# 1NC Round 2 Yale

### CP – COVID Supply Chain

#### CP: The member nations of the World Trade Organization should maintain existing intellectual property protections and

* Build up the US vaccine supply chain
* Expand US vaccine production capacity with existing and new manufacturers
* Stopping US vaccine stockpiling to send doses to lower income nations

Borio and Gottlieb 5/9, (Luciana, Scott, May 9th 2021) [Dr. Borio is a senior fellow for global health at the Council on Foreign Relations and was Director for Medical and Biodefense Preparedness at the National Security Council, 2017-19. Dr. Gottlieb is a resident fellow at the American Enterprise Institute and a board member of Pfizer. He was commissioner of the Food and Drug Administration, 2017-19.], Patent Busting Won’t Help Vaccinate the World Faster, Wall Street Journal https://www.wsj.com/articles/patent-busting-wont-help-vaccinate-the-world-faster-11620591133?reflink=desktopwebshare\_twitter

While the U.S. Covid pandemic has been contained, the situation in many countries, particularly India, is dire. It’s essential to get as much of the world vaccinated as quickly as possible to save lives and prevent new variants from emerging. The Biden administration’s support for breaking vaccine patents is a bad precedent that would do no immediate good and substantial long-term harm. There isn’t enough vaccine supply to meet world-wide demand. Many countries have access only to inferior vaccines produced in Russia or China. Understandably, they want the same safe and effective vaccines that are available to Americans. By the end of 2022, U.S. manufacturers will produce more than 12 billion doses of high-quality vaccines, enough to satisfy global needs. And other vaccine candidates are in the pipeline and may be authorized over the next year. But over the next six months, global supply will remain tight. The Biden administration caved to pressure at the World Trade Organization to support waiving intellectual-property protections for Covid vaccines. Some activists have declared victory, even though patent breaking wouldn’t solve the immediate problem and could make a global agreement much more difficult. France, Germany and the U.K. all oppose the idea, and the WTO should reject it. Here are four productive steps the developed world could take instead: First, the U.S. government should stop hoarding doses and make them available for export. Some of the biggest vaccine makers have shown that their manufacturing is stable and growing. The supply chain is reliable, and the U.S. doesn’t need to stockpile hundreds of millions of doses. More can be made available on a rolling basis to countries like India and Brazil. Second, **countries** that produce quality vaccines such as Belgium, France, Japan, Australia and the U.K., to name only a few, should invest in a major expansion of manufacturing facilities and the attendant supply chain, in return for a guarantee that a high percentage of the vaccines that flow from these efforts go to low- and middle-income nations. This would secure stable production and guarantee a steady supply of high-quality vaccines for vulnerable nations. Third, the U.S. should work with the World Health Organization to deal with legitimate liability concerns from U.S. manufacturers that donate vaccines to low-income nations. Companies are worried about being sued by all manner of individuals all over the world. Patients need recourse if they’re harmed, and vaccine companies need some backstop on unbounded liabilities. This could take the form of a compensation system for injuries, overseen by the World Bank. Similar measures are in place for manufacturers that make doses available to Americans under an emergency-use authorization. Finally, American drug makers can work with existing vaccine manufacturers in middle-income nations such as Brazil and South Africa. Some of these countries may be able to expand their capacity to take on international “fill and finish” capacity, receiving vaccines in bulk and placing them in smaller vials for distribution, the insufficiency of which could otherwise become a bottleneck. These kinds of tech transfers could take time—at least six months and probably a year or longer—and would need to be started in short order. All these steps depend on a global agreement to protect intellectual property. The proposal to suspend portions of the WTO’s agreement on intellectual property has long been sought by China as a way to pirate Western intellectual property legally. **Drug makers can** work exclusively with leaders in the European Union to put together a package that would **address** immediate and long-term **needs of** lower-income **nations while continuing to protect intellectual property, which is vital to the development of future vaccines and therapies**. Many nations are still suffering deeply from Covid-19. There’s no time to waste on symbolic measures that set a poor precedent and don’t solve the crisis.

#### Non-IP related solutions solve better – the 1ac undermines innovation and spills over to tank long term economic growth and drug development – building up supply chain directly solves the 1AC

Bacchus 12/16 (James, December 16, 2020) [James Bacchus is a member of the [Herbert A. Stiefel Center for Trade Policy Studies](https://www.cato.org/herbert-stiefel-center-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. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland], “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> //Edgemont AJ

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 After years of debate, WTO members clarified in the Doha Ministerial Declaration in November 2001 that each WTO member “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”9 In August 2003, WTO members followed up on the 2001 declaration by adopting a waiver that allows poorer countries that do not have the capacity to make pharmaceutical products—and thus cannot benefit from compulsory licensing—to import cheaper generic drugs from countries where those drugs are protected by patent.10 In such a case, both the importing and exporting countries are excused from what would otherwise be their obligations under the TRIPS Agreement. This waiver was transformed into an amendment in the WTO IP rules in 2017.11 Compulsory licensing of medicines is not popular with private drug manufacturers because it is a derogation from the customary workings of market‐​based capitalism. However, as these actions by WTO members in 2001, 2003, and 2017 illustrate, compulsory licensing is not a derogation from the balance struck by the members of the WTO between protecting IP rights and ensuring access to essential medicines. Rather, it is a crucial part of that balance. The balance struck in the WTO treaty includes the option of compulsory licensing during health emergencies. Does a Novel Virus Present Novel Issues? Now comes the COVID-19 crisis. In the debate over the proposed COVID-19 waiver, mostly we have heard the usual arguments, all of them reminiscent of the HIV/AIDS debate. The pharmaceutical companies in the global vaccine chase have been quick to express their opposition to the proposed waiver of IP rights for the pandemic’s duration. They have warned that allowing their COVID-19 vaccines to be copied without their permission through recourse to compulsory licensing “would undermine innovation and raise the risk of unsafe viruses.”12 The reaction of most nongovernmental health organizations and other global advocacy groups to these arguments is summed up in the Access Campaign’s response: “Since the start of the pandemic, pharmaceutical companies have continued with their ‘business‐​as‐​usual’ approaches either by maintaining rigid control over their proprietary IP rights or by pursuing secretive and monopolistic commercial deals and excluding countries affected by COVID-19.”13 What we have not heard in the waiver debate is any clear explanation from waiver advocates of why they believe that the right to compulsory licensing that they already possess will prove insufficient to ensuring access to COVID-19 vaccines. In requesting a broad waiver of IP rights to COVID-19 vaccines, India and South Africa maintained that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available” under existing WTO rules. They also noted that a “particular concern for countries with insufficient or no manufacturing capacity” is that the 2017 amendment that permits countries that produce generic medicines under compulsory license to export all of those medicines to least‐​developed countries that lack their own manufacturing capabilities will lead to a “cumbersome and lengthy process.”14 India and South Africa did not offer any further explanation or any evidence to support these assertions. In an effort at an explanation, two Canadian university professors contended, “The TRIPS flexibilities are important policies but they are not perfect. Rules allowing compulsory licensing apply only on a case‐​by‐​case and product‐​by‐​product basis. This slows down the ability of countries to scale up production of needed COVID-19 products.”15 But this is advocacy, not evidence. At the time, this point was purely prospective; it was a prejudgment before any COVID-19 vaccine had been given final approval or reached the market. Before such a sweeping waiver of IP rights is taken up, it should first be demonstrated that the option of compulsory licensing and other flexibilities under the current trade rules will not suffice. At this point, the developed countries that have opposed the waiver are correct. There is no evidence of the need for such a waiver. Action by the WTO should be contemplated only if, and when, the current flexibilities in WTO rules prove to be inadequate. Should that happen, any such action should be no broader than necessary to address the global medical need. At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for … profitability in decision‐​making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”16 This view is myopic. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.17 To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs? With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded. Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19 As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”20 This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐​related intellectual property rights.”21 Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs. Conclusion The solution is not another impassioned and prolonged multilateral impasse inside the WTO. The solution is multilateral action in international institutions and international endeavors outside the WTO. It is the slow pace and the uncertain success in those other global arenas that have led developing countries to seek a waiver from the WTO. Rather than continuing to press for an unnecessary WTO waiver, they should redouble their combined efforts to reach solutions in those other arenas. And the United States, the European Union, the United Kingdom, and other developed countries should do more to work with them toward that end. In no event should IP rights become legal obstacles to ensuring early access to affordable medicines for everyone in the world during a pandemic that has already killed more than a million people worldwide and threatens to kill millions more. But also, in no event should WTO members act in ways that would eliminate the incentives that are essential to inspire the innovations that make new medicines possible. The right balance in the WTO trade rules on IP is a balance that provides all countries with sufficient flexibility to protect IP rights while also promoting access to life‐​saving medicines.22 For COVID-19 medicines, there is no proof at this time that this balance does not exist. Maintaining this balance must remain the aim of the WTO, and it must be the aim of every endeavor of multilateral cooperation in the fight to end this pandemic.

## Pharma

#### New tech is boosting research productivity.

Deloitte 12/20/17, "A new future for R&D? Measuring the return from pharmaceutical innovation 2017", https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/measuring-return-from-pharmaceutical-innovation.html

R&D process transformation through technology In the coming years, the biopharma operating model will necessarily become leaner, as the future of work becomes a reality. This ‘industrialisation’ of biopharma will bring numerous transformational changes to how the industry functions, particularly in R&D. We see opportunities for biopharma to increase returns in the coming years if the industry embraces advanced technologies that can impact R&D across the entire value chain. Artificial intelligence, real-world evidence, and robotic and cognitive automation, to name a few, have the potential to improve study design, physician and patient recruitment and in-trial decision making, as well as increase efficiency and accuracy in repetitive tasks all the way through to regulatory filing. Similarly, social media, mHealth, wearables, connected devices, and telemedicine all have the potential to transform how patients are engaged in clinical trials, enabling expedited enrolment and improvements in study design and data quality, and increasing adherence and retention. Applying these technologies could lead to a vibrant and sustainable biopharma industry focused on high value outcomes – an objective that is vital to the future of global public health.

#### The AFF destroys the value of pharma R&D that fuels biotech startups—US market is key.

Robert J. Easton 18, Harvard MBA and co-chairman of Bionest Partners, 1-22-2018, "Price controls would stifle innovation in the pharmaceutical industry," STAT, https://www.statnews.com/2018/01/22/price-controls-pharmaceutical-industry/

Consumer access to affordable and effective medicines is an important issue. As the cost of many drugs continues to rise, sometimes astronomically, some have suggested imposing price controls on the U.S. pharmaceutical industry. Doing that risks ~~crippling~~ [devastating] our only hope of curing the many serious diseases that still plague us. The global pharmaceutical industry is among the most profitable, driven by its ability to price to value, especially in the United States. High profits attract investors and generate money for research. The global pharmaceutical industry’s investment in research and development is second, barely, to the computer and electronics industry and well beyond that of most other industries. For comparison, the top 10 pharmaceutical companies spend five times more on research and development as a percent of sales than do the top 18 U.S. chemical companies. The pharma industry’s efforts have been quite productive in attacking some of the most vexing problems in medicine. Cardiovascular mortality in the U.S. has declined more than 50 percent since the introduction of propranolol, the first beta blocker, in 1964. Many cancers, such as childhood leukemia, have almost been cured. AIDS is now a chronic disease, as the death rate has declined from near 100 percent to near 0 percent. Hepatitis C is now curable. Even metastatic melanoma, formerly a death sentence for 95 percent of its victims, is now curable for many. Lung cancer may be next. All these miracles have been brought through the clinic and into the market by commercial pharmaceutical companies. Yet there remain huge unmet needs for new and better treatments for most cancers; all neurological problems, especially Alzheimer’s disease; most autoimmune diseases; most major gastrointestinal disorders; macular degeneration; and diabetes — not to mention the global scourge of drug-resistant bacterial and viral infections. Advances in these areas will come if money continues flowing to pharmaceutical companies and their primary sources of innovation, biotechnology startups. But if U.S. drug prices come under bureaucratic control, as they have in most of Europe and Japan, it will be a different story. Little pharmaceutical innovation occurs in price-control jurisdictions. The United States has always, by a large margin, led the world as a source of new drugs, and that lead has widened as Japan and Germany have imposed price controls over the past few decades. All major international pharmaceutical companies, without exception, have instituted R&D and commercial operations in the U.S. to take advantage of its pricing environment. If price controls pressure the U.S. industry into a more conventional process industry model, like that of the chemical industry, pharmaceutical R&D budgets would be slashed. To achieve the chemical industry’s rate of R&D spending, as would be required to achieve profitability competitive with the chemical industry, top pharmaceutical companies would have to reduce their R&D budgets by 80 percent — almost $50 billion in total. This reduction in spending would take a few years to realize, but would be completely evident by 2023 or earlier. An important corollary is that, if profitability and value creation opportunities for new drugs declined, the appetite of the venture community for risky, long-term biopharmaceutical investments would shrink exponentially. Price controls on drugs would have the surprising effect of accelerating the flow of investment into high technology, where timelines to market are shorter, less regulated, and less risky. The venture capital community is flush with cash and anxious to invest where high returns can be achieved — ideally within a much shorter time than is typically possible in the realm of drug R&D. As a society, if we force pharma into a chemical industry model, where there is no biotech equivalent and no venture investing, we will be trading better and sooner effective drugs for better and sooner virtual reality devices and self-driving cars. Squeezing pharmaceutical R&D spending down to one-fifth of what it is today would also have an enormous impact on the problems that drug developers often choose to address. Orphan diseases would be deprioritized, as the returns under price controls would not warrant the investment. Complex diseases would also be deselected. While Alzheimer’s disease and diabetes have huge patient populations, the extremely high cost of conducting the difficult research and the need for huge and complex clinical trials would dissuade all but the largest companies from pursuing those illnesses if the potential pricing upside was to be significantly constrained. Moreover, for difficult diseases like schizophrenia, where today’s treatments are mostly inadequate, the flow of more effective new treatments would slow from a trickle to a rivulet, depriving those with these conditions from the possibility of relief. The upshot is simple. Forcing drug prices down would surely shave a few percentage points off what we spend on health care today. By 2032, drug prices could be half of what they are today, as every drug would be a generic. But our ability to treat or cure the many serious diseases that still afflict us will have been ~~crippled~~ and squandered. In my view that is terrible policy.

#### Biopharma 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, https://www.rand.org/pubs/perspectives/PEA407-1.html] TDI

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. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

## Backlash

#### Congress won’t withdraw the US from the WTO now, but more unfair trade practices abroad causes widespread backlash that ends involvement

**Johnson 20** [Keith Johnson, a senior staff writer at Foreign Policy, 05-07-2020, “U.S. Effort to Depart WTO Gathers Momentum,” Foreign Policy, https://foreignpolicy.com/2020/05/27/world-trade-organization-united-states-departure-china/]/Kankee

Frustration with hyperglobalization, China’s “economic imperialism,” and a seemingly **broken** world trading system is **boiling over** into **serious** calls for the United States to withdraw from the World Trade Organization (WTO)—which would have potentially disastrous implications for the country if carried out. For the first time since 2005, lawmakers from both parties and both houses of Congress are **pushing** to pull the United States out of the trading body it helped create and which was the culmination of decades of postwar efforts to boost free trade and economic integration. By law, the United States has a chance to vote every five years on staying inside the WTO, but staying on board was such a no-brainer in recent years that no such resolution was even presented. But this year—powered by a rise in **economic nationalism**, growing concern about China, and **frustration** with two decades of paralysis at the WTO—the **knives** on Capitol Hill **are out**, to the delight of some of the trade hard-liners in the White House. “The WTO has been a **disaster** for the United States,” said Rep. Peter DeFazio, an Oregon Democrat, who introduced House legislation to withdraw this month. “No trade regime can last when it no longer serves the people of the countries who are part of it,” said Sen. Josh Hawley, a Missouri Republican, in a recent Senate floor speech after introducing his own resolution to leave. “Our interests and those of the WTO **diverged** long ago.” It’s doubtful that the measures could secure enough votes for passage in either chamber, and a tight legislative calendar makes the push for withdrawal doubly hard to pull off. But the **rush for the exit** is still a serious indication of **deep and growing dissatisfaction** with how global trade has evolved,

highlighted by the vulnerability of cross-border supply chains that have begun to come apart under the stress of the COVID-19 pandemic. If the United States were to pull out of the system it helped build, the implications would be dire. Other countries would be able to discriminate against U.S. goods and services with no limits. Tariffs would almost certainly rise and export markets shrink. Meanwhile, others like China and the European Union would increasingly be in a position to write the rules of the future economy, from data protection and privacy to intellectual property and state subsidies. “We’d have no rights, and we’d lose a seat at the table,” said Wendy Cutler, a former U.S. trade negotiator now at the Asia Society. Why the big push now? For years, different aspects of the global trading system have stirred concern and at times anger in the United States and other countries; the WTO has essentially been stuck in place since the collapse of its last big negotiating round in 2008. For years, economists have debated the impact of the so-called “China shock” on U.S. jobs and manufacturing, and some evidence has shown that the competition from low-wage Chinese labor and the rapid movement of U.S. companies offshore hit the U.S. middle class harder than many economists expected. For years, Republicans have **railed** against international organizations—from the WTO to the International Criminal Court—that they see as encroaching on U.S. sovereignty. Now, all those forces have come together in a kind of **imperfect storm**.

#### Even small changes make pharma companies fear patent reform

**Asgari et al. 21** [Nikou Asgari, markets reporter for the Financial Times, Donato Paolo Mancini, FT's pharma reporter, and Hannah Kuchler, FT’s global pharmaceutical correspondent, 05-06-2021, "Pharma industry fears Biden’s patent move sets precedent," FT, https://amp.ft.com/content/f54bf71b-87be-4290-9c95-4d110eec7a90]/Kankee

Profits in the pharmaceutical industry are protected by a **fortress of patents** that **guarantee** drugmakers a stream of income until they expire. On Wednesday, Joe Biden broke with decades of US orthodoxy and made a crack in the wall. His administration’s decision to support a temporary waiver of Covid-19 vaccine patents prompted **instant outrage** in the pharmaceutical sector, which argues that the move rides roughshod over their intellectual property rights and will discourage US innovation while sending jobs abroad. “Intellectual property is the **lifeblood** of biotech, it’s like oxygen to our industry,” said Brad Loncar, a biotech investor. “If you take it away, you don’t have a biotech sector.” Biden’s top trade adviser Katherine Tai said that while the US government still “believes strongly” in intellectual property protections, it supported waiving patents for Covid-19 vaccines to help boost global production of jabs. The move comes as some countries, including India, struggle to tackle further waves of the virus even as others have rolled out successful vaccination campaigns that are driving down infections, hospitalisations and deaths. The waiver proposal was put forward at the World Trade Organization in October and has since been supported by more than 60 countries who say worldwide vaccine production must increase dramatically. Washington’s support marks a pivotal step in making the proposal a reality and Tai said the US would engage in negotiations to hammer out the details at the WTO. Tedros Adhanom Ghebreyesus, the WHO’s director-general, told the Financial Times the decision was a “**monumental moment**” in the fight against Covid-19. “I am not surprised by this announcement. This is what I expected from the administration of President Biden.” However, the pharma industry did not expect it; the US has tended to **fiercely protect** domestic companies’ intellectual property rights in trade disputes. Industry leaders described the decision as a heavy blow for innovation that would do little to boost global production because there is a shortage of manufacturing facilities and skilled employees. In an earnings call Thursday, Stéphane Bancel, chief executive of Moderna, said a patent waiver “will not help supply more mRNA vaccines to the world any faster in 2021 and 2022, which is the most critical time of the pandemic”. “There is no idle mRNA manufacturing capacity in the world,” he said. “The administration’s steps here are very unnecessary and damaging,” said Jeremy Levin, chair of biotech trade association Bio. “Securing vaccines rapidly will not be the result, and worse yet, it sets a principle that companies who invested in new tech will stand the risk of having that taken away.” Shares in the big makers of Covid-19 vaccines were hit by the announcement. Frankfurt-listed shares in BioNTech closed down 12 per cent on Thursday while Moderna and Novavax pared losses after tanking on Wednesday in New York, trading 2.4 per cent lower and 1 per cent lower, respectively. CanSino Biologics, a Chinese private company that developed a single-shot adenovirus-vectored vaccine with Chinese military researchers, fell 14 per cent on Thursday. Fosun Pharma, which has a deal to supply BioNTech vaccines in China, lost 9 per cent. Sven Borho, a managing partner at OrbiMed Advisors, a healthcare investment company, said pharma executives **feared** the administration’s move set a **precedent** that would make it easier to suspend patents in the future. “They are **worried** in the long term that this is a **foot in the door** — ‘OK, we did it with Covid-19, let’s do it with the next crisis, and the next one’,” he said. “And then suddenly it’s a cancer drug patent that needs to be invalidated. They fear it is a mechanism that sets the stage for actions in the future.” Peter Bach, director of Memorial Sloan Kettering’s Center for Health Policy and Outcomes, said there was a potential trade-off that pitted the imminent need to contain the pandemic against the risk that drugmakers would be more cautious when investing in pioneering therapies in the future.

#### Big pharma always wins – the link alone causes Congress to water down the aff

**Florko and Facher 19** [Nicholas Florko, Stat News Washington correspondent, and Lev Facher, Stat News health and life sciences writer, 07-16-2019, “How pharma, under attack from all sides, keeps winning in Washington,” Stat News, https://www.statnews.com/2019/07/16/pharma-still-winning/]/Kankee

It does not seem to matter how angrily President Trump tweets, how pointedly House Speaker Nancy Pelosi lobs a critique, or how shrewdly health secretary Alex Azar drafts a regulatory change. The pharmaceutical industry is still winning in Washington. In the past month alone, drug makers and the **army of lobbyists** they employ **pressured** a Republican senator not to push forward a bill that would have limited some of their intellectual property rights, according to lobbyists and industry representatives. They managed to water down another before it was added to a legislative package aimed at lowering health care costs. Lobbyists also convinced yet another GOP lawmaker — once bombastically opposed to the industry’s patent tactics — to publicly commit to softening his own legislation on the topic, as STAT reported last month. Even off Capitol Hill, they found a way to block perhaps the Trump administration’s most substantial anti-industry accomplishment in the past two years: a rule that would have required drug companies to list their prices in television ads. To pick their way through the policy minefield, drug makers have successfully deployed dozens of lobbyists and devoted **record-breaking sums** to their federal advocacy efforts. But there is also a seemingly new strategy in play: industry CEOs have targeted their campaign donations this year on a pair of vulnerable Republican lawmakers — and then called on them not to upend the industry’s business model. In more than a dozen interviews by STAT with an array of industry employees, Capitol Hill staff, lobbyists, policy analysts, and advocates for lower drug prices, however, an unmistakable disconnect emerges. Even though Washington has stepped up its rhetorical attacks on the industry, and focused its policymaking efforts on reining in high drug prices, the pharmaceutical industry’s time-honored lobbying and advocacy strategies have kept both lawmakers and the Trump administration from landing any of their prescription-drug punches. “**Big Pharma has replaced Big Tobacco** as the most powerful brute in the ranks of Washington power brokers,” Sen. Dick Durbin (D-Ill.) said in a statement to STAT. Durbin, who recently saw the industry successfully oppose his proposal to curtail some of the industry’s patent maneuvering, added that, “Pharma’s billions allow them to continue to rip off American families and taxpayers.” The industry doesn’t get all the credit; it has also benefited from a fractured Congress and discord between President Trump’s most senior health care advisers. PhRMA, the drug industry’s largest lobbying group here, declined to comment for this article. But industry leaders have broadly argued against efforts to rein in the industry’s practices in terms of price hikes and patents, making the case that that could irreparably stifle medical innovation. The battle is far from over, and industry representatives and lobbyists are quick to hypothesize that the worst, for them, is yet to come. They point to several ongoing legislative initiatives, including in the Senate Finance Committee, that could take more concerted direct aim at their pricing strategies in Medicare. They’re waiting, too, to see if House Democrats can cut a drug pricing deal with the White House to empower Medicare to negotiate at least some drug prices. Another pending regulation, loathed by drug makers, might tie their pricing decisions in Medicare to an index of international prices. They’ve also bemoaned the Trump administration’s decision last week to abandon a policy change that would have ended drug rebates — which, the pharmaceutical industry has said, could have given drug makers more space to lower their prices voluntarily. “We’re getting killed!” one pharma lobbyist told STAT. Of course, the Trump administration’s supposedly devastating decision to abandon that proposal simply maintains the status quo. “Big Pharma has replaced Big Tobacco as the most powerful brute in the ranks of Washington power brokers.” n Valentine’s Day, Sen. Thom Tillis (R-N.C.) enjoyed a showering of love that is familiar in Washington: a flood of campaign contributions, many at the federal limit of $2,800 for a candidate or $5,000 for an affiliated political committee. One donation came from Pfizer’s CEO, Albert Bourla, who donated $5,000 to Tillis and another $10,000 to Sen. John Cornyn (R-Texas) and associated campaign committees. Another came from Kenneth Frazier, the top executive at Merck. The Tillis campaign committee eventually cashed checks from CEOs and other high-ranking executives at those companies as well as Amgen, Eli Lilly, Sanofi, and Bristol Myers-Squibb, plus two high-ranking officials at the advocacy group PhRMA. Six lobbyists at one firm that works with PhRMA, BGR, also combined to contribute $100,000 to a bevy of Republican lawmakers and the party’s campaign arms. Tillis raised an additional $64,500 from drug industry political action committees in the past quarter, according to disclosures released on Monday. A Pfizer spokeswoman declined to comment about Bourla’s contributions, and representatives for the other companies did not respond to STAT’s request for comment. Tills was one of few individual lawmakers — in many cases, the only one — to whom the executives had written personal checks during the current election cycle. While drug industry CEOs frequently contribute to political committees for congressional leadership, the breadth of executives who donated Tillis specifically is notable, particularly considering his outspoken role on pharmaceutical industry issues. While lobbyists pushed back on the notion that campaign contributions directly influence votes, the donations targeted so specifically to a particular candidate could be seen as a prime example of Washington’s system for rewarding loyalty and how industries protect their interests. The same PhRMA PAC that donated to Tillis has given generously in recent years: nearly $200,000 in the 2018 campaign cycle, roughly 58% of which was targeted toward Republicans. Drug industry PACs donated $10.3 million in total in that cycle, according to the Center for Responsive Politics. The figure two years before was even higher: a total of $12.2 million from industry-aligned PACs alone. It is no accident that the pharmaceutical industry has maintained its reputation among the nation’s **most powerful lobbies**, said Sheila Krumholz, the executive director of the Center for Responsive Politics, an organization that tracks political influence. “Their access and influence goes beyond this Congress or even the administration,” Krumholz said in an interview, adding that she “was **struggling** to think of evidence” it had waned. Pharma has a reputation here for winning on policy — often thanks to the lawmakers who are among the biggest recipients of the millions that drug corporations, employees, and the industry political arms donate each year. Even as the rhetoric has escalated, the industry has quietly worked to insulate itself from any major legislative changes. Take, for example, a recent about-face from Cornyn, the Texas Republican who took in some campaign cash alongside Tillis. As recently as February, Cornyn seemed to be positioning himself as a rare Republican figurehead for anti-pharma congressional wrath. At a widely publicized hearing before the Senate Finance Committee, he went head-to-head with AbbVie CEO Richard Gonzalez, pressing him to explain why the company had filed more than 100 patents on its blockbuster arthritis drug Humira. Cornyn introduced legislation soon after the skirmish to crack down on patent “thicketing,” a term for a drug company tactic to accumulate tens, if not hundreds, of patents to shield a drug from potential generic competition. Pharma sprung into action. They recruited congressional allies, including Tillis, to pressure Cornyn to significantly rework the bill, and they succeeded. The version of the bill that eventually cleared the Senate Judiciary Committee was stripped of language that would have empowered the Federal Trade Commission to go after patent thicketing. Instead, the bill limited how many patents a drug maker could assert in a patent lawsuit. The new version of the bill lost “a lot of teeth” and “solves a narrower problem in a narrow way,” advocates told STAT when the change was first introduced. It is far from the only example of the industry’s **aggressive interventions** to **water down** legislation. “In lots of ways they’re like the [National Rifle Association], because they have an **incredible power** to **squash** out any negative opinion, nor to feel any of the ill effects of those things,” said Pallavi Damani Kumar, an American University crisis communications professor who once worked in media relations for drug manufacturers. “It just speaks to how incredibly savvy they are.” Pharmaceutical industry lobbyists also successfully fought to keep another anti-drug industry patent proposal from Sen. Bill Cassidy (R-La.) and Dick Durbin (D-Ill.) out of a bipartisan drug pricing package moving through the Senate HELP Committee. The legislation would have allowed the FDA to approve cheaper versions of drugs, even when the more expensive product was protected by certain patents. Cassidy’s proposal never even made it into the HELP package. As the lobbyist who bemoaned the withdrawal of the rebate rule put it, Cassidy “simmered down” in the face of industry pressure. In recent weeks, the industry had targeted Cassidy in particular, in recent weeks, for fear he would break with many of his GOP colleagues to support a cap on some price hikes for drugs purchased under Medicare, a proposal so far pushed only by Democrats. “Sen. Cassidy doesn’t care what lobbyists think — he is going to do what’s best for patients,” said Ty Bofferding, a Cassidy spokesman. “Sen. Cassidy fought for the committee to include the REMEDY Act in the package, despite strong opposition from the pharmaceutical industry.” The committee eventually included half the bill’s provisions, he added, as well as four other pieces of legislation meant to prevent the industry from taking advantage of the patent system. The drug industry also notched a win by watering down another proposal in that package from Sen. Susan Collins (R-Maine) that would have blocked drug makers from suing over patents they didn’t disclose to the FDA. The version of the bill that actually made it into the package doesn’t block drug makers from suing, but instead directs the FDA to create a public list of companies that fail to disclose their patents. “This change is a big win for drug makers,” Michael Carrier, a Rutgers University professor and expert on patent gaming, told STAT. “Shaming is something drug makers don’t seem worried about.” Matthew Lane, the executive director of the Coalition Against Patent Abuse, likewise added that the altered bill “doesn’t seem to be doing much anymore.” Not all of the pharma-endorsed changes, however, are self-serving. Patent experts and federal regulators too had raised concerns with some of the bill being proposed. Cornyn’s patent bill was particularly controversial. “These provisions encourage ‘fishing expeditions’ by zealous bureaucrats, politically motivated by the popularity of efforts to reduce drug prices and garner the political benefits of being seen to be pursuing these ends,” Kevin Noonan, a patent lawyer at McDonnell Boehnen Hulbert & Berghoff wrote in a recent blog post, referring to the original Cornyn bill. Drug-pricing advocates said lobbyists have even managed to convince lawmakers to introduce some legislation they say has explicitly favored the drug industry, including intellectual property-focused legislation that would allow drug makers to patent human genes. That particular bill would “undo the bipartisan effort underway to fix pharma’s exploitation of the patent system,” said the Coalition Against Patent Abuse. And they were far from the only group raising concerns. The American Civil Liberties Union and more than 150 other groups wrote to lawmakers last month opposing the bill. Pharma’s **list of** policy **victories** goes on: Drug companies and allied patient groups forced the Trump administration to back off a proposal to make relatively minor changes to Medicare’s so-called protected classes policy. Currently, Medicare is required to cover all drugs for certain conditions, including depression and HIV. The Trump administration proposed in November that private Medicare plans should be able to remove certain drugs in those classes from their formularies, if the drugs were just new formulations of a cheaper, older version of the same drug, or when a drug spiked in price. But drug industry opposition helped convince the administration to spike that effort. A week ago, the industry struck its biggest blow yet. Three of the country’s largest pharmaceutical companies —Amgen, Eli Lilly, and Merck — prevailed in a lawsuit to strike down a Trump administration requirement that they disclose list prices in television advertisements. The lack of congressional action — despite the Democratic enthusiasm and bipartisan appetite — is still further evidence of industry’s ability to **stave off defeat**. As the dozens of Democrats running for president ramp up their anti-pharma rhetoric, both Trump and progressives have begun to fret that Washington’s efforts have proven to be **all bark and no bite**. With two weeks remaining before the August recess and an escalating 2020 campaign, some advocates fear that the window for bold action is closing quickly. “It’s appalling that we are six months into this Congress and we haven’t seen meaningful legislation passed on American’s number one issue for this congress,” said Peter Maybarduk, who leads drug-pricing initiatives for the advocacy group Public Citizen. “Congress needs to get its act together.”

#### US withdrawal from the WTO collapses global trade and causes WWIII

**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?