaining the high-skill jobs in the life sciences sector.” – James Edwards, IP consultant in [IP Watchdog](https://www.ipwatchdog.com/2020/03/10/wont-stop-coronavirus-without-ip/) Strong IP protections support America’s robust innovation ecosystem by striking a balance between promoting innovation and meeting the needs of patients who rely on lifesaving therapies, like those in development to treat COVID-19. America’s biopharmaceutical companies are committed to ensuring that treatments and vaccines developed for COVID-19 are available to all who need them. For more information on the importance of IP rights, visit our [IP page](https://www.phrma.org/advocacy/intellectual-property) and stay tuned for our next IP Explained post.

#### IPR hasn’t harmed access – manufacturing capacity alt cause

Mercurio 2/12 (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review“, No Publication, accessed: 8-8-2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3789820) ajs

2. Intellectual property rights have not hampered access to COVID-19 vaccines A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26 Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level. Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31 While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs. Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices. Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill . Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability. While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such factories and logistics exist in only a handful of countries.34 Regardless of whether an IP waiver is granted, the remaining countries will be left without enhanced vaccine access and still reliant on imported supplies. With prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices. Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the licence fee or royalty to the innovator. Thus, the waiver would simply serve to benefit advanced generic manufacturers, most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary licence from the patent holder, as such licences include provisions for the transfer of technology, know-how and ongoing quality assurance support.

#### The 1AC misdiagnoses the problem – the problem isn’t production of vaccines it’s the demand for them

Reed 21 (TRISTAN REED|JUNE 17, 2021, In the COVID-19 vaccine market, the problem has always been demand, n, ot supply, WorldBank Blogs, <https://blogs.worldbank.org/developmenttalk/covid-19-vaccine-market-problem-has-always-been-demand-not-supply)//ww> pbj

Some economies have now vaccinated more than half of their populations against COVID-19 and are reopening, while low- and middle-income economies still have limited access in the face of devastating outbreaks. Supply bottlenecks have been blamed. Though vaccine manufacturers report substantial capacity, essential vaccine manufacturing supplies like giant plastic bags and glass vials are hard to come by, understandably, as countries ordered more vaccines at one time than ever before. However, these supply-side challenges are overemphasized. The reason why low- and middle-income countries are not further along in their vaccination campaigns comes down to insufficient demand. As Ruchir Agarwal of the IMF and I show in a recent research paper, even though governments have substantial experience implementing vaccination campaigns and most individuals are not hesitant to take vaccines, governments did not commit to buy Covid-19 vaccines from manufacturers early enough (Figure 1). Figure 1: As of April 2021, despite available capacity for 10 vaccines showing effectiveness in Phase 3 trials, there were not enough advance purchases to cover the world’s population

