# **1NC – WTO**

**Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.**

# **Value: my value for today’s debate is protecting quality of life because with threats to our quality of life we either live miserably until we die or there is a risk of extinction.**

# **Criterion: The criterion is minimizing suffering. IPR is central to innovation and preventing WTO backlash.**

# **Contention 1: Innovation**

#### **Patents are the prerequisite to medical innovation increase average life expectancy**

**Roin 9** [Benjamin Roin, Assistant Professor of Technological Innovation at MIT, 02-2009, “Unpatentable Drugs and the Standards of Patentability,” Texas Law Review, https://www-proquest-com.ezproxy.library.unlv.edu/docview/203704797?pq-origsite=primo]/Kankee

II. Background: Patents and Pharmaceutical Innovation Pharmaceutical innovation is often seen as the golden child of the patent system, with patents taking credit for the discovery and development of valuable new drugs that provide tremendous health benefits to the public.4 The purpose of the patent system is to encourage socially valuable investments in R&D that firms would not otherwise make due to the profit-eroding effects of competition. In the pharmaceutical industry, firms must invest hundreds of millions of dollars in clinical trials on their drugs before they can be sold to the public, while their generic rivals are exempted from those requirements and can enter the market at low cost. Without some way to delay generic competition, therefore, pharmaceutical companies would usually find it impossible to recoup their R&D investments and would likely invest their money elsewhere. With strong patent protection, however, firms can expect to enjoy a lengthy monopoly over their drugs, providing them an opportunity to profit from their investment in R&D. Although the public suffers from high prices for drugs while they are covered by a patent, most of those drugs probably would not have been developed without that protection. As a result, it is widely thought that the benefits of drug patents far outweigh their costs. The economic function of the patent system is to promote the creation, development, and commercialization of inventions.5 Successful innovation can be of great value to society, but it often requires significant investments in R&D.6 The public relies on private industry to provide most of that investment,7 and unless firms expect to profit from their R&D efforts, they are likely to spend their money on something else. Appropriating the returns from an R&D investment can be difficult in a competitive market since other firms may be able to imitate successful inventions without incurring the same costs and risks.8 The resulting price competition can undermine the original inventors' profits as competitors free ride off of their efforts. The patent system is an attempt to preserve the incentive to invest in R&D that would otherwise be vulnerable to free riding by awarding inventors temporary exclusive rights to make, use, and sell their inventions, thereby protecting them from the profit-eroding effects of competition.9 Although patent-law scholars typically focus on the role of patents in promoting inventive activity,10 patents can be equally important in encourag- ing investment in the subsequent development and commercialization of inventions." The idea for an invention is usually of little value to the public until it has been turned into a marketable product,12 and the process of doing so can be both risky and expensive. Indeed, the cost and risk of bringing an invention to market is often much greater than that faced during the initial research that gave rise to the invention.13 If competitors can produce and sell copies of the invention while avoiding its development and commercializa- tion costs, then there may be little or no incentive for firms to ever bring that invention to market. Under these circumstances, a patent can be essential for the investment that enables the practical use of an invention - a fact known to economists for at least 100 years.14 Even when patents are unnecessary for motivating the creation of an invention, therefore, they can still be critical for encouraging the subsequent investment in its development. Of course, not all inventions need a patent to incent their development and commercialization.15 In many cases the costs and risks of getting an invention to market are relatively small, and the inherent lead-time advantage that the inventors will enjoy over competitors is sufficient for them to recoup their R&D investments.16 In other cases patents are unnecessary for motivating post-invention spending because those investments are not vulnerable to free riding. For example, a firm might be willing to build an expensive new manufacturing plant to produce an unpatented invention because competitors would have to make the same investment in building their own plant before they could launch an imitation product.17 Additionally, on some occasions the underlying invention does not need a patent because the efforts to develop and commercialize it give rise to their own patentable invention,18 which can make it difficult for competitors to capitalize on the innovative firm's post-invention expenses.19 In any of these situations, the absence of patent protection for an invention may not deter its development. For some inventions, however, patents do play an essential role in promoting development and commercialization, and drugs are a clear example.20 Pharmaceutical companies on average spend upwards of $800 million on R&D for each new drug that reaches the market.21 Roughly half of that money is spent satisfying the FDA's clinical-trial requirements to establish the safety and efficacy of new drugs,22 producing data that cannot be protected with patents.23 Meanwhile, generics are exempted from the FDA's clinical-trial requirements and enter the market based on the clinicaltrial data submitted by the original pharmaceutical company.24 As a result, generic-drug manufacturers spend on average only about $2 million on the approval process.25 Once they are on the market, those drugs dramatically reduce the sales of (and profits from) the brand-name drugs they imitate.26 Pharmaceutical companies therefore rely on a lengthy period of market exclusivity to recoup their investments in developing new drugs. With strong patent protection, they are usually able to keep generics off the market for somewhere between ten and fourteen years27 and will invest hundreds of million of dollars in R&D in anticipation of this reward.28 For this reason, scholars often view drug development as "the paradigm of patents spurring innovation."29 Relying on the patent system to promote pharmaceutical innovation admittedly has its costs, since patents allow manufacturers to charge premium prices for their products.30 Although pharmaceutical companies sink vast sums of money into R&D of new drugs, the actual costs of manufacturing those drugs is usually quite low.31 Generic drugs are sold at prices that reflect these lower production costs, whereas patented drugs are priced much higher.32 When a drug is patented, therefore, some consumers who would be willing to buy it at the generic price are forced out of the market, and they must wait until the patent on the drug expires before benefiting from its use. Economists refer to this harm as deadweight loss, and it is a problem inherent in the patent system.33 With pharmaceuticals, the deadweight loss caused by patent protection is especially troubling because some people must forgo the use of drugs that would improve their health and sometimes even save their lives.34 Although the temporary high prices that result from patent protection are a significant problem, the benefits of the patent system can sometimes outweigh these costs. The public may suffer for a time from the higher prices charged for a patented invention, but that harm is necessarily smaller than the injury that would result if no one ever created or developed the invention in the first place, or if it had taken much longer for the invention to reach the public. As a rule of thumb, therefore, patents are socially desirable when, in their absence, the public would not otherwise benefit from the invention or there would be a substantial delay in the public's receipt of that benefit.35 The pharmaceutical industry is probably the best example of where patents are socially desirable under this rule of thumb because patents appear to be a prerequisite for the vast majority of pharmaceutical innovation.36 Given their high R&D costs compared to those of their generic rivals, pharmaceutical companies rely on lengthy periods of market exclusivitynormally ten or more years for the drugs currently developed- to support their investments in bringing drugs to market.37 Not surprisingly, firms in the industry consistently report that patent protection is essential to their efforts to discover and develop new drugs.38 Moreover, it is well known that pharmaceutical companies generally refuse to develop new drugs unless they have strong patent protection over them.39 Indeed, drug researchers who work in government and academia report that when they are looking for partners in private industry to fund the development of the drugs they discover, it is almost impossible to attract interest unless the drugs are patented.40 Some scholars even worry that the patent system may be too effective at promoting pharmaceutical innovation,41 although the available evidence indicates that society's investment in pharmaceutical R&D continues to generate substantial positive returns. In theory, the patent system could be harming the public by causing wasteful and duplicative R&D in "patent races."42 In the case of pharmaceuticals, however, numerous economic studies have found that the social benefits produced by new medical technologies signifi- cantly outweigh the costs of society's investment in medical R&D.43 According to one estimate, the average new drug launch in the United States increases average life expectancy among the U.S. population by about one week, leading to a cost-effectiveness ratio for pharmaceutical R&D spending of $6,750 for each additional year of life saved.44 Since most studies put the value of a year of life at $75,000 to $150,000,45 the social return on pharma- ceutical R&D investments appears to be extraordinarily high.46 This is not to say that all investments in pharmaceutical R&D are beneficial, because some of that spending goes toward drugs that fail to complete the FDA's clinical- trial requirements,47 drugs that offer little or no therapeutic advantage over existing drugs,48 and sometimes even drugs that do more harm than good,49 such as the now-infamous pain reliever Vioxx®.50 On the whole, however, society's investments in discovering and developing new drugs seem to yield substantial net benefits. The discussion above demonstrates why the case for the patent system is at its strongest in the pharmaceutical industry: innovation in the field is incredibly valuable to society and most of it would not occur without the patent system.51 Indeed, it is considered well established that the availability of patent protection for drugs improves social welfare.52 This is not to say that the patent system is perfect; no one questions that the public suffers greatly from high drug prices. At the moment, however, the public depends on the patent system to promote pharmaceutical innovation, and the public usually benefits when the system is successful in that task. III. The Patentability Standards for Pharmaceuticals: Rewarding the Invention of Drugs but Not Their Development

#### **Patents are key to global South pharmaceutical industries that stop neglected diseases**

**Soyeju and Wabwire 18** [Olufemi Soyeju, Lecturer at Lagos State University, and Joshua Wabwire, educator at the Catholic University of Eastern Africa, 01-2018, “The WTO-TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional Framework,” World Trade Review; Cambridge <https://www-proquest-com.ezproxy.library.unlv.edu/docview/1994279823?accountid=3611&pq-origsite=primo>]/Kankee

Conclusions The problem that this research has highlighted is the already too familiar tension between patent protection and access to medicines. The legal framework for patents and access to medicines in the EAC region consists of the Policy and the accompanying Protocol. What has emerged from the analysis is that the policy tools are aimed at enhancing access to medicines mainly through price reduction. This is done at the direct expense of promoting research and development of medicines, which, in line with the utilitarian justification, is achievable through patent protection. This policy position that weakens patent protection is not appropriate for developing African countries. This is because African countries are faced with peculiar, region-specific diseases. Currently, these diseases are largely neglected by the profit-driven pharmaceutical companies, which do not have economic incentives to invest in developing medicines for populations that cannot afford to pay for them. Most of these pharmaceutical companies are foreign, largely based in the Global North. Since these companies do not have economic incentives to invest in the research and development of medicines for developing countries' diseases, even patent protection has not necessarily been an attractive incentive.194The focus of these companies is now on developed countries' diseases. In these circumstances, the only standing incentive, especially for spurring domestic innovation from within developing countries, is patent protection. Consequently, any strategy that eliminates this last straw will only worsen the already bad situation. The situation described above underscores the urgent need to develop local pharmaceutical industries and to create alternative incentives for investment in research and development of medicines for neglected diseases, for example through Public-Private Partnerships (PPPs). Both of these can be attained through an appropriate patent protection regime that does not weaken patent protection. Such a regime must, for instance, be omniscient of domestic innovators' limited capacity and, consequently, avoid strict patentability criteria, which cannot be met by the small-scale, underfunded domestic innovators. Strict patentability criteria may also discourage disclosure of certain important discoveries, for fear of not attaining the criteria and losing out by disclosure. In developing local pharmaceutical industries, it is also necessary to find ways of affording patent protection to indigenous medicines and practices, which, for centuries, have been as useful to the populations as western medicine now is. It is the failure to protect these medicines and practices in the first place that has resulted in foreign pharmaceuticals appropriating the knowledge and patenting it, only to return with expensive medicines.195 It is the argument here that a patent protection policy would only achieve the greatest good for the greatest number of people, in line with utilitarianism, if it balances the goal of price reduction with the need to encourage further research and development of medicines by ensuring that inventors are able to recoup their investments in research and development. It is only through research and development that the medicines will be made available.

#### **Empirics prove lower vaccine profit margins harms future innovation – R&D investments solve the aff by supplying vaccines globally**

**Roberts 6-25** [James M. Roberts, Research Fellow For Economic Freedom and Growth at the Heritage Foundation with a master’s degree in international and development economics from Yale University, 6-25-2021, "Biden’s OK of Global Theft of America’s Intellectual Property Is Wrong, Dangerous," Heritage Foundation, <https://www.heritage.org/public-health/commentary/bidens-ok-global-theft-americas-intellectual-property-wrong-dangerous>]/Kankee

Mr. Biden wants to waive the World Trade Organization’s “Trade-Related Aspects of Intellectual Property Rights” (TRIPS) agreement for U.S. vaccines and let foreign countries issue “compulsory licenses“ allowing their domestic pharmaceutical companies to manufacture the medicines without adequately compensating the companies that invented them. Practically speaking, countries such as India and South Africa are unlikely to manufacture the vaccines. They lack an advanced infrastructure for cold supply-chain distribution and many other crucial resources required by these products’ capital-intensive, state-of-the-art manufacturing process. But the Biden policy is bad for many other reasons. Developing breakthrough medications takes tremendous ingenuity and immense financial investments. It’s an extraordinarily high-risk endeavor, and the prospect of making a profit is what convinces private companies to undertake those risks. Signaling that the United States will not fight to defend their intellectual property rights actively undermines innovation and manufacturing in American health care and medicines. It also erodes patient protections by undermining quality control. Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes. Already there are reports of ineffective and even dangerous counterfeit COVID-19 vaccines being sold around the world. Those pushing to break U.S. pharmaceutical patents say they want to do so for altruistic reasons. Consequently, they also insist that the prices for the medications be set far below their actual value. But history shows us that forcing private companies to provide vaccines at an “affordable price,” regardless of the cost to the companies, actually impedes the manufacture of high-quality vaccines. Moreover, it inhibits the future development of vaccines needed to meet as-yet-unknown diseases. Washington first imposed vaccine price controls as part of Hillary Clinton’s 1993 healthcare-for-all crusade. As the Wall Street Journal later noted, it was a body blow to the U.S. vaccine industry. Ironically, government-decreed prices left the companies unable to produce enough vaccines to meet Mrs. Clinton’s admittedly admirable goal of universal immunization of children. Since then, U.S. firms have largely eschewed the vaccine market because they could not recoup their R&D and manufacturing costs and earn enough profit to fund future innovation. Ultimately, compulsory licensing legalizes the theft of intellectual property. Recognizing this, senators from both sides of the aisle have joined with other government officials and industry leaders to call on the administration to reverse this bad decision. The U.S. patent protection system has served the nation well since its founding. It is and has been a bulwark of American prosperity, but the strength of that protection has been weakening in the past few decades. Compulsory licensing contributes to the erosion of that protection. As the U.S. and the rest of the world emerge from the pandemic, it is clear that more innovative medicines and vaccines will be needed for future protection from viruses and other emerging biological threats. The best way to prevent and treat those new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production. That way, U.S.-manufactured vaccines can be made available to all Americans quickly. And governments can subsidize their export and sale to other countries far more effectively and less expensively than through compulsory licensing schemes. Meanwhile, let’s hope Mr. Biden listens to the more reasonable and less-agenda driven voices in this debate and reverses course on the TRIPS waiver.

#### **High drug prices are a substitute for government funding the aff can’t provide**

**Mullainathan 17** [Sendhil Mullainathan, University Professor of Computation and Behavioral Science at Chicago Booth, 6-30-2017, "High Drug Prices Are Bad. Cutting Them Could Be Worse. (Published 2017)," No Publication, <https://www.nytimes.com/2017/06/30/upshot/high-drug-prices-are-bad-cutting-them-could-be-worse.html>]/Kankee

High drug prices are harmful. Medical costs and out-of-pocket expenses result in high rates of bankruptcies, and 10-25 percent of patients either delay, abandon or compromise treatments because of financial constraints. Survival is also compromised. For example, in chronic myeloid leukemia, the 8-10 year survival rate is 80 percent in Europe (where treatment is universally affordable); in the U.S., where finances may limit access to drugs, the 5-year survival is 60 percent. In surveys, 78 percent of Americans worry most about costs of drugs. Sadly, three years after the issue was raised, there has been little progress. The problem is compounded by 2 additional factors. First is the increasing shift in the cost of care and drugs to patients. Insurers justify this "skin-in-the-game" strategy as effective in reducing costs, but the high out-of-pocket expenses have turned this into "deterrence-in-the-game," discouraging patients from seeking care or purchasing drugs. In a recent survey, one-third of insured Texans delayed or did not pursue care because of high out-of-pocket expenses. Second is the spill-over of high drug prices to generics. Complex regulatory issues and shortages allow companies to increase prices of generics to levels as high as patented drugs. The latest scandals – Turing, Valiant and Mylan – are only the most extreme examples of a common strategy in pricing drugs. Generic Imatinib to treat chronic myeloid leukemia is priced at $5,000-8,000/year in Canada, $400/year in India, but $140,000/year in the U.S. For generic drugs to be priced low, four to five generics have to be available. The average cost of filing for FDA approval of a drug is $5 million in 2016, and the average time to approval is 4 years. There are currently more than 3,800 generic drug applications awaiting FDA action. The FDA should overhaul its procedures to reduce the cost of filing to less than $1 million per drug, reduce the timeline to approval to 6-12 months and monitor for the availability of multiple generics at all times. Because industry pays for a large share of research, high drug prices do not just generate profits; they also become a funding source for important scientific work. In some cases, the experimental drugs that provide meager benefits to the patients taking them are indirectly providing a much broader public good. Take Inclisiran, a drug that recently completed Phase 2 trials in which it showed remarkable reductions in LDL cholesterol levels. Since cholesterol levels are only a marker for disease, more trials are needed to determine how the drug actually affects more consequential outcomes such as heart attacks and strokes. It’s possible that these future trials will yield disappointing news: Cholesterol reductions may simply not translate into particularly impressive health benefits. Yet whatever its ultimate health benefits turn out to be, Inclisiran is anything but incremental. To the contrary, it is cutting edge in one important way. It relies on a novel mechanism for producing its effects, directly targeting genes that are known to increase cholesterol levels via a mechanism known as RNA interference. Biologists have known about RNA interference for some time: Andrew Z. Fire and Craig C. Mello shared the 2006 Nobel Prize for their 1998 work on it. But translating these insights into medical advances is an arduous process. The Inclisiran effort is not only one of the largest drug trials that exploits this mechanism, but it also manages to target an ailment that afflicts a broad swath of the population. In short, the drug’s ultimate value cannot be measured in its immediate benefits to patients alone. The research that went into this drug — from basic science all the way through to the clinical trial — can have ripple effects. Work like this expands our understanding of how to harness a biological mechanism into a practical therapeutic. Who knows how many unexpected therapeutics based on RNA interference will build on the lessons learned in the process of producing this and other drugs like it? Research is not just about what is discovered but facilitating others’ discovery. Groundbreaking work is needed to lay the foundation for someone else’s skyscraper: The wonder drugs of today are built on previous failures and marginal successes. Perversely, curbing prices risks squeezing out this kind of innovation. The consequences will not be felt today, but it could be a disaster in years to come. Constrict that research pipeline, and we reduce our chance of future breakthroughs. Of course, research that benefits many others, not just the researcher, is exactly what government should be funding. Such research is a public good, yet we are relying largely on the private sector to provide it. Huge pharmaceutical profits from overpriced drugs are an extremely indirect way to fund the foundational research. Now let me be clear. I am not supporting the current setup. It’s an extremely indirect and wasteful way to build the foundation of knowledge. Most of the additional profits from overly lucrative drugs go elsewhere, not to research. Even the dollars that are funneled toward research and development do not go toward the cutting-edge foundational research that others can build upon. Worst of all, even when the money does go toward such research, no one else may ever benefit from it. The Inclisiran trial was published in The New England Journal of Medicine, but pharmaceutical research is not always so public: Results may never be published. Hidden discoveries or failures do not contribute to the public good. Despite these glaring problems, current policy choices must confront the real world we are living in. In the current situation, drug pricing and research funding are intertwined. This link is only becoming more important. But, unfortunately, the Trump administration has been considering an executive order that eases regulations on drug companies, even as it has proposed cuts in federal funding for drug research. The net effect would increase our reliance on private companies to provide public research. Instead, we should look to cut drug prices, but couple those cuts with increased funding, in some form, for work on novel drugs that lay the foundation for future discoveries. While the current setup may be a foolish way of funding research, it would be much worse to have no funding at all.

# **Contention 2: WTO 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.

#### **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

#### **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.

#### **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?