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## Contention 1 - Innovation DA

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#### Costs for R&D are increasing, requiring increasing drug prices as well.

**WTO 20** [World Trade Organization, 2020, “Promoting Access to Medical Technologies and Innovation”, World Trade Organization, https://www.wto.org/english/res\_e/booksp\_e/who-wipo-wto\_2020\_e.pdf]/Triumph Debate

Costs of pharmaceutical R&D can be viewed in various ways. “Out-of-pocket” costs describe actual cash expenditures by the developer. These costs can be further risk adjusted to account for the cost of a failed drug candidate. The costs can also be “capitalized”; capitalized costs include the theoretical losses incurred from investing in pharmaceutical R&D instead of an alternative investment that would have earned returns at a certain percentage over the years before the R&D yields a successful product. **One series of studies has estimated the cost of bringing an [new drug] to market was US$ 114 million (US$ 231 million capitalized) in 1987, US$ 403 million (US$ 802 million capitalized) in 2000, and US$ 1.4 billion (US$ 2.6 billion capitalized) in 2013** (DiMasi et al., 1991; DiMasi et al., 2003; DiMasi et al., 2016). Both lower and higher estimates are available, ranging from US$ 100 million to US$ 5 billion (DNDi, 2014; Morgan et al., 2011; Herper, 2012; Prasad and Mailankody, 2017). **In some disease areas, returns on R&D investments can be very large;** for example, in oncology, for drugs approved during the period 1989– 2017, **sales of final products brought in US$ 14.50 for every US$ 1.00 invested in R&D** (Tay-Teo et al., 2019).

#### Patents protect 80% of revenue for pharma - removing them combined with increasing R+D costs guts their financial solvency and ability to make drugs.

**CRS 12** [CRS, 10/28/2021, “Drug Patent Expirations: Potential Effects on Pharmaceutical Innovation”, Congressional Research Service, https://www.everycrsreport.com/files/20121128\_R42399\_8beca70723872957efe4a267a5ae0df4805469ad.pdf] /Triumph Debate

A critical component of many of these federal efforts concerns patents.3 **Patent ownership can provide an economic incentive for companies to take the results of research and make the often substantial investment necessary to bring new goods and services** to the marketplace**.** The grant of a patent provides the inventor with a mechanism to capture the returns to his invention through exclusive rights on its practice for a limited time. In the pharmaceutical industry, patents are perceived as particularly important to innovation due, in part, to the ease of duplicating the invention. **Recently, patents on a significant number of “blockbuster”4 drugs have expired.** At the end of 2011, Lipitor, with 2010 retail sales in the United States of $5.8 billion5 and the world’s best selling medication, lost patent protection. Between 2012 and 2016, branded pharmaceuticals with an estimated $117.2 billion in U.S. sales are expected to go off patent.6 **Once patent protection is lost, these drugs are expected to lose up to 80% of the revenue generated for the innovator companies. “In the case of the top selling drugs, generics are capturing most of the market within weeks of their launch.”**7 Innovator companies depend on the funds generated from sales of blockbuster drugs to invest in additional R&D leading to new products that can improve the health and welfare of the public. **At the same time, generic versions of these pharmaceuticals benefit the public due to their lower cost and greater availability;** according to one estimate, **over the 10 years between 2001 and 2010, generic drugs “saved the U.S. health care system more than $931 billion.**”8 However, “while consumers and companies [that] provide health benefits could gain from the substantial slashes in costs, big pharma has to look at new ways and strategies to fill the [revenue] gap” created by the unprecedented number of patent expirations on blockbuster drugs.

#### Thus, higher drug prices are justified - removing them would collapse the pharma industry and complete destroy innovation

**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.

#### Protecting patents are necessary for a few reasons:

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

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

IPRs Strengthen Innovation

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46

IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that *without protection from potential abuse of their newly developed technologies*, foreign *enterprises may be less willing to reveal technical information associated with their innovations*.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development. The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D in an economy. Studies by Varsakelis and by Kanwar and Evenson found that and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

#### 2] Continuing Biopharmaceutical innovation is key to prevent future pandemics and bioterror

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

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, mak[ing] 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.

#### A] That causes extinction

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

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

## Contention 2 – Debt Ceiling DA

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#### Biden’s PC is key to swing 10 Reps to pass debt ceiling in the CR

Everett et al 9-16-21 (John Burgess Everett, co-congressional bureau chief for POLITICO, specializing in the Senate, BA journalism, University of Maryland College Park; and Laura Barrón-López, White House Correspondent for POLITICO, formerly covered Democrats for the Washington Examiner, Congress for HuffPost, and energy and environment policy for The Hill, BA political science, California State University, Fullerton; “Dems call in big gun as they face huge Hill tests,” POLITICO, 9-16-2021, https://www.politico.com/news/2021/09/16/biden-influence-capitol-democrats-511952)

The next few months will push President Joe Biden to wield every drop of his influence over Congress.

Democrats are plunging into messy internal debates over social programs from child care to drug pricing as they try to beat back GOP resistance on voting rights while steering the United States away from economic catastrophe. And in order to avert a government shutdown, avoid a debt default and fight ballot access restrictions passed in some GOP states, Democratic lawmakers are urging Biden to get more directly involved.

Senate Majority Whip Dick Durbin said that Biden, “more than anyone,” maintains sway over his caucus’s 50 members: “There is no comparable political force to a president, and specifically Joe Biden at this moment.”

Biden appears to be answering the call. The president is getting increasingly involved in Congress’ chaotic fall session as he battles sagging approval ratings, heightened concerns around the pandemic and some internal criticism over his withdrawal from Afghanistan.

Rebounding as the midterms draw nearer will depend on whether his big social spending ambitions are realized and if his party can dodge a government shutdown and credit default. But even if he has success on those fronts, he still needs to maintain momentum on Democrats’ elections legislation, which Republicans look certain to torpedo.

“I have full faith and confidence in Joe Biden in all of this,” said House Majority Whip Jim Clyburn, who's pressed Biden to endorse a filibuster carve out for voting rights legislation. “He is working this … and that’s how it should be.”

Biden met with two key Democratic holdouts on his domestic spending agenda on Wednesday, part of a sustained push to keep Sens. Joe Manchin (D-W.Va.) and Kyrsten Sinema (D-Ariz.) on board with his legislative program. Biden’s met with Sinema four times this year, in addition to telephone calls made between the two, and has spoken to Manchin a similar number of times.

“Now is the time” for Biden to jump full-force into the reconciliation conversation, said Sen. Tim Kaine (D-Va.). And the White House made clear that Biden is diving into the series of tricky issues.

Andrew Bates, a spokesperson for Biden, said that Biden and his administration "are in frequent touch with Congress about each key priority: protecting the sacred right to vote, ensuring our economy delivers for the middle class and not just those at the top, and preventing needless damage to the recovery from the second-worst economic downturn in American history.”

To help corral all 50 Senate Democrats for the social spending bill, the president and his party need to create an “echo chamber” around its substance, said Celinda Lake, a pollster on Biden’s campaign. But that won't be easy. Manchin has told colleagues he’s worried about whether the bill’s safety net, climate action and tax reforms will be popular in his state, according to one Senate Democrat. He's also said he won't support a measure at the current spending level: $3.5 trillion.

If Biden can hammer home the popular aspects of the spending plan, it may help assuage Manchin and improve his whip count in Congress. Underscoring the degree to which he's become the face of the multi-trillion dollar reconciliation bill, a Democratic aide said the party is increasingly seeking to frame it as Biden’s agenda, not that of Sen. Bernie Sanders (I-Vt.) or any single Democrat.

“People think they like the reconciliation package, but they really don't know what's in it,” said Lake, who added that her polling shows popularity for the measure, particularly among women and seniors.

The coming months will also challenge Biden’s relationship with Republicans, who are threatening to block a debt limit hike after many of them supported a suspension or increase three times under former President Donald Trump. Biden campaigned as a Democrat who could work with Republicans, and he succeeded this summer by rounding up 19 Senate GOP votes for a $550 billion infrastructure bill.

Yet he’s running into a brick wall in convincing Senate Minority Leader Mitch McConnell to provide at least 10 GOP votes to lift the nation's borrowing limit. Republicans say Biden’s dip in the polls isn’t driving their strategy on the debt ceiling. But it’s not helping either.

“I don’t think anything in the last month has increased the likelihood that he can now create an atmosphere of: Let’s work together,” said Sen. Roy Blunt (R-Mo.), who voted for the infrastructure bill and debt ceiling increases under Trump.

The White House is, so far, sticking by its plan to try and call McConnell’s bluff. Aides in the West Wing consider attaching a debt ceiling suspension or increase to a government funding measure the best way to pressure Republicans on the routine step required by law. Should that approach fail, they may be forced to separate the two fiscal measures to avert a shutdown.

On the debt limit, congressional Democrats are in lockstep with the administration's strategy. But they're looking for Biden to exhibit more of his arm-twisting and back-slapping skills on their social spending plan and their bid to shore up voting rights protections.

Biden “knows better than anyone the power of the United States [presidency] in persuading and sometimes cajoling the key members of Congress, when push comes to shove,” said Sen. Richard Blumenthal (D-Conn.).

#### 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[‘s] 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 default causes an irreparable, global economic crisis

Egan September 8th [Matt Egan, financial reporter for Cnn Business with a degree from the College of New Jersey, 9-8-2021, "'Financial Armageddon.' What's at stake if the debt limit isn't raised," CNN, https://www.cnn.com/2021/09/08/business/debt-ceiling-default-explained/index.html]/Kankee

The easiest way to spark a financial crisis and wreck the US economy would be to allow the federal government to default on its debt. It would be an epic, unforced error — and millions of Americans would pay the price. And yet that unlikely situation is once again being contemplated. If Congress doesn't raise the limit on federal borrowing the federal government will most likely run out of cash and extraordinary measures next month, Treasury Secretary Janet Yellen warned lawmakers on Wednesday. In short, a default would be an economic cataclysm. Interest rates would spike, the stock market would crater, retirement accounts would take a beating, the value of the US dollar would erode and the financial reputation of the world's only superpower would be tarnished. "It would be financial Armageddon," Mark Zandi, chief economist at Moody's Analytics, told CNN. "It's complete craziness to even contemplate the idea of not paying our debt on time." But it's a crazy world. Lawmakers in Washington are again playing chicken with America's creditworthiness. And the path to raising the debt ceiling is not clear. Even though Congress has in the past raised the debt ceiling with a bipartisan vote, Senate Minority Leader Mitch McConnell vowed in July that Republicans will not vote to raise the debt ceiling. JPMorgan Chase (JPM) CEO Jamie Dimon urged lawmakers not to even think about going down this path again. During a hearing in May, Dimon said an actual default "could cause an immediate, literally cascading catastrophe of unbelievable proportions and damage America for 100 years." 'Irreparable damage' In her letter to Congress, Yellen said history shows that waiting "until the last minute" to suspend or increase the debt limit "can cause serious harm" to business and consumer confidence, raise borrowing costs for taxpayers and hurt America's credit rating. "A delay that calls into question the federal government's ability to meet all its obligations would likely cause irreparable damage to the U.S. economy and global financial markets," Yellen wrote. A US default would undermine the bedrock of the modern global financial system. "We pay our debt. That's what distinguishes the United States from almost every other country on the planet," Zandi of Moody's said. Because of America's long track record of paying its debt, it's very cheap for Washington to borrow. But a default would force ratings companies to downgrade US debt and shatter that borrowing advantage. Markets plunged in 2011 when that debt ceiling standoff caused Standard & Poor's to downgrade America's credit rating. Higher borrowing costs would make it much harder for Washington to borrow to pay for infrastructure, the climate crisis or to fight future recessions. And refinancing America's nearly $29 trillion mountain of existing debt would become that much more expensive. Interest expenses, which totaled $345 billion in fiscal 2020, would quickly rival what Washington spends on defense. Market chaos Soaring Treasury rates would set off a chain reaction in financial markets. That's because Treasuries, viewed as risk-free investments backed by the full faith and credit of the federal government, serve as the benchmark by which virtually all other securities are measured. Everything from stocks and bonds to exotic securities take their cues from Treasuries. A spike in Treasury rates sparked by a default would cause booming stock markets to become unglued. "Stock prices would crater," Zandi said. "We'd all be less wealthy, instantaneously." Not only would millions of Americans lose money in the stock market, but it would suddenly become more expensive for families and companies to borrow. That's because Treasuries serve as the benchmark for mortgages, car loans, credit cards and corporate debt. A spike in borrowing costs is a huge problem for an economy that relies on access to credit. If the debt ceiling is not lifted, then the federal government will technically default on some of its obligations. It would be forced to prioritize payments, deciding who will get paid and who won't. Ultimately, someone will lose out, whether it's federal employees, veterans, Social Security recipients or defense contractors. For all these reasons, investors are not freaking out about the debt ceiling. Wall Street expects Washington will eventually raise borrowing limit, like it always does. Failure to do so would simply be too dangerous. 'Uniquely childish' The precise timing of when the debt ceiling must be lifted is a bit unclear. In late July, the nonpartisan Congressional Budget Office projected that if the debt limit is not raised, Treasury would probably "run out of cash" and be unable to make payments sometime during the final three months of the year, most likely in October or November. But that so-called "X date" could shift based on how much tax revenue the federal government takes in. For now, Treasury is taking extraordinary measures to avoid a default. Those moves are not a permanent fix, however, and eventually the debt limit will need to get lifted to avoid a financial disaster. "Once all available measures and cash on hand are fully exhausted, the United States of America would be unable to meet its obligations for the first time in our history," Yellen wrote. Yellen put a finer point on it later in Wednesday's letter, saying "based on our best and most recent information, the most likely outcome is that cash and extraordinary measures will be exhausted during the month of October." Of course, this debate isn't taking place in a vacuum.

#### Decline causes nuclear war

Stein Tønnesson 15, Research Professor, Peace Research Institute Oslo; Leader of East Asia Peace program, Uppsala University, 2015, “Deterrence, interdependence and Sino–US peace,” International Area Studies Review, Vol. 18, No. 3, p. 297-311

Several recent works on China and Sino–US relations have made substantial contributions to the current understanding of how and under what circumstances a combination of nuclear deterrence and economic interdependence may reduce the risk of war between major powers. At least four conclusions can be drawn from the review above: first, those who say that interdependence may both inhibit and drive conflict are right. Interdependence raises the cost of conflict for all sides but asymmetrical or unbalanced dependencies and negative trade expectations may generate tensions leading to trade wars among inter-dependent states that in turn increase the risk of military conflict (Copeland, 2015: 1, 14, 437; Roach, 2014). The risk may increase if one of the interdependent countries is governed by an inward-looking socio-economic coalition (Solingen, 2015); second, the risk of war between China and the US should not just be analysed bilaterally but include their allies and partners. Third party countries could drag China or the US into confrontation; third, in this context it is of some comfort that the three main economic powers in Northeast Asia (China, Japan and South Korea) are all deeply integrated economically through production networks within a global system of trade and finance (Ravenhill, 2014; Yoshimatsu, 2014: 576); and fourth, decisions for war and peace are taken by very few people, who act on the basis of their future expectations. International relations theory must be supplemented by foreign policy analysis in order to assess the value attributed by national decision-makers to economic development and their assessments of risks and opportunities. If leaders on either side of the Atlantic begin to seriously fear or anticipate their own nation’s decline then they may blame this on external dependence, appeal to anti-foreign sentiments, contemplate the use of force to gain respect or credibility, adopt protectionist policies, and ultimately refuse to be deterred by either nuclear arms or prospects of socioeconomic calamities. Such a dangerous shift could happen abruptly, i.e. under the instigation of actions by a third party – or against a third party. Yet as long as there is both nuclear deterrence and interdependence, the tensions in East Asia are unlikely to escalate to war. As Chan (2013) says, all states in the region are aware that they cannot count on support from either China or the US if they make provocative moves. The greatest risk is not that a territorial dispute leads to war under present circumstances but that changes in the world economy alter those circumstances in ways that render inter-state [make] peace more precarious. If China and the US fail to rebalance their financial and trading relations (Roach, 2014) then a trade war could result, interrupting transnational production networks, provoking social distress, and exacerbating nationalist emotions. This could have unforeseen consequences in the field of security, with nuclear deterrence remaining the only factor to protect the world from Armageddon, and unreliably so. Deterrence could lose its credibility: one of the two great powers might gamble that the other yield in a cyber-war or conventional limited war, or third party countries might engage in conflict with each other, with a view to obliging Washington or Beijing to intervene.

## Framing

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#### The standard is maximizing expected wellbeing. [util]. Prefer –

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

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

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

#### 2] Util (the doctrine of minimizing pain and maximizing happiness) is key to debates about IP.

Kar 19 [Mohit; Writer at the Original Position; “Utilitarianism in the Context of Intellectual Property,” The Original Position; 9/18/19;<https://originalpositionnluj.wordpress.com/2019/09/18/utilitarianism-in-the-context-of-intellectual-property/>]

Jeremy Bentham is known as the founder of modern utilitarianism. He believed in production of the *greatest possible quantity of happiness*, on the part of those whose interest is in view. With regards to intellectual property, he had opined that inventors and authors should be given absolute privilege over their work, which would ensure they get remunerated duly for their work, thus leading to further creative actions being taken by them. In this article, the author will make an analysis of the utilitarian theory as proposed by Jeremy Bentham and its *interplay[s] with IP*

According to utilitarians, the main purpose of property rights is the *maximization of common well-being*.[i] According to Jeremy Bentham, the common well-being here mentioned is the good for the greatest number of people in a population. He defined the principle of utility as carrying an *object of production* of maximum happiness in a given time in a particular society.[ii]

The wealth of a society consists of the cumulative wealth of each of its individual members. The most effective way to increase individual wealth is to leave the management of wealth to the individual himself, since – between the individual and the government – it is the individual who can best manage his own wealth. The society gains benefits because the increase in individual wealth is also the increase of collective wealth. Sharing this wealth is managed by the government, through taxes. Bentham argued that the value of outcome of a society is positive if the total quantity of pleasure gained by each individual under its influence is greater than the total quantity of pain.[iii] Thus, Bentham put stress on the happiness and wealth of individuals in a society.

Jeremy Bentham’s utilitarianism advocates the maximization of common well-being and the proper use of resources available. To show us a practical point of view, he criticized the kind of trade strategies where a country prevents the purchase of cheaper products from another country only to protect its market. In his opinion, to pay more for a product that can be manufactured elsewhere with the same quality standards only to favor the national industry is a waste of resources.[iv] Bentham believed that trade barriers to foreign imports cannot increase trade and commerce in a particular country.[v] He termed it as a necessary evil which would give rise to monopolies and lower the quality of production.[vi]

Transposing this theory to intellectual property rights, for the maximization of common welfare to be made, the legislators should *strike a balance between, the monopoly of rights to stimulate creation and giving access to the population to inventions*. Bentham defended the idea of ​​a limited period of protection for patents and he believed in the absolute privilege of the inventor, so that the latter can recover the amounts invested during the inventive process, while being paid for his creative activity.[vii] The right must also help the inventor since without any laws to protect him; any third party could copy his invention and thus enjoy his work without any compensation being granted. The logic to defend the monopoly stems from the fact that, without the latter, the inventor would not be encouraged to put his product or invention on the market. In this case, it would be the society that would have lost wealth which could have been added to the common well-being. In the name of enriching common well-being, Bentham stresses the importance of patents in a society and even argues that their concession should be a free service offered to inventors.[viii]

The contemporary version of this theory has been presented to us by William Landes and Richard Posner in two separate works, one on copyright and the other on trademark law.[ix] *Economic* analysis of intellectual property rights presented by these two authors demonstrates that the protection of intellectual property may be too expensive for society and it limits the use of products. If we extrapolate a little, this contemporary utilitarian vision can assert that the products by intellectuals should be easily copied since the copies of a product do not prevent the use of the *same product by several people.*

William Landes and Richard Posner consider the creative process as divided into two parts.[x] If we use a book as an example, its production is split between the part comprising author’s time and effort plus publishing costs, and the second part includes publication and distribution costs of the book. Generally, it is the first of these two elements that demands the most investment. The second will be more or less expensive, depending on the quantity of copies that will be produced. When the work is complete, its reproduction does not require any investment at the creative level. Hence, they stated that striking a correct balance between access and incentives is one of the central problems of copyright law.[xi] In this way, as already mentioned, the lack of remuneration of creators for the exploitation of their works may have as a consequence the diminution of the cultural wealth of a society, given that the creators will not have the desire to continue to create unless paid. It is important to note that the lack of protection conferred by copyright would not change this problem. In a society where copyright protection does not exist, a book could be easily copied without the act of copying being considered an offense. When the contemporary utilitarian vision is applied, it indicates that the benefits that they bring to a society are: It makes it easier for consumers to choose the product which has the qualities corresponding most to its needs. Since consumers already know the brand, they should not search among a whole range of products available on the market; It encourages producers to maintain good quality of their products, because consumers associate the product quality with the brand attached to it; It improves the language. Landes and Posner believe that the brands create new words that end up being incorporated in the lexicon of the language.[xii]

Suppose the utilitarian theory – that of Bentham, or Posner’ and Landes’ – would be applied to intellectual property as it stands today: the *benefits* that would be brought to society by this analysis would be the *incentive for creativity*, the *optimization of production* and the disappearance *or diminution of similar inventions* made by different individuals.

Among these three advantages, we can consider the incentive to creation as the most important. In this case, the monopoly guaranteed by intellectual property stimulates creation in a society and, especially with regard to patents; inventions will bring more happiness and pleasure to society in general. This justifying argument is in harmony with Bentham’s utilitarianism. The problem here is that no one really knows what kind of invention would bring more or less happiness or pleasure to the society. Moreover, the term “monopoly concession” for patents, trademarks and copyright is not based on any empirical or objective study and is rather random.

Optimization of production sees ownership monopolies intellectual property as a “service” to society since data from sale indicates the products for which the company has the most need. This approach could even justify increasing the period of protection of intellectual property products. The logic here is that the decrease in the protection period or even the removal of the protection would deprive the producers of information that enables them to optimize their production. Thereby, the withdrawal or diminution of protection could even be considered harmful to society. However, if we do not impose limitations to this theory, the result could be a disparity of investments in intellectual property over investments in other areas, such as education and health, as well as in general research activities.

CONCLUSION

Utilitarianism, as it stands today, is *intimately linked to the information obtained from the use of intellectual property* monopolies. The goal is to avoid duplication of production. The problem in this case is that in a society which values ​​and encourages the production of new patents and new technologies, the plethora of patents complicates the process. This finding is based on the fact that new inventions normally rely on existing patents and the production of a new patented product will require a large number of licenses before it can begin. As Richard Posner said in his blog: ‘Patents are a source of great social costs, and only occasionally of commensurate benefits. Most firms do not actually want patents; for those firms, the costs involved in obtaining licenses from patentees are not offset by the prospect of obtaining license fees on their own patents.’

# Case

#### Patents are key to vaccine standards and preventing counterfeits to ensure trust

Kappos 5-25 [David J. Kappos, Former Under Secretary of Commerce for Intellectual Property of United States, 5-25-2021, "Waiving Covid-19 vaccine patents won't get shots in arms faster. It slows down new vaccines.," NBC News, <https://www.nbcnews.com/think/opinion/waiving-covid-19-vaccine-patents-won-t-get-shots-arms-ncna1268099>]/Kankee

On that small point, at least, we agree: The nations that spearheaded the petition to waive the patent rights at the WTO, India and South Africa, have been unable to provide any evidence that the international system of respecting intellectual property rights under the law have impeded the development, production or distribution of Covid-19 vaccines and treatments. And it is hard to imagine that any such evidence will be forthcoming, as intellectual property is facilitating — not inhibiting — the pharmaceutical industry's pandemic response. Normally fierce rival companies have been able to cooperate on vaccine production precisely because inventors know their property rights are — and will remain — secure. For instance, Johnson & Johnson invited Merck to help manufacture its viral-vector vaccine, while Pfizer and BioNTech, which jointly developed their revolutionary mRNA vaccine, are similarly working with French drug giant Sanofi to boost its production. And generics manufacturers are already working around the clock on a contract basis with innovator firms to produce vaccines. For instance, India's largest generics manufacturer, the Serum Institute, is producing billions of doses of the AstraZeneca vaccine for low-income countries, while South Africa's largest generics firm, Aspen Pharmacare, is producing hundreds of millions of doses of Johnson & Johnson's vaccine. India and South Africa's petition to nullify intellectual property protections, were it to have been in effect, would have made those collaborations impossible. Suspending intellectual property rights will not get shots in arms any faster at this point and would, in fact, undermine efforts to scale up vaccine production. As Okonjo-Iweala herself pointed out last week, though it will take time to negotiate a wholesale change to WTO treaties, the capacity to manufacture Covid-19 vaccines already exists in Pakistan, Bangladesh, Indonesia, Thailand, Senegal and South Africa but is currently sitting idle despite existing frameworks giving manufacturers in those places the right to start. The EU, in the meantime, has offered a counterproposal to waive or minimize export restrictions on vaccines and vaccine components, to pledge to supply vaccines to countries with shortages at cost and to allow more countries to take advantage of existing WTO rules that allow countries to license intellectual property without the consent of the patent holders, essentially allowing for an increasing production capacity without waiving the patent rights altogether. So while the appeal of an intellectual property waiver is tempting in the short-run, doing so imperils our ability to develop new medicines and combat future pandemics. The Biden administration, however, announced its support for such a petition earlier in May and progressive groups cheered, contending that the intellectual property suspension would hasten and make more equitable the global vaccine rollout by enabling more manufacturers to produce the vaccines developed by Western firms. And, certainly, the rapid and equitable distribution of Covid-19 vaccines is absolutely critical to ending this pandemic. But sacrificing the innovation ecosystem in order to achieve this end would be myopic policy. There are already very real challenges to inoculating the world, including a widespread lack of proper refrigeration (let alone the ultracold storage required for some vaccines), a shortage of trained professionals to administer them and conduct follow-up evaluations, and a lack of patient compliance with the two-dose regimen for the Pfizer-BioNTech and Moderna jabs. Plus, there have already been issues with fakes and a lack of trust in the government that have come into play. In Mexico and Poland, authorities have identified counterfeit versions of the Pfizer-BioNTech vaccine. In Malawi, the New York Times reported that "people are asking doctors how to flush the AstraZeneca vaccine from their bodies." Suspending intellectual property rights will not remove any of these roadblocks and would likely exacerbate them. Without certain quality controls implemented by original patent holders, especially in places with existing levels of government or industrial corruption, we could see ineffective vaccines manufactured using substandard processes, and then administered without adequate refrigeration, professional handling or required counseling and follow up. In this moment, leaders and policymakers in the developed world should focus their efforts on helping other nations overcome these challenges, rather than debating the finer points of intellectual property law at the WTO. The latter is a waste of precious time, especially since without intellectual property protections, there might never have been vaccines to debate — at least not yet.

#### Link turn – competition for rare medical resources for vaccines will make them more expensive

McMurry-Heath 08-18 [Michelle McMurry-Heath, physician-scientist and president and CEO of the Biotechnology Innovation Organization, 08-18-2021, “Waiving intellectual property rights would compromise global vaccination efforts,” Stat, https://www.statnews.com/2021/08/18/waiving-intellectual-property-rights-compromise-global-vaccination-efforts/]/Kankee

The resurgence of Covid-19 cases in the United States and around the world, in large part due to the highly transmissible Delta variant, makes it even more crucial to step up the pace of the global vaccination campaign. To do that, some countries have sought to suspend intellectual property (IP) protections on Covid-19 vaccines and therapies. India and South Africa sponsored a proposal to that effect at the World Trade Organization (WTO). The proposal has since been endorsed by other countries, including the United States. They argue that eliminating IP protections would allow any willing company to produce lifesaving Covid-19 vaccines, making them cheaper and more widely accessible in low-income nations. If true, that would be a compelling argument. But it isn’t. Covid-19 vaccines are already remarkably cheap, and companies are offering them at low or no cost to low-income countries. Poor access to clinics and transportation are barriers in some countries, but the expense of the shot itself is not. In fact, if the World Trade Organization grants the IP waiver, it could make these vaccines more expensive.Here’s why. Before Covid-19 emerged, the world produced at most 5.5 billion doses of various vaccines every year. Now the world needs an additional 11 billion doses — including billions of doses of mRNA vaccines that no one had ever mass-manufactured before — to fully vaccinate every eligible person on the planet against the new disease. Even as Covid-19 vaccines were still being developed, pharmaceutical companies began retrofitting and upgrading existing facilities to produce Covid-19 vaccines, at a cost of $40 to $100 million each. Vaccine developers also licensed their technologies to well-established manufacturers, like the Serum Institute of India, to further increase production. As a result, almost every facility in the world that can quickly and safely make Covid-19 vaccines is already doing so, or will be in the next few months. The cutting-edge mRNA vaccines from Moderna and Pfizer-BioNTech face an even bigger capacity issue. Since the underlying technology is new, there are no mRNA manufacturing facilities sitting idle with operators just waiting for licensing agreements to turn on the machines. Nor are there trained personnel to run them or ensure safety and quality control. Embedding delicate mRNA vaccine molecules inside lipid nanoparticle shells at temperatures colder than Antarctica isn’t as easy as following a recipe from Bon Appetit. Another big barrier to producing more shots is a shortage of raw materials. Suspending intellectual property protections and allowing any manufacturer to try to produce these vaccines, regardless of preparedness or experience, would increase the demand for scarce raw materials, driving up prices and impeding production.Nor could all companies that suddenly get a green light due to suspended intellectual property rights produce vaccines as cheaply or quickly as existing manufacturers. Building a new vaccine manufacturing facility costs about $700 million, takes many months — if not years — to build and, once opened, requires another four to six months to start producing vaccine doses. And because negotiations surrounding the WTO waiver, which began this summer, could take until December before they are completed, it wouldn’t be until well into 2023 or later that any additional doses would become available. That’s slower than our current production rate. According to a report from Duke University’s Global Health Innovation Center, companies are on track to manufacture enough shots in 2021 to fully vaccinate at least 70% of the global population against Covid-19 — the level required to achieve herd immunity. Covid-19 vaccines are saving millions of lives and protecting trillions of dollars of economic activity for an exceptionally low cost. Israel, for example, which has one of the world’s highest vaccination rates, paid $23.50 per dose for early shipments, for a total of about $315 million. That’s approximately equal to the gross domestic productivity losses incurred during just two days of shutdowns in the country. Many countries are buying shots for under $10 per dose. India and South Africa — the two countries leading the petition to gut IP rights — are paying just $8 and $5.25 per dose, respectively. For reference, a regular flu shot costs about $14 in the United States, and pediatric vaccines average about $55 per dose. Meanwhile, low-income countries that can’t afford even modest prices are getting their vaccines at no charge. COVAX, the international nonprofit vaccine distributor, aims to deliver 2 billion doses to developing nations by the end of the year. President Biden vowed to make America the world’s “arsenal of vaccines.” The U.S. has already committed $4 billion to COVAX, has donated more than 100 million vaccine doses abroad, and is on track to donate 500 million more by the end of summer. Other countries are following the administration’s leadership and ramping up their donations. To be sure, the United States and other wealthy nations still need to give considerably more. But the fact remains that ramping up production in bona fide facilities and donating doses are the most straightforward steps to producing the vaccine doses needed to end the pandemic. The effort to strip intellectual property rights, by contrast, would put success against the global scourge of Covid-19 even further out of reach.

#### Strong IP protections allows for counterfeit tracking, detailed product info and mobile laboratory testing which helps keep fakes from entering the market.

Fifarma 4/27 [Latin American Federation of the Pharmaceutical Industry created in 1962. We represent 16 research-based biopharmaceutical companies and 11 local associations dedicated to discovering and developing innovative, quality and safe health products and services that improve the lives of patients in Latin America and the Caribbean and advocate for patient-centric, sustainable health systems characterized by high regulatory standards and ethical principles. ["This Is How We Fight Counterfeit Medicines with Intellectual Property." Fifarma. Fifarma, Apr. 2021. Web. 27 Aug. 2021.] //Lex VM

In addition to functioning as a tool to maintain constant innovation in the industry, IP helps reducing counterfeit medicines because medicines have better technologies and ingredients are more difficult to copy. This means that, through market incentives, the industry manages to have high quality infrastructure, new technology and trained personnel, to create specialized and specific medicines and therapies, which is why they are difficult to replicate. On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines. In short, IP allows quality standards to be clearer and stricter, and regulators to have greater knowledge and traceability of each product that enters the market. Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines. Consequently, the best way to fight counterfeit medicines is through accessing the best quality medicines and for this to happen, an ecosystem between countries, regulators and industry is needed. This ecosystem shall take into account the structural deficiencies of each country and addresses them in a holistic manner, to provide the best quality medicines. In the end, with the Intellectual Property associated with the creation of the product, there are also associated standards of transparency and detailed information that every regulatory agency can access. Moreover, the value chains will receive all this information in order to be aware of the appearance of products that are not registered with the standards of a product protected by IP. Also,IP helps to combat counterfeit medicines internationally, since there are laws that cover all member countries of the United Nations and punish more severely those who commit this crime. Likewise, these laws provide countries with the necessary mechanisms to take concrete action once a counterfeit medicine is discovered. This, of course, must go hand in hand with the political will of each country, because only with collaboration between different actors will it be possible to prosecute the entire chain of counterfeit medicines. Plus, IP owners can receive electronic notifications worldwide more quickly and can take direct communication actions. In a nutshell, IP allows the industry to show the public almost immediately that there is a counterfeit medicine in a country or that a website is selling counterfeit medicines. This is because legally infringing a product protected by IP allows action to be taken to prosecute the counterfeit products. This is especially important for those consumers or small organizations that do not have access to information like a hospital or public health center has. However, it is necessary to involve other actors of the health system so that information about counterfeit medicines reaches remote regions or places, which do not have an internet connection. On the other hand, thanks to IP, the industry is creating specialized safety technology in order for each country to easily identify a drug that comes with a brand but does not belong to that brand. The industry has also used mobile laboratories to test samples of suspected medicines and report them quickly to the value chain. Thus, technology is becoming an important element in fighting this problem.