### T

### 1NC

#### Interpretation: Reduce means a net decrease – the aff can’t transfer or offset their reduction

Public Law 87-253

(Omnibus Budget Reconciliation Act of 1982, 97th US Congress, Sept 8, 1982, Lexis)

E) Prior to approving any application for a refund, the Secretary shall require evidence that such reduction in market- ings has taken place and that such reduction is a net decrease in marketings of milk and has not been offset by expansion of production in other production facilities in which the person has an interest or by transfer of partial interest in the produc- tion facility or by the taking of any other action. which is a scheme or device to qualify for payment.

#### Violation: The affirmative replaces their reduction with giving prizes, they concede this in CX

Kentucky Ct of Appeals 84 (Paducah v. Moore, 662 S.W.2d 491, Lexis---gender edited)

No one quarrels with the appellants' argument that HN3 the city has the power to transfer or even discharge employees at will. The right to do so, however, is restricted by Statutes of the Commonwealth of Kentucky. The language of KRS 90.360(1) above is quite clear in prohibiting reduction in grade of a classified service employee of the City except for cause and after a hearing upon appropriate written charges. In interpreting identical language concerning prohibition against reduction in grade provided for in KRS 95.450(1), our former Court of Appeals stated in Schrichte vs. Bornhorn, Ky., 376 S.W.2d 683 (1964):∂ . . . we are of the opinion that the term 'grade' means rank, whereas it appears that the appellant interprets it more broadly as job classification. Obviously by the use of the word 'reduce,' the Statute envisages a verticle scale. If a [person] is transferred without a loss in pay from one job category to another with comparable authority, his classification is changed, but his grade is not reduced.

#### Vote neg for limits and stable ground – allowing the affirmative any ground besides reducing IP protections explodes neg prep burdens and makes infinite new “replace” affs that dodge core of the topic DAs. Extra topicality is a voting issue because it is unpredictable and allows the aff to fiat out of neg arguments.

# Compulsory License Threat CP

#### CP Text: Member nations of the WTO should inform patent holders that unless they reach voluntary licensing agreements with countries in need the WTO will pursue compulsory licensing.

### 1NC

#### The CP is mutually exclusive- licensing requires IP protections. The CP doesn’t reduce IP, it *solidifies* it

Raju, PhD, 17

(K D , Rajiv Gandhi School of Intellectual Property Law, Indian Institute of Technology Kharagpur, West Bengal-721 302, India Received 27 March 2016; accepted 11 November 2016 Compulsory v Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries Journal of Intellectual Property Rights Vol 22, January 2017, pp 23-31)

It has been observed that the pharmaceutical patents under the TRIPS Agreement have increased the drug prices exorbitantly, especially in developing countries. This made the patent regime itself most unpopular especially in developing countries. Right to health is the heart of the idea of CL provisions. Voluntary licenses and patent pools are promising and a new approach to delivering affordable medicines to developing and least developed countries under the TRIPS regimes of intellectual property protection. These concepts may be converted into practical realities in treating poor patients throughout the world rather than only protecting the intellectual property rights and the interest of multinational pharmaceutical companies. There must be a balancing act between the social welfare and the protection of innovation and intellectual property rights. The system of voluntary license in any form will make the medicines more affordable and faster delivery in developing country markets. The WTO members should promote voluntary agreement system at international level like MPP and through their domestic legal system with more incentives for VL. It is not an easy task for the developing countries on the background that CL is always issued when VL is denied.

#### The Counterplans threat of compulsory licensing causes companies to approve voluntary licenses. This is goldilocks- its solves the advantage while avoiding the disads

Raju, PhD, 17

(K D , Rajiv Gandhi School of Intellectual Property Law, Indian Institute of Technology Kharagpur, West Bengal-721 302, India Received 27 March 2016; accepted 11 November 2016 Compulsory v Voluntary Licensing: A Legitimate way to Enhance Access to Essential Medicines in Developing Countries Journal of Intellectual Property Rights Vol 22, January 2017, pp 23-31)

The philosophy of granting patent is to provide incentive to innovation and monopoly for a limited period of time.1 The patenting supporter argues that the patent system is indispensable as it encourages research and creativity, and enhances a country’s technological and economic development.2 However, patent rights should not be a license to exploit and misused by the benefit of the multinational companies that are detrimental to the interest of public health protection. The social good and public rights cannot be overridden by private rights under the intellectual property protection umbrella of the TRIPS agreement. The human right to health guarantees a system of health protection for all under many international law conventions.3 “Compulsory licensing (CL)” is a nonvoluntary licensing from the Government without the consent of the patentee in order to protect public interest which acts as a cushion to balance the interest between patentee’s rights and rights of public at large. Thus the “CL therefore serves to strike balance between two disparate objectives- rewarding patentees for their invention and making the patented products, particularly pharmaceutical products, available to large population in developing and under developed countries at a cheaper and affordable price”.4 The CL may constitute an important tool to promote competition and increase the affordability of drugs, while ensuring that the patent owner obtains compensation for the use of the invention.5 However, the pharmaceutical industry all over the world has opposed to CL and they argue that it will kill innovation and discourage R&D.6 India issued its first compulsory licensing order in favour of a domestic pharma company NATCO against the pharmaceutical giant Bayer, which has generated a lot of attention all over the world and compulsory licensing, has been viewed as a remedy to curb abuse of exclusivity protected by IPRs. One of the conditions for granting CL is that, before filing of an application, the applicant must take efforts to get a voluntary license from the patent owner in mutual terms and such effort must have been failed. The first CL grant itself is met with stiff opposition from the multinational pharma companies and end up in a series of litigations and apex court later upheld the validity of the CL. These litigations take lot of time, cost and tension between the patent owner and the prospective licensees. On the other hand, voluntary licensing between the patent holder and another manufacturer in developing countries may reduce the cost as well as offer opportunities to the patent owner as well as the licensee. The kind of opportunity depends upon the terms of license and the capacity of the licensee to build a relationship in a longer term within the purview of the intellectual property regimes. This paper argues that a threat of issuing CL encourages the parties to negotiate a voluntary licensing and agreements which enable reduction of opportunity cost and availability of patented drugs in developing countries. But it is not my intention to argue that voluntary licensing can be replaced by CL in all circumstances. It analyses the CL provisions in the TRIPS agreement followed by CL provisions in the Indian patent law and first CL case in India in order to expose the arguments of multinational companies and will examine how India was successful in granting the CL. Third part of the paper will examine the voluntary licensing system and agreements which can demonstrate how it can provide an alternate mechanism for a harmonious relationship between the patent owner and the domestic industries and thus a viable and TRIPS legitimate mechanism to enhance access to medicines in developing countries.

#### Compulsory licensing solves better while avoiding innovation DA- industry support proves

Deutsche Welle 7-5-21 https://www.dw.com/en/covid-vaccine-patent-waivers-divide-eu-leaders/a-57464976

The pharmaceutical industry, which has strongly opposed an outright patent waiver, favors a system of licensing that it says is already being implemented on an unprecedented scale. It points to AstraZeneca's deal with the world's largest vaccine maker, India's Serum Institute, and Johnson & Johnson teaming up with South Africa's Aspen Pharmacare to produce its vaccine. A licensing agreement is mostly voluntary and involves a vaccine developer sharing not just patents but the technology and complete know-how with a manufacturer. If required, governments can force developers to share their licenses. A patent waiver, on the other hand, forces a vaccine developer to share the recipe of its vaccine. A temporary IP relief by the WTO would mean that any company looking to manufacture COVID-19 vaccines would be free to do so without having to pay royalties to vaccine developers and without worrying about being sued for patent infringement.

#### Compulsory licensing solves faster and is less complex

Usher 20

(Ann Danaiya <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext#%20>, 12-5)

John-Arne Røttingen, who chairs the WHO Solidarity Trial of COVID-19 treatments, agrees that technology transfer is crucial, but says that voluntary mechanisms are a better way to achieve this. The patent waiver, he says, is the “wrong approach” to the problem because COVID-19 therapeutics and vaccines are complex biological products in which the main barriers are production facilities, infrastructure, and know-how. “IP is the least of the barriers”, he says. Røttingen, recently appointed as Norway's Global Health Ambassador, says waiving IP might help in producing small molecular weight substances. “But if you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological samples, cell lines, or bacteria” to be able to document to regulatory agencies that you have an identical product. Instead, he says, individual companies should be pressured to allow non-exclusive licences and technology transfer of their products, along the lines of the agreements that AstraZeneca and Novavax have established with the Serum Institute of India for vaccines. This partnership model would be much faster, he says. “Instead of going for an unreachable, ‘ideal’ solution that will not fly, they should identify where the barriers are and work on those.”

#### Waiving IP in any instance sets a precedent devastating Pharma research- the CP avoids the DA

Miron, PhD, and Soares, 21

(Jeffrey, Director of Economic Studies, Pedro, Grad Student@Pontifical Catholic <https://www.cato.org/commentary/waiving-covid-19-vaccine-patents-would-be-disastrous> , 5-19)

Pharmaceutical companies operate in a heavily regulated sector with enormous research costs, whereas restaurants face milder regulation coupled with lower product‐​development costs. Perhaps it makes sense that drugs be patentable, but not recipes. But stripping away IP protection from the current holders of COVID-19 vaccines patents is deeply misguided. Pharmaceutical companies have created a product of astronomical value. One estimate suggests 3 billion vaccine courses in 2021 would generate a global benefit of $17.4 trillion, or over $5,800 per course. Ex‐​post appropriation of existing patents signals both domestically and abroad that the U.S. government puts political expedience before the rule of law. This sets a terrible precedent. Imagine if governments demanded repayment of Social Security benefits because deficits are getting large or reversed antitrust‐​approved mergers because key political supporters opposed them. Society cannot function unless individuals and organizations can rely on previously settled deals. Some believe the U.S. government is entitled to the IP benefits of COVID‐​related research because it played a major funding role both directly and indirectly. Operation Warp Speed indeed spent $12.4 billion by December 2020, but almost half was entirely on manufacturing, with the other half not differentiating between manufacturing and development. Pfizer PFE, -1.17%, for example, took no government money for its vaccine research. Indirectly, National Institutes of Health (NIH)-funded basic research has helped our understanding of mRNA mechanisms. But successful vaccine products took decades of large, risky research by private companies like Moderna MRNA, -0.70%. All this discussion, moreover, misses a fundamental point. When government decided to fund companies through Operation Warp Speed or research through the NIH, it did not do so with the caveat that companies would have to forego IP rights in the future. If this had been clear from the outset, it would be defensible for government to claim the right to waive patents now. But had the companies known, they might not have taken the money or conducted the research in the first place. Further, the waiver is not likely to achieve the goals of increased production in the short term. Many experts have stressed that IP is not the hurdle keeping production from increasing in the near future. AstraZeneca AZN, 0.14% AZN, 0.08% has licensed production to 15 countries and 25 manufacturing sites and Moderna stated it would not enforce its COVID-19 related patents during the pandemic. Instead, manufacturing components and raw materials are the relevant bottlenecks. Finally, even if patents were an obstacle to increased production, an alternative for producing more vaccines exists: pay for them. Governments could buy patents, or doses, from pharmaceutical companies and donate them around the world. Such buyouts have the same upsides as waivers, but without risking long‐​term vaccine innovation. The rule of law could live to see another day.

**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 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts.

Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.

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 activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that R&D to GDP ratios are positively related to the strength of patent rights, 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

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

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

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

**That causes extinction, which outweighs.**

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

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to **remote populations**, overcome **rare genetic resistances**, and **evade detection**, cures, and **countermeasures**. Even evolution itself may work in humanity's favor: **Virulence and transmission is often a trade-off**, and so **evolutionary pressures** could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they **do not rule** the possibility **out** entirely. Although rare, there are recorded instances of **species going extinct due to disease**—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include **native American tribes** exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But **many diseases are proof** of principle that **each worst-case attribute can be realized independently**. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, **natural evolution** would be an **unlikely** source for pathogens with the **highest possible levels of transmissibility, virulence, and global reach**. But **advances in 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

## Case

**Prizes fail to drive research**

**Stevens, MA LSE, 20**

(Philip, founded Geneva Network in 2015, https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work)

Prizes have a place, but as the following sections argue, there are **many weaknesses** with a delinkage approach that would make prizes the primary mechanism for incentivizing global life-sciences innovation. The first and most significant is that it is extremely unlikely governments would truly adequately fund such prizes as the primary mechanism for underpinning global life-sciences innovation. If anything, a pure prize system would likely stimulate more **free-riding** by nations, and thus **actually exacerbate underinvestment.** The second is a prize approach would be unlikely to engender the risk-intensive innovative activity necessary to develop new medicines, and certainly not in comparison with a global life-sciences innovation system that is generally working effectively today toward new drug discovery. Third, there are significant administrative, mechanical, and operational challenges associated with administering prize systems that would likely introduce **inefficiency and politicization.** Fourth, while there are certainly myriad challenges in the provision of global health care, other approaches can more effectively help solve many of these problems. Put simply, while the use of prizes can make important and meaningful contributions to addressing some of these challenges, prizes cannot represent the “be all end all” approach to underpinning the global biomedical innovation system or tackling difficult public health challenges.

**Politicization guts solvency**

**Stevens, MA LSE, 18**

(Philip, founded Geneva Network in 2015, https://geneva-network.com/wp-content/uploads/2018/02/Delinkage.pdf)

Opponents of the market-based system of drug development decry funds spent by the pharmaceutical industry on lobbying governments to ensure a favourable policy regime. But a prize system would hand significant new discretionary powers to government officials, who would be the ultimate arbiters of whether a new medicine wins a prize. **This would create major new incentives for rent-seeking and crony capitalism** and result in the wholesale politicisation of drug development. According to economic historian Zorina Khan, some of the earliest (and most famous) prizes were tainted by politics. John Harrison, a poor, uneducated clockmaker, is credited as the inventor of the method of determining a ship’s longitude at sea, yet the Longitude prize was never officially won and it took him 47 years to receive compensation for his invention – which came eventually from a different source. His lack of social standing, difficulties in dealing with the prize board and political interference from better connected competitors may have been responsible for his maltreatment, according to Dr Khan. In fact, Dr Khan’s statistical analysis of dozens of prizes granted to British inventors in the 19th century shows that those with an elite, Oxbridge education were twice as likely to win awards. Technical qualifications or accomplishments had little bearing on the likelihood of prize success. 8 **Under a prize-based system, there is a risk that political factors could influence decision-making, rather than clinical demand**. Political connections and lobbying could both play a role in securing a prize, while elected officials may attempt to influence R&D spending by government agencies. Patents, on the other hand, are far less arbitrary form of innovation incentive. Government merely sets the framework of patent law, under which all companies compete.

#### Aff doesn’t attack all of the root causes of disease spread- lack of materials, equipment, and facilities when faced with skyrocketed demands means solving IP protections alone isnt enough

Brant & Burns 7-29-21 [Jennifer Brant, CEO and Founder of Innovation Insights, and Thaddeus Burns, Head of Life Science Government & Public Affairs at Merck and served in senior positions at the US Department of Commerce and the White House Office of the US Trade Representative, served as a member of the National Academy of Sciences Committee charged with preparing a report on the science and technology capabilities of the U.S. Department of State. “Trade restrictions are delaying the COVID response. The WTO must act.” July 29, 2021. <https://www.weforum.org/agenda/2021/07/wto-members-must-launch-new-work-to-reinforce-the-covid-response-in-november/>] AL

The COVID-19 pandemic hit at a time when bio-manufacturing was undergoing a process of democratization. Technological progress had enabled growing capacity in many countries including Brazil, Indonesia, South Africa, Tunisia, Argentina, and Egypt. By 2020, the business model for bio-manufacturing had fundamentally changed and it was becoming the norm for companies to distribute research, development and manufacturing across geographies and work with partners. As recently as 15 years ago, building a facility to produce biologics such as monoclonal antibodies or vaccines could require an investment of as much as €500m, and it would take up to 3 years to bring that facility online. New manufacturing technologies have made it cheaper and easier to build new facilities and to scale up existing ones. Today, an investment of €20m can get a bio-manufacturing plant up and running. Such changes are part of the reason the global community was able to launch production of new COVID-19 vaccines so quickly. The urgency of COVID-19 accelerated further innovations in bio-manufacturing equipment and processes, and compressed production time in a way that will have positive impacts in the future. But the pandemic also revealed major weaknesses in global value chains. It was difficult for manufacturers to keep up with the sudden surge for demand for raw materials and equipment, as many new research and development and manufacturing partnerships rapidly took off. To extend capacity, new employees, intensive training and collaboration, and more infrastructure were needed. The global community was faced with the reality that facilities cannot be built everywhere in an instant, and that there are bottlenecks in the supply chain. Government action in some cases made things worse. Some countries enacted export restrictions on COVID-related products, which made it extremely difficult to run a global supply chain. Another difficult issue has been the tariffs applied on biologics and the products needed for their manufacture. Eighteen months into the pandemic, biologics manufacturers are still trying to cope with a range of challenges. There is still surging demand for equipment and raw materials. In some cases, they have expanded manufacturing capacity to produce more equipment such as filters and bioreactors. This continues to require time and significant investments.

#### Squo solves--cost and bureaucracy are barriers to patent protection and other countries violate IP laws without punishment now.

Chao and Mody 15 (Tiffany Chao [Editor in Chief of Journal of Medical Insight, adjunct professor at Stanford Med School] and Gita Mody [MPH Harvard, assistant professor at UNC Chapel Hill Med School], The impact of intellectual property regulation on global medical technology innovation, BMJ Innovations, 3/5/2015, https://innovations.bmj.com/content/1/2/49) hwof

Inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices.[i](https://innovations.bmj.com/content/1/2/49#fn-4) High cost, time and logistics are oft-cited reasons for not pursuing patents. Factors influencing the cost include not just the expense of filing (which can be thousands of dollars) but also fees for legal counsel and maintenance of the patent. These costs are a barrier in their own right, and they can also lead to increases in the price of the end product, which can be significant in a highly cost-sensitive market. An additional barrier is limited knowledge of complicated international patent laws with inadequate access to qualified IP lawyers. In cases where out-of-country universities are involved in patenting the technologies, the bureaucracy involved in dealing with the technology transfer office and their inexperience in executing foreign filings is a barrier (though there are counterexamples of very significant university partnerships in developing bottom-of-the-pyramid technologies). Another major reason for limited IP protection of technology for low-resource settings is the spirit behind the innovation in the first place; inventors designing for low-resource settings are often interested in keeping their device design open source, to maximise spread and impact. Also, consumers of the technologies are highly focused on affordability. Prosecution of infringement of IP laws in low-resource settings is limited, and violating IP laws is a pragmatic way for ‘copycats’ to reduce their investment costs in research and development, and quickly sell products, getting healthcare technology to those who need it. Most countries do operate under patent laws compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, a framework that requires IP laws to resemble those of developed areas. This agreement applies to all WTO member countries. Therefore, unless a developing country wishes to withdraw from the WTO, its IP laws are required to resemble those in the USA or Europe, leaving little flexibility to tailor to local needs.[4](https://innovations.bmj.com/content/1/2/49#ref-4) This means that international IP laws are often in the economic interests of developed countries rather than in the innovation interests of other countries.[5](https://innovations.bmj.com/content/1/2/49#ref-5) As a result of these issues, the most prevalent strategy among global health technologies has often been to develop without regard for IP protection. A major advantage of this approach is that it can allow for open-source innovation, permitting technological learning through imitation. This approach can also eliminate the many costs of foreign protection or patent enforcement, allowing for a frugal approach to the initial development of the technology itself. Furthermore, this approach is most in line with the collaborative spirit of global health innovation.

\*\* Mercurio is COVID specific but warrants apply generally too

#### The TRIPS agreement and cheap vaccines in the squo solve the aff--independently, lack of manufacturing power and licensing transparency deck solvency.

Mercurio 21 (Bryan Mercurio [Simon F.S. Li Professor of Law at The Chinese University of Hong Kong], WTO WAIVER FROM INTELLECTUAL PROPERTY PROTECTION FOR COVID19 VACCINES AND TREATMENTS: A CRITICAL REVIEW, Virginia Journal of International Law, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820>, 2/12/2021) hwof

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26 Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level. Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31 While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs. Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices. Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability.